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Abstract N°: 87

Effectiveness and safety of risankizumab in bio-naïve psoriasis patients – a 2 year interim analysis from the German cohort of the VALUE study

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Introduction & Objectives:

Risankizumab (RZB) is an IL 23 p19 inhibitor biologic drug approved for the treatment of moderate-to-severe plaque psoriasis and psoriatic arthritis. Real world data of RZB on the long-term effectiveness is limited, especially for bio-naïve patients. This abstract analyzes the effectiveness and safety of RZB compared to other biologics in the German bio-naïve patient cohort of a multi-country non-interventional real-world observational study (VALUE).

Materials & Methods:

VALUE evaluates real-world durability of response and time to first treatment change for RZB compared to other biologic treatments (2:1 allocation ratio). Treatment decisions were made at the physician's discretion, according to local label and clinical practice. Here, the German subpopulation was analysed. Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), Treatment Satisfaction Questionnaire for Medication (TSQM) and changes to treatment were collected at weeks 0, 4, and every 12 weeks thereafter. Safety was assessed through reported adverse events. Results presented here are r from an interim analysis with database lock on 26 Sep 2022 for the German cohort.

Results:

At the timepoint of interim analysis, 571 patients in Germany with moderate to severe psoriasis were included in the study; 387 RZB patients (206/53.2% bio-naïve) and 191 patients treated with other biologics (109/59.2% bio-naïve). At baseline, bio-naïve patients receiving RZB had significantly higher PASI scores (19.1 [SD 9.83] vs 16.4 [7.44]; p=0.0068) and higher DLQI scores (15.1 [SD 7.12] vs 13.1 [7.40]; p=0.0217) than bio-naïve patients receiving other biologics. Compared to bio-naïve patients treated with other biologics, bio-naïve RZB patients demonstrated significantly lower PASI scores at week 52 (0.9 [SD 2.46] vs 2.6 [6.32]; p=0.0326) and week 100 (0.7 [SD 1.61] vs 3.3 [4.52]; p=0.0052). DLQI scores were lower in RZB bio-naïve patients than in bio-naïve patients with other biologics at week 52 (1.7 [3.31] vs 2.9 [4.66]) and at week 100 (1.5 [2.66] vs 4.2 [7.29]). A significantly higher TSQM global satisfaction scores was also reported for patients receiving RZB at week 52 (92.4 vs 84.5%; p=0.0044) and week 100 (93.5 vs 82.7%; p=0.0206).

Within 100 weeks, any change of treatment (including discontinuation, dose escalation and dosing interval shortening) was lower in bio-naïve RZB patients (9.2%) compared to bio-naïve patients with other biologics (18.3%) (p=0.0193). Overall numbers of adverse events (n=65, 31.6%), serious AEs (n=16; 7.8%) and discontinuation due to AE (n=12, 5.8%) were low in bio-naïve patients treated with RZB.

Conclusion:

At week 52 bio-naive patients receiving RZB had significantly lower absolute PASI and lower DLQI scores than patients treated with other biologics. Results were maintained over 100 weeks. Patients treated with RZB were less likely to switch treatment.

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Abstract N°: 94

Real-world effectiveness of tildrakizumab in a UK cohort: A drug survival analysis

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Introduction & Objectives

Tildrakizumab is a high-affinity anti-interleukin-23p19 monoclonal antibody approved for moderate-to-severe psoriasis.1 According to its summary of product characteristics (SmPC), consideration should be given to discontinuing treatment in patients who have shown no response after 28 weeks of treatment. Drug survival is an indication of sustained disease control in the real-world setting. Survival data will be important in meeting the 2022/23 NHS priorities and operational planning guidance. This aims to reduce outpatient follow-ups by at least 25% against 2019/20 activity.2 Well tolerated medicines with consistent efficacy reduce outpatient attendance rates and improve new patient access to finite NHS resources. This study provides interim data on the drug survival of tildrakizumab in a real-world clinical practice setting in the UK.

Materials & Methods

This was a real-world prospective cohort study of UK tildrakizumab outpatient psoriasis patients between May 2019 and March 2023. Data was collected from three UK clinical homecare providers: Pharmaxo, Lloyds, and HealthNet. Study participants were patients prescribed tildrakizumab 100 mg or 200 mg every 12 weeks as indicated. Homecare providers delivered the drug, which was injected subcutaneously by a nurse at the patients' home address for the first three doses. Drug survival rate for tildrakizumab at one year was estimated through Kaplan-Meyer analysis for the total cohort of patients and separately for a subgroup of patients who surpassed 28 weeks of initial treatment.

Results

A total of 1078 psoriasis patients prescribed tildrakizumab 100 mg or 200 mg were included in this analysis. Evaluation of pre-28-week stoppages was carried out, of whom 867 out of 933 patients (92.9%; 95% confidence interval [CI]: 91.1-94.4%) had been on treatment for at least 28 weeks and had not stopped treatment prior to 28 weeks. Despite the SmPC recommendation of discontinuing treatment in patients who have shown no response after 28 weeks of treatment, 7.1% of our cohort stopped treatment before this period (66 patients during the first 28 weeks). The drug survival for tildrakizumab at one year was 84.6% (95% CI: 82.1-86.9%) for all analysed patients. The overall drug survival of tildrakizumab was 90.7% (95% CI: 88.4-92.5%) at one year if patients surpassed 28 weeks of initial treatment.

Conclusion

Based on the data collected in this UK real-world cohort, patients with psoriasis treated with tildrakizumab had a high drug survival rate at one year when treatment was continued at week 28. These data provide evidence of the potential long-term sustained effectiveness of tildrakizumab in daily clinical practice.

References

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Abstract N°: 115

Efficacy and safety of vunakizumab in moderate-to-severe chronic plaque psoriasis: a randomized, double-blind, placebo-controlled phase 3 trial

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Introduction & Objectives: Plaque psoriasis is a chronic inflammatory disease with prominent skin manifestations that imposes a substantial disease burden on the quality of life in patients. Vunakizumab (SHR-1314) is a novel

humanized monoclonal IgG1/K antibody targeting IL-17A. In our previous phase 2 trial, 12-week treatment of vunakizumab (240 mg regimen) demonstrated promising efficacy, with a favorable safety profile in patients with moderate-to-severe plaque psoriasis. Herein, we conducted a phase 3 trial to further assess the efficacy and safety of vunakizumab in this population, with 12-week and 52-week data reported.

Materials & Methods: This 52-week, multicenter, randomized study (NCT04839016) comprised a 12-week, double-blinded, placebo-controlled induction treatment period, followed by a 40-week, double-blinded maintenance period. Eligible patients with moderate-to-severe chronic plaque psoriasis were randomized (2:1) to receive vunakizumab 240 mg or matching placebo subcutaneously at weeks 0, 2, 4 and 8. At week 12, patients initially assigned placebo were switched to receive vunakizumab 240 mg (weeks 12, 14, 16 and Q4W thereafter) and other patients continued vunakizumab treatment (Q4W; with an additional dose of placebo given at week 14) through week 52. The coprimary endpoints were the proportion of patients with ≥90% improvement from baseline in the psoriasis area-and-severity index score (PASI 90) and a static Physicians Global Assessment (sPGA) score of 0 (clear) or 1 (almost clear) at week 12.

Results: Between Apr. 21, 2021 and Dec. 3, 2021, 690 patients were enrolled and randomized (vunakizumab, n=461; placebo, n=229). At week 12, the proportion of patients achieving the primary endpoints of PASI 90 (76.8% [95% CI 72.7-80.5] vs 0.9% [95% CI 0.2-3.1]) and sPGA 0/1 (71.8% [95% CI 67.5-75.8] vs 0.4% [95% CI 0.1-2.4]) were significantly higher with vunakizumab than with placebo (P <0.0001 for each comparison; Table 1). The response rates of PASI 75, PASI 100 and sPGA 0 also favored the vunakizumab group (Table 1). During the maintenance period, the response rates of PASI 90 and sPGA 0/1 were sustained through week 52 in patients on continuous vunakizumab (Figure 1). Up to week 12, adverse events were mostly mild, with comparable overall incidence rates between groups (69.1% with vunakizumab vs 71.6% with placebo). No new safety signal was noted with prolonged treatment with vunakizumab during the maintenance period.

Conclusion: Vunakizumab provided robust clinical response at week 12 and through week 52, with good tolerability. Our data support vunakizumab as a new treatment option for patients with moderate-to-severe chronic plaque psoriasis.

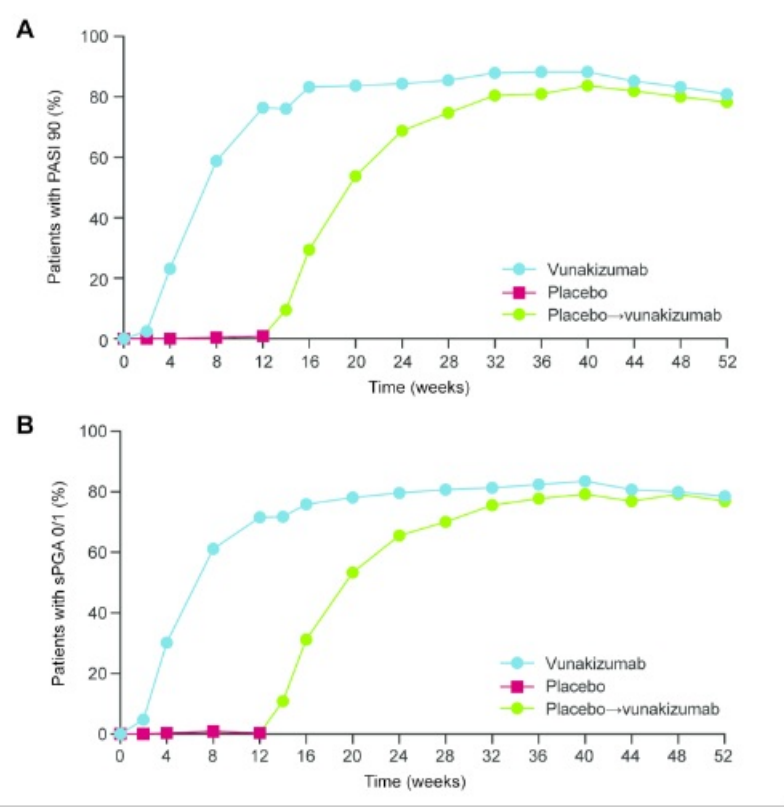

Figure 1. Proportion of patients achieving clinical response through to week 52 (intention-to-treat set). (A) PASI 90. (B) sPGA 0/1. Missing data were imputed as non-responses.

Table 1. Efficacy outcomes at week 12 (intention-to-treat set)

	Vunakizumab (n=461)	Placebo (n=229)	Difference (95% CI)*	P value (2-sided)*
Primary endpoints				
PASI 90 response	76.8	0.9	76.0 (72.0-80.1)	<0.0001
sPGA 0/1 response	71.8	0.4	71.5 (67.3-75.7)	<0.0001
Key secondary endpoints				
PASI 75 response	93.6	4.0	89.7 (86.3-93.1)	<0.0001
PASI 100 response	36.6	0	36.6 (32.1-41.0)	<0.0001
sPGA 0 response	38.2	0	38.2 (33.7-42.6)	<0.0001

Data are rates or otherwise indicated. Missing data were handled using multiple imputation. *Analyzed using the Minimum Risk method stratified by weight (<90 kg vs ≥90 kg).

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Abstract N°: 116

Drug survival of IL-17 and IL-23 inhibitors for psoriasis: a systematic review and meta-analysis

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Title: Drug survival of IL-17 and IL-23 inhibitors for psoriasis: a systematic review and meta-analysis

Introduction & Objectives:

The most recently approved biologics for moderate-to-severe psoriasis are the interleukin (IL)-17 and IL-23 inhibitors. Drug survival is a frequently used outcome to assess drug performance in practice. An overview of the available drug survival studies regarding IL-17 and IL-23 inhibitors is lacking. Therefore, our objective was to perform a systematic review and meta-analysis of drug survival of IL-17 and IL-23 inhibitors for psoriasis.

Materials & Methods:

A systematic review and meta-analysis was conducted by searching 4 databases until July 2022 (PubMed, Embase, Cochrane Library and Web of Science), assessing drug survival of IL-17 and IL-23 inhibitors in patients with psoriasis. The QUIPS tool was used to assess the quality of included studies. A non-parametric random effects model as described by Combescure was used to retrieve distribution-free summary survival curves. Survival probabilities at monthly intervals were extracted from Kaplan-Meier curves using a semi-automated tool. Summary survival curves were constructed per biologic for different discontinuation reasons: overall, ineffectiveness and adverse events, and split for the effect modifier biologic naivety. Results were analyzed separately for real-world patients' data (registries/medical records) and for prescription data (claims/pharmacy).

Results:

Of 1310 abstracts screened for eligibility, 46 studies were included for analysis. Drug survival outcomes of 24,669 patients on secukinumab, ixekizumab, brodalumab, guselkumab and risankizumab were aggregated. Summary survival estimates of real-world studies for overall, ineffectiveness and adverse event related drug survival were high (all point estimates >0.8 at year 1) for included biologics, with similar estimates for secukinumab, ixekizumab, and brodalumab, and higher estimates for guselkumab. All estimates for drug survival were higher in biologic naive than in experienced patients. Estimates of prescription databases were substantially lower than estimates from the primary analyses based on real-world data.

Conclusion:

This meta-analysis showed that the investigated IL-17 and IL-23 inhibitors had high drug survival rates, with very high rates for five-year guselkumab drug survival. We showed that effect modifiers such as biologic naivety, and the source of data used (real-world data vs. prescription databases) is relevant when interpreting drug survival studies.

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Abstract N°: 134

Efficacy and safety of AK101 in Patients with Moderate to Severe Plaque Psoriasis: Results from a Randomized, Double-Blind, Placebo-Controlled Phase III Clinical Study

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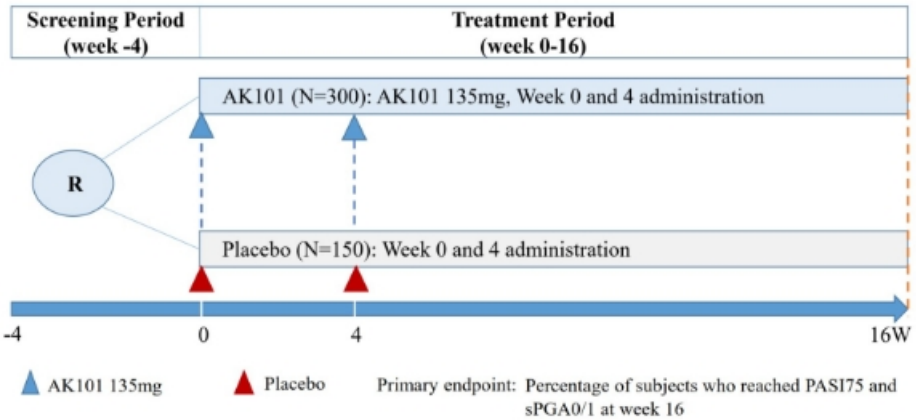
Introduction & Objectives:

Interleukin-12 (IL-12) and interleukin-23 (IL-23) are two essential cytokins involved in the immune-mediated inflammatory disorders of psoriasis. Anti-IL-12/IL-23 therapy has been developed for the treatment of psoriasis. AK101 is a fully human monoclonal antibody (mAb) targeting IL-12/IL-23 pathway. It specifically binds to the P40 subunit of both IL-12 and IL-23, resulting in inhibition of the signaling of IL-12 and IL-23 cytokines. This study was aimed to evaluate the efficacy, safety, dermatology life quality index (DLQI), Pharmacokinetics (PK) and Anti-drug antibody (ADA) of AK101 in Chinese patients with moderate to severe plaque psoriasis.

Materials & Methods:

A total of 450 psoriasis patients (male and female) with age over or equal to 18 years were planned to be enrolled. There were 2 cohorts (AK101 135mg and placebo) in this study. In each cohort, subjects were enrolled and randomized in 2:1 ratio to receive either the active drug AK101 (N=300) or matching placebo (N=150). The treatment period was 16 weeks in duration; subjects were followed until week 16 after the end of the treatment period. See the figure below for the detail of study design.



R:randomization N:sample size W:week PASI: Psoriasis Area and Severity Index sPGA: Static Physician Global Assessment

Results:

Efficacy: AK101 has potential to increase the percentage of subjects who achieved PASI75 and sPGA 0/1 responses at week 16 in subjects with moderate to severe plaque psoriasis. The response rates of PASI 75 and sPGA0/1 in AK101 group were 79.4% (239/300) and 64.0% (193/300) respectively at week 16 ($P<0.0001$), which were higher than those in placebo group [16.5% (25/150) and 11.7% (18/150), $P<0.0001$]. At the same time, AK101 can improved the response rate of PASI90 at week 16 (51.8% in the AK101 group and 7.7% in the placebo group, $P<0.0001$), and improved DLQI score of those subjects as well.

Safety: A total of 196 (65.3%) subjects received AK101 treatment and 106 (70.7%) subjects received placebo

experienced at least one treatment-emergent adverse event (TEAE). 85 (28.3%) subjects experienced at least one treatment-related adverse events(TRAE) in the AK101 treatment group, and 45 (30.0%) subjects in the placebo group. TEAEs with an incidence rate of ≥ 5% occurred in AK101 treatment group were hyperuricemia (11.3%), Hyperlipidemia (7.7%) and upper respiratory tract infection (5.7%); 3 subjects experienced serious adverse event (SAE) in AK101 group and all of the subjects have improved or recovered. There were no AEs leading to the permanent discontinuation of the treatment. No adverse events with special interest (AESI) and no AEs leading to death of subjects in this study.

PK and ADA: After subcutaneous(SC) administration of AK101 135mg at week 0 and week 4, the drug concentration at week 8 was 11.4 ± 4.37 μg/mL. The trough concentration reached 2.37 ± 1.59 μg/mL at week 16. Only 2 out of 299 subjects who received 135mg SC administration of AK101 at weeks 0 and 4 developed ADA positive at baseline. The incidence of ADA positive after baseline treatment was 7.7% (23/299), and the incidence of NAb positive was 5.0% (15/299).

Conclusion:

AK101 was generally safe and able to improve PASI and sPGA0/1 response, as well as DLQI score in Chinese subjects with moderate to severe plaque psoriasis. There was no significant difference in the incidence of AEs between the AK101 group and the placebo group.

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Abstract N°: 154

The Evaluation of Serum Prolactin levels in Psoriasis.

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Introduction & Objectives:

Psoriasis is a common, chronic inflammatory and proliferative condition of the skin, associated with systemic manifestations in many organ systems. Prolactin is a polypeptide hormone, secreted mostly by the anterior pituitary gland and has multiple immune-stimulatory effects and autoimmunity. Prolactin has a proliferative effect on keratinocytes, epithelial cells and lymphocytes. Apart from keratinocyte proliferation, prolactin enhances T-lymphocyte IFN-γ production and promotes angiogenesis. It also enhances secretion of chemokines such as CXCL9, CXCL10, CXCL11, which leads to the infiltration of type-1 T-helper cells into the psoriatic lesions. Few studies worldwide had shown both elevated and decreased levels of serum prolactin in psoriatic patients. However, in India only very few studies had been done. Therefore, the study was undertaken to evaluate the serum prolactin levels in psoriasis.

Objectives:

1. To evaluate the epidemiological profile of patients with Psoriasis.
2. To compare the values of serum prolactin levels among Psoriasis patients with controls.

Materials & Methods:

A case-control study conducted in outpatient Department of Dermatology from February 2021 to June 2022. The study included a total of 120 participants out of which 60 were psoriatic and 60 were non-psoriatic patients. Detailed history, thorough examination of the patients and laboratory estimation of serum prolactin levels in both cases and controls were done. Data was entered into Microsoft excel data sheet and analysis was done by using SPSS 22 version software.

Results:

In our study, the highest incidence of psoriasis was observed in the age group of 18-30 years (38.3%). There was a male predominance with male to female ratio of 2.53:1. The majority of the patients (63%) had age of onset of < 40 years and most of the patients (38.3%) had a disease duration of 0-6 months. 50% of the patients showed seasonal variation. 11.7% of patients had joint involvement. 51.6% of the cases had nail changes and the most common nail change noted was pitting (93.54%). Most of the cases (65%) showed BMI 18.5-24.9 followed by BMI 25-29.9 (35%). The majority of the cases (71.7%) had BSA of 3-10% followed by BSA of > 10% (23.3%). Most of the cases (51.7%) had PASI 26-40 followed by PASI 41-55 (33.3%).

In our study, the mean serum prolactin levels in the cases and controls was 12.57+8.875 and 6.71+2.684 respectively. The serum prolactin levels were higher in females (17.57+12.54 ng/ml) than in males (10.59+6.01 ng/ml). In our study, there was statistically significant difference between serum prolactin and PASI (P=0.001).

Conclusion:

The results of this study showed statistically significant difference between cases and controls with respect to prolactin (P< 0.001) and also with the severity of the disease (PASI).

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Abstract N°: 242

Bimekizumab 3-year safety and tolerability in moderate to severe plaque psoriasis: Long-term pooled analysis from five phase 3/3b trials

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Introduction & Objectives

Since psoriasis is a chronic disease, assessment of longterm safety of psoriasis treatments is essential to inform clinical decision-making and to manage risks for patients.1 Data pooled over 2 years have shown that bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,2 is well-tolerated in the treatment of moderate to severe plaque psoriasis.3 Here, 3-year safety data for BKZ are evaluated from the largest available pool of phase 3/3b data at the time of this report.

Materials & Methods

Data were pooled from the BE SURE, BE VIVID, and BE READY phase 3 trials, their ongoing open-label extension (OLE) BE BRIGHT (data cut-off: 23 October 2021), and the ongoing BE RADIANT phase 3b trial (data cut-off: 6 May 2022).4–8 Included patients received BKZ 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W); all received BKZ Q8W from Week 64 (BE RADIANT) or Week 100/104 (BE BRIGHT), or the next scheduled clinic visit.

Treatment-emergent adverse events (TEAEs) are reported over 3 years using exposure-adjusted incidence rates (EAIRs) per 100 patient-years (PY) for all patients who received ≥1 BKZ dose (BKZ Total); data are also reported separately for Years 1 (Week 0–52), 2 (Week >52–104), and 3 (Week >104–156) of BKZ exposure.

Results

Total BKZ exposure was 5,461.4 PY (N=2,186) (Year 1: 2,104.6 PY, n=2,186; Year 2: 1,905.2 PY, n=1,962; Year 3: 1,316.9 PY, n=1,547). TEAEs occurred at an EAIR of 174.4/100 PY, serious TEAEs at 5.6/100 PY, and TEAEs leading to discontinuation at 3.1/100 PY; EAIRs did not increase with longer exposure to BKZ (**Table**). Over the 3-year period, 21 deaths occurred; none were reported as treatment-related. Overall rates of TEAEs, in particular *Candida* infections, were lower in patients receiving BKZ Q8W compared with BKZ Q4W (**Table**).

The most common TEAEs were nasopharyngitis (14.1/100 PY), oral candidiasis (10.0/100 PY), and upper respiratory tract infection (6.2/100 PY), consistent with previous reports.3 The majority of oral candidiasis events were mild or moderate (99.1%); among patients who experienced oral candidiasis, few discontinued as a result (1.7%). Serious infections had an EAIR of 1.3/100 PY (**Table**); the most frequently reported serious infection was

coronavirus infection (0.3/100 PY). No cases of active tuberculosis were reported. EAIRs of laboratory elevations in aspartate aminotransferase or alanine aminotransferase >3x and >5x the upper limit of normal were 2.0 and 0.5/100 PY, respectively, and did not increase with longer BKZ exposure. EAIRs of adjudicated inflammatory bowel disease (0.2/100 PY), major adverse cardiac events (0.5/100 PY), and suicidal ideation and behaviour (0.1/100 PY) were low. EAIRs of other TEAEs of interest are reported in the **Table**.

Conclusion

Over 3 years of treatment, BKZ demonstrated a favourable safety profile, with no new safety signals observed. EAIRs of TEAEs did not increase with longer exposure to BKZ.

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Table. Summary of treatment exposure, TEAEs, and TEAEs of interest in BKZ-treated patients over 3 years

	By time period[a]			Over 3 years		
	BKZ Total			BKZ 320 mg Q4W (N=2,025)	BKZ 320 mg Q8W (N=1,935)	BKZ Total[b] (N=2,186)
	Year 1 (N=2,186)	Year 2 (N=1,962)	Year 3 (N=1,547)			
Total exposure, PY	2,104.6	1,905.2	1,316.9	2,431.4	3,035.3	5,461.4
Summary of TEAEs, EAIR/100 PY (95% CI)						
Any TEAE	227.7 (217.3, 238.4)	136.5 (129.3, 144.0)	106.9 (100.0, 114.1)	224.5 (213.8, 235.6)	121.8 (115.6, 128.3)	174.4 (166.9, 182.2)
Serious TEAEs	6.4 (5.3, 7.6)	5.9 (4.8, 7.1)	5.7 (4.4, 7.1)	6.1 (5.1, 7.2)	5.6 (4.7, 6.5)	5.6 (4.9, 6.2)
TEAEs leading to discontinuation	4.5 (3.6, 5.5)	2.3 (1.7, 3.1)	2.2 (1.5, 3.2)	3.9 (3.2, 4.8)	2.5 (1.9, 3.1)	3.1 (2.7, 3.6)
TEAEs leading to death[c]	0.3 (0.1, 0.6)	0.3 (0.1, 0.7)	0.5 (0.2, 1.1)	0.4 (0.2, 0.7)	0.4 (0.2, 0.7)	0.4 (0.2, 0.6)
TEAEs of interest, EAIR/100 PY (95% CI)						
Serious infections	1.6 (1.1, 2.3)	0.8 (0.5, 1.4)	1.4 (0.9, 2.3)	1.4 (1.0, 2.0)	1.3 (0.9, 1.8)	1.3 (1.0, 1.7)
Active tuberculosis	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Fungal infections	29.9 (27.5, 32.6)	18.8 (16.8, 21.0)	12.4 (10.5, 14.6)	26.9 (24.6, 29.3)	14.1 (12.7, 15.6)	17.5 (16.3, 18.9)
Candida infections	21.7 (19.6, 23.9)	12.7 (11.1, 14.4)	8.1 (6.6, 9.8)	19.5 (17.6, 21.5)	8.7 (7.6, 9.9)	11.7 (10.7, 12.7)
Oral candidiasis	18.5 (16.6, 20.5)	10.6 (9.1, 12.2)	7.2 (5.8, 8.8)	16.7 (15.0, 18.5)	7.5 (6.5, 8.6)	10.0 (9.1, 11.0)
Adjudicated IBD[d]	0.3 (0.1, 0.7)	0.2 (0.0, 0.5)	0.1 (0.0, 0.4)	0.3 (0.1, 0.6)	0.1 (0.0, 0.3)	0.2 (0.1, 0.4)
Adjudicated MACE	0.5 (0.3, 0.9)	0.3 (0.1, 0.7)	0.7 (0.3, 1.3)	0.6 (0.3, 1.0)	0.5 (0.3, 0.8)	0.5 (0.3, 0.7)
Malignancies	0.9 (0.5, 1.4)	1.1 (0.7, 1.7)	0.8 (0.4, 1.5)	0.7 (0.4, 1.1)	1.0 (0.7, 1.5)	0.9 (0.6, 1.2)
Excluding NMSC	0.4 (0.2, 0.7)	0.6 (0.3, 1.1)	0.6 (0.3, 1.2)	0.3 (0.1, 0.6)	0.7 (0.4, 1.1)	0.5 (0.3, 0.7)
Adjudicated SIB	0.1 (0.0, 0.4)	0.2 (0.0, 0.5)	0.0 (0.0, 0.0)	0.1 (0.0, 0.4)	0.1 (0.0, 0.3)	0.1 (0.0, 0.2)
Neutropenia events	0.8 (0.5, 1.3)	0.5 (0.3, 1.0)	0.2 (0.0, 0.5)	0.8 (0.5, 1.3)	0.3 (0.1, 0.6)	0.5 (0.3, 0.7)
ALT or AST elevations						
>3x ULN	2.6 (1.9, 3.3)	2.3 (1.7, 3.1)	2.1 (1.4, 3.0)	2.7 (2.1, 3.5)	1.7 (1.3, 2.3)	2.0 (1.6, 2.4)
>5x ULN	0.8 (0.5, 1.3)	0.3 (0.1, 0.7)	0.5 (0.2, 1.0)	0.7 (0.4, 1.1)	0.4 (0.2, 0.7)	0.5 (0.3, 0.7)
Serious hypersensitivity reactions[e]	0.1 (0.0, 0.4)	0.1 (0.0, 0.4)	0.0 (0.0, 0.0)	0.1 (0.0, 0.4)	0.1 (0.0, 0.2)	0.1 (0.0, 0.2)
Injection site reactions	3.2 (2.5, 4.1)	1.1 (0.6, 1.6)	1.1 (0.6, 1.9)	2.9 (2.2, 3.6)	1.2 (0.8, 1.6)	1.9 (1.5, 2.3)

Data and any adjudication are shown as of the data cut-offs (BE BRIGHT: 23 October 2021; BE RADIANT: 6 May 2022). [a] Year 1: Week 0–52 of BKZ exposure; Year 2: Week >52–104 of BKZ exposure; Year 3: Week >104–156 of BKZ exposure. BE RADIANT has a duration of 144 weeks only whilst the BE BRIGHT OLE is ongoing beyond Week 144; data beyond Week 144 in BE RADIANT are therefore from the safety follow-up period; [b] Patients are included in the relevant BKZ dose group based on the dose most recently received prior to the date of the adverse event. All patients received BKZ 320 mg Q8W dosing from Week 64 (OLE Week 16, BE RADIANT) or Week 100/104 (OLE Week 48, BE BRIGHT), or the next scheduled clinic visit. Patients who received both BKZ 320 mg Q4W and Q8W are included in the population count of both treatment groups, but only once in each BKZ total group; [c] Causes of death were reported under the following MedDRA preferred terms, each for one patient unless otherwise specified (patients could have multiple preferred terms identified as leading to death): aortic aneurysm rupture, brain neoplasm, cardiac arrest (5 patients), cardiopulmonary failure, chronic obstructive pulmonary disease, circulatory collapse, completed suicide, coronavirus infection (5 patients), death (2 patients, unknown cause approximately 3 months after last BKZ dose), haemorrhagic anaemia, hepatic pain, hypovolaemic shock, myocardial infarction, and road traffic accident; [d] Includes any TEAE adjudicated as definite or probable IBD; [e] No anaphylactic reactions associated with BKZ were reported. ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; IBD: inflammatory bowel disease; MACE: major adverse cardiac event; MedDRA: Medical Dictionary for Regulatory Activities; NMSC: non-melanoma skin cancer; OLE: open-label extension; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; SIB: suicidal ideation and behaviour; TEAE: treatment-emergent adverse event; ULN: upper limit of normal.

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Abstract N°: 244

Efficacy and Safety of Apremilast for the Treatment of Psoriasis in Special Areas in Pediatric Patients in the SPROUT Study

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Introduction & Objectives: Psoriasis (PsO) in special areas is difficult to treat and causes significant disease burden. Approved systemic therapies for moderate to severe plaque PsO in pediatric patients (pts) are limited and require subcutaneous injection. Apremilast (APR), a unique oral immunomodulator that inhibits phosphodiesterase 4, is approved in multiple countries for use in adults with PsO regardless of severity. This analysis assessed APR efficacy for PsO in special areas in pediatric pts in SPROUT over 16 weeks.

Materials & Methods: SPROUT (NCT03701763) is a phase 3, multicenter, randomized, double-blind, placebo (PBO)-controlled, parallel study in pts aged ≥6 to ≤17 years with moderate to severe plaque PsO (Psoriasis Area and Severity Index [PASI] ≥12, body surface area [BSA] ≥10%, and static Physician Global Assessment [sPGA] ≥3) inadequately controlled by or inappropriate for topical therapy. Pts were randomized 2:1 and stratified by age group to receive either APR (20 mg BID [pts weighing ≥20 to <50 kg] or 30 mg BID [pts weighing ≥50 kg]) or PBO for 16 weeks, after which all pts received APR through Week 52. Endpoints assessed through Week 16 included Scalp Physician Global Assessment (ScPGA) response (0 [clear] or 1 [almost clear] with ≥2-point reduction from baseline), modified sPGA of genitalia (sPGA-G) response (0 [clear] or 1 [almost clear] with ≥2-point reduction from baseline), Whole Body Itch-Numeric Rating Scale (WBI-NRS) response (≥4-point reduction from baseline), and change from baseline in Children's Dermatology Life Quality Index (CDLQI). For clinical endpoints, last observation carried forward (LOCF) was used for Week 16 assessments and nonresponder imputation (NRI) was used in longitudinal assessments. Multiple imputations were used for CDLQI analyses.

Results: A total of 245 pts (aged 6–17 years) were randomized (APR: 163; PBO: 82) from December 2018 to December 2021. Of these, 101 (41.2%) pts were aged 6 to 11 years and 144 (58.8%) were aged 12 to 17 years; 120 (49.0%) pts weighed ≥20 to <50 kg and 125 (51.0%) weighed ≥50 kg (**Table 1**).

At baseline, 81.0% of pts in the APR group and 84.1% of pts in the PBO group had moderate to severe scalp PsO (ScPGA ≥3). Significantly more pts achieved ScPGA response at Week 16 with APR vs PBO (36.4% vs 18.8%; *P*=0.0091; **Figure 1**). A total of 110 pts (44.9%; 45.4% of APR pts and 43.9% of PBO pts) had moderate to severe genital PsO (sPGA-G ≥3) at baseline. Achievement of sPGA-G response at Week 16 was numerically greater with APR than PBO (39.2% vs 25.0%), although this was not significant, possibly due to small sample size (APR: n=74; PBO: n=36). Significantly more pts achieved WBI-NRS response at Week 16 with APR vs PBO (52.0% vs 32.1%; *P*=0.0110; **Figure 2**). Greater improvements in CDLQI were also seen at Week 16 with APR vs PBO (least-squares mean change from baseline −5.1 vs −3.2; *P*=0.0009) (**Figure 3**). Limitations include use of LOCF and NRI for sensitivity analyses. No new safety signals were identified, and adverse events were consistent with the known APR safety profile. In 21 pts vaccinated during the study (including COVID-19, influenza, diphtheria, pertussis, tetanus, meningococcus, and hepatitis B), no new safety issues occurred.

Conclusion: APR significantly improved scalp PsO, itch, and quality of life in pediatric pts with moderate to severe

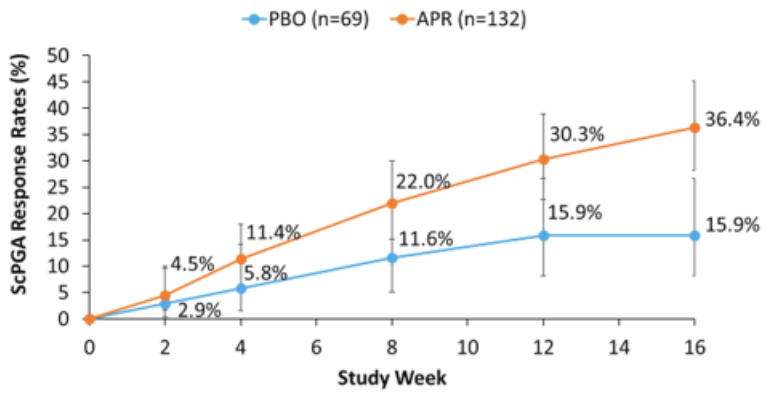
PsO. At Week 16, pts with moderate to severe genital PsO showed a trend toward improvement, although not significant due partially to sample size.

Table 1. Baseline Demographics and Disease Characteristics

Parameter	PBO (n=82)	APR (n=163)	Total (N=245)
Age, mean (SD), y	12.2 (3.25)	12.3 (3.32)	12.2 (3.29)
Age, n (%)			
6 to 11 y	34 (41.5)	67 (41.1)	101 (41.2)
12 to 17 y	48 (58.5)	96 (58.9)	144 (58.8)
Sex, n (%)			
Female	39 (47.6)	89 (54.6)	128 (52.2)
Race, White, n (%)	73 (89.0)	140 (85.9)	213 (86.9)
Weight, mean (SD), kg	51.83 (22.172)	52.04 (21.123)	51.97 (21.435)
Weight, n (%)			
≥20 to <50 kg	40 (48.8)	80 (49.1)	120 (49.0)
≥50 kg	42 (51.2)	83 (50.9)	125 (51.0)
Duration of plaque PsO, mean (SD), y	3.99 (3.394)	4.27 (3.346)	4.18 (3.358)
sPGA score, n (%)			
3 (Moderate)	63 (76.8)	122 (74.8)	185 (75.5)
4 (Severe)	19 (23.2)	41 (25.2)	60 (24.5)
ScPGA score, n (%)			
0 (clear)	4 (4.9)	7 (4.3)	11 (4.5)
1 (almost clear)	3 (3.7)	3 (1.8)	6 (2.4)
2 (mild)	4 (4.9)	17 (10.4)	21 (8.6)
3 (moderate)	49 (59.8)	90 (55.2)	139 (56.7)
4 (severe)	20 (24.4)	42 (25.8)	62 (25.3)
sPGA-G score, n (%)			
0 (clear)	27 (32.9)	65 (39.9)	92 (37.6)
1 (almost clear)	2 (2.4)	8 (4.9)	10 (4.1)
2 (mild)	15 (18.3)	12 (7.4)	27 (11.0)
3 (moderate)	34 (41.5)	60 (36.8)	94 (38.4)
4 (severe)	2 (2.4)	14 (8.6)	16 (6.5)
WBI-NRS score, mean (SD)	5.1 (2.8)	5.4 (2.9)	5.3 (2.9)
CDLQI total score, mean (SD)	7.6 (5.0)	8.8 (5.8)	8.4 (5.6)

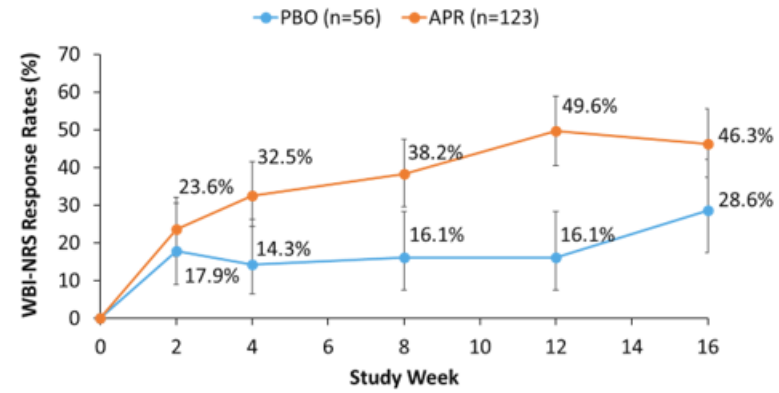
Intent-to-treat population.
Pts in the APR arm were assigned to 20 mg BID (baseline weight ≥20 to <50 kg) or 30 mg BID (baseline weight ≥50 kg).
APR=apremilast; CDLQI=Children's Dermatology Life Quality Index; PBO=placebo; PsO=psoriasis; ScPGA=Scalp Physician Global Assessment; sPGA=static Physician Global Assessment; sPGA-G=static Physician Global Assessment of Genitalia; WBI-NRS=Whole Body Itch Numeric Rating Scale.

Figure 1. ScPGA Response Rates Over Time



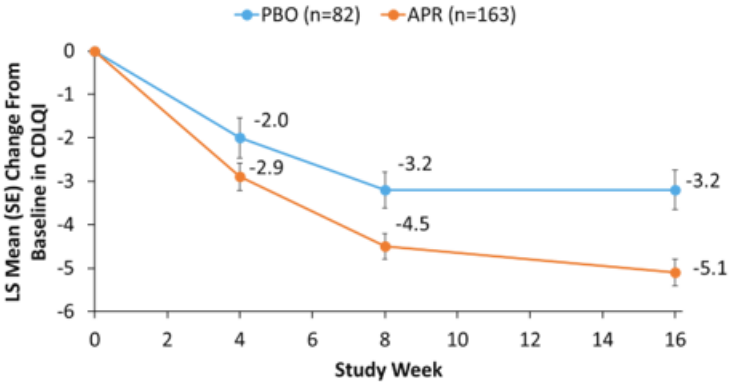
Intent-to-treat population with baseline score ≥3.
Nonresponder imputation used for missing data.
Error bars represent 95% CI.
APR=apremilast; PBO=placebo; ScPGA=Scalp Physician Global Assessment.

Figure 2. WBI-NRS Response Over Time



Intent-to-treat population with baseline score ≥4.
Nonresponder imputation used for missing data.
Error bars represent 95% CI.
APR=apremilast; PBO=placebo; WBI-NRS=Whole Body Itch Numeric Rating Scale.

Figure 3. CDLQI Total Score Change From Baseline Over Time



Intent-to-treat population.
Multiple imputations used for missing data. Error bars represent SE.
APR=apremilast; CDLQI=Children's Dermatology Life Quality Index; PBO=placebo.

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Abstract N°: 364

Estimation of Keratins K5/K14 and miRNA-21 Levels in Keratinocytes of Psoriasis Vulgaris Lesions

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Introduction & Objectives: Psoriasis is a common inflammatory skin disease with a global incidence of 1.9%. Its clinical features are red scaly plaques that can affect any part of the body. The aim of this study is to investigate K5 and K14 tissue levels and the possible role of microRNA 21 on their levels in keratinocytes of psoriasis vulgaris patients.

Materials & Methods: The present study included 80 participants divided into 40 psoriasis vulgaris patients and 40 healthy subjects of matched age and gender. All participants were subjected to full history taking and clinical examination. Quantitative real-time PCR was done to estimate the expression level of tissue microRNA 21. As well as estimation of tissue levels of K5 and K14 by ELISA techniques

Results: Results revealed that both K14 level and microRNA 21 were significantly increased in Psoriasis patients compared to the healthy group with p-value <0.001. Results showed also a significant positive correlation between K5 and K14 among the control group with p-value <0.001, while a negative correlation was found between K14 and microRNA 21.

Conclusion: Marked elevation of K14 was found in psoriasis vulgaris epidermis, though K5/K14 is usually paired there was a discrepancy between their levels in the psoriatic lesions, also miRNA-21 was markedly upregulated and was negatively correlated to the high levels of K14. Further studies are needed on wider population for more elucidation of their relationship and their role in the pathogenesis of Psoriasis vulgaris.

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Abstract N°: 365

Possible role of LncRNA MEG3-microRNA-21 and endoplasmic reticulum stress (ER stress) proteins in the pathogenesis of Psoriasis Vulgaris.

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Introduction & Objectives: Psoriasis is a chronic inflammatory immune mediated disease arising from interaction between genetic risk variants and the environment. Maternally expressed gene3 (MEG3) is a long noncoding RNA (lncRNA) known for gene transcription regulation and inhibiting proliferation. MEG3 competes with microRNA (miRNA-21) influencing cell proliferation and apoptosis balance. Endoplasmic reticulum (ER) stress proteins promote cell survival via unfolded protein response (UPR) influenced by MEG3. We aimed to detect the possible role of MEG3, miRNA-21 and ER stress proteins in pathogenesis of psoriasis vulgaris.

Materials & Methods: The present study included 80 participants divided into 40 psoriasis vulgaris patients and 40 healthy subjects of matched age and gender: Human GRP78, ATF6, caspase3 tissue levels were assayed by Enzyme Linked Immunosorbent Assay (ELISA). Assessment of long non-coding MEG3 and miRNA 21 expressions was done by quantitative real time polymerase chain reaction (qRT-PCR).

Results: Expression of MEG3 was significantly downregulated, while miRNA-21 was remarkably upregulated, ER stress proteins GRP78, ATF6 and caspase 3 all showed low levels in homogenized psoriatic lesions when compared to normal skin. miRNA 21 and MEG3 were identified as possible diagnostic markers for psoriasis vulgaris.

Conclusion: MEG3 is barely expressed in psoriatic lesions while miRNA-21 expression is remarkably elevated but when correlated to each other there was unexpected positive correlation. MEG3 and miRNA-21 were identified aspossible diagnostic markers for psoriasis. Undifferentiated psoriatic lesions have very weak UPR.

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Abstract N°: 379

Efficacy and safety of tildrakizumab for the treatment of moderate-to-severe plaque psoriasis of the scalp: A multicenter, randomized, double-blind, placebo-controlled, Phase 3b study

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Introduction & Objectives: Tildrakizumab is an anti–interleukin-23 p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis. Efficacy and safety of tildrakizumab for the treatment of scalp psoriasis were investigated in a Phase 3b, randomized, double-blind study (NCT03897088).

Materials & Methods: Patients with moderate-to-severe plaque psoriasis of the scalp (Investigator's Global Assessment [IGA] mod 2011 [scalp] ≥3, Psoriasis Scalp Severity Index [PSSI] ≥12, ≥30% scalp surface area affected) were randomized 1:1 to receive tildrakizumab 100 mg or placebo at Week (W)0 and W4. The primary efficacy endpoint was IGA mod 2011 (scalp) response, defined as "clear (0)" or "almost clear (1)" with ≥2-point reduction from baseline, at W16 (modified intention-to-treat [mITT] population); key secondary endpoints were PSSI 90 response at W16 and W12 and IGA mod 2011 (scalp) response at W12 (all mITT). Missing data were imputed as nonresponse. Safety was assessed in all patients as treated.

Results: The safety population included 231 patients (58.0% male, mean age 45.2 years; mITT, 171 patients). The primary endpoint of IGA mod 2011 (scalp) response at W16 was achieved in significantly more patients receiving tildrakizumab vs placebo (49.4% vs 7.3%; P <0.00001). Tildrakizumab was superior to placebo for all key secondary endpoints (PSSI 90 response, 60.7% vs 4.9% at W16, 48.3% vs 2.4% at W12; W12 IGA mod 2011 [scalp] response, 46.1% vs 4.9%; all P <0.00001; Table). No serious treatment-related adverse events occurred.

Conclusion: Tildrakizumab was efficacious vs placebo for the treatment of moderate-to-severe plaque psoriasis of the scalp. No new safety signals were detected.

Table. Primary and key secondary endpoints through Week 16

	Week 16		Week 12	
	TIL 100 mg (n = 89)	PBO (n = 82)	TIL 100 mg (n = 89)	PBO (n = 82)
IGA mod 2011 (scalp), n (%)	44 (49.4)	6 (7.3)	41 (46.1)	4 (4.9)
Response rate difference, TIL vs PBO (%)	40		39	
95% CI	28.2, 51.8		27.6, 50.4	
P-value	<0.00001		<0.00001	
PSSI 90, n (%)	54 (60.7)	4 (4.9)	43 (48.3)	2 (2.4)
Response rate difference, TIL vs PBO (%)	53		44	
95% CI	42.3, 63.7		33.3, 55.1	
P-value	<0.00001		<0.00001	

The primary and secondary endpoints were analyzed in the mITT analysis set with NRI. The *P*-value was less than the prespecified α level of 0.0025; therefore, the primary and key secondary endpoints were statistically significant per the step-down sequential testing approach, and testing of endpoints proceeded for all. Treatment difference and 95% CI are shown.

CI, confidence interval; IGA mod 2011 (scalp), Investigator Global Assessment modified 2011 (scalp) score of 0 or 1 with a ≥2-point reduction from baseline; mITT, modified intention-to-treat; NRI, nonresponder imputation; PBO, placebo; PSSI, Psoriasis Scalp Severity Index score; TIL, tildrakizumab.

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Abstract N°: 396

Response to IL-17A inhibitors according to prior biologic exposures: a Danish nationwide study

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Introduction & Objectives: Studies suggest that patients with previous exposure to an interleukin (IL)-17 inhibitor do not necessarily fail treatment with another IL-17 inhibitor. Whether response to an IL-17 inhibitor is different in patients with previous IL-17 inhibitor exposure compared with patients with exposure to biologics with other cytokine targets remains to be elucidated. We wanted to assess and compare the proportion of patients responding to treatment with IL-17A inhibitors with previous exposure to IL-17A inhibitors and in patients with previous exposure to (an)other biologic(s) than IL-17A inhibitors.

Materials & Methods: All patients in DERMBIO with a treatment series with an IL-17A inhibitor (secukinumab or ixekizumab) between April 2015 and October 2019 were eligible for inclusion. Patients were categorized in those treated with IL-17A inhibitors with previous exposure to an IL-17A inhibitor and in those with previous exposure to (an)other biologic(s) than IL-17A inhibitors. Response according to absolute psoriasis area and severity index (PASI)≤2 as response. The proportion of patients responding in the groups was assessed using chi2 test.

Results: In total, 100, 93, and 83 patients with previous exposure to an IL-17A inhibitor and 414, 372, and 314 patients with previous exposure to an(other) biologic(s) than an IL-17A inhibitor were assessed after 3, 6, and 12 months respectively. No differences in the proportion of patients achieving PASI≤2 was observed between the two groups after 3 months (54% vs. 57%, p=0.59), 6 months (n: 70% vs. 66%, p=0.42), and 12 months (69% vs. 60%, p=0.14). Patients with previous failure to an IL-17A inhibitors were further categorized into those with previous treatment failure and into those with drug discontinuation due to other reason than treatment failure. In total, 93 stopped the previous IL-17A inhibitor due to treatment failure and 28 stopped due to other reasons. No differences in proportion of patients achieving PASI≤2 after 3 months (54% vs. 55%, p=0.95), 6 months (71% vs. 71%, p=0.96), and 12 months (69% vs. 69%, p=0.97) were observed between the two groups

Conclusion: In conclusion, when treating patients with IL-17A inhibitors the cytokine target of the previous biologic does not seem to affect the response and the reason for discontinuation of previous biologic do not seem to affect the response.

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Abstract N°: 400

Low-incident Anti-Guselkumab Antibodies Did Not Reduce PASI Response in the Phase 3 NAVIGATE Trial, Whereas Anti-Ustekinumab Antibodies Were Associated With Reductions in PASI Response

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Introduction & Objectives: Anti-drug antibodies (ADA) can potentially diminish clinical response. Among patients with plaque psoriasis, anti-ustekinumab (UST) ADA in the PHOENIX 1 clinical trial were mostly neutralizing1 whereas anti-guselkumab (GUS) ADA in the VOYAGE 1 & 2 trials were not.2 In the phase 3 NAVIGATE trial,3 psoriasis patients with inadequate response to UST had improved response when switched to GUS. In this post hoc analysis of the NAVIGATE data, the association of ADA against UST or GUS with Psoriasis Area and Severity Index (PASI) response was explored.

Materials & Methods: In NAVIGATE, patients with moderate-to-severe plaque psoriasis (n=871) were initially treated with open-label UST through Week (W)16. Patients with inadequate response (Investigator Global Assessment [IGA] ≥2) at W16 were then randomized to GUS (n=135) or UST (n=133) through W52. Patients with adequate response (IGA=0/1) at W16 (n=585) continued with UST. Serum samples were measured for ADA (among patients with evaluable samples) using electrochemiluminescence immunoassays at W16 and W52 for UST and W36 and W52 for GUS. PASI90 and PASI100 responses represent 90% and 100% reductions from baseline in PASI.

Results: After 16 weeks of initial treatment with UST, 8.0% of 585 patients with adequate response (IGA=0/1) had anti-UST ADA (Figure 1). Among those with inadequate response (IGA ≥2) at W16 (before randomization), 17.2% of 267 patients had anti-UST ADA. Of those randomized to GUS at W16, only 3.0% had anti-GUS ADA by W36. By W52, incidence of each ADA had increased (Figure 1). As expected, the highest proportions of patients with PASI responses at W52 had IGA=0/1 at W16 after initial treatment with UST (Figure 2). However, those with anti-UST ADA had lower PASI90 and PASI100 response rates compared to those without anti-UST ADA (Figure 2). Anti-UST ADA were also associated with lower W52 PASI90 and PASI100 response rates in patients with W16 IGA ≥2 randomized to UST (Figure 2). Among UST inadequate responders randomized to GUS at W16, the presence of anti-UST ADA appeared to be associated with much smaller reductions in W52 PASI responses compared to those randomized to UST (Figure 3). In contrast, anti-GUS ADA were not associated with reductions in PASI90 or PASI100 response rates in these patients (Figure 3). The apparent increase in PASI responses with anti-GUS ADA could be due to the small number of patients with anti-GUS ADA.

Conclusion: Anti-UST ADA were more common in patients with inadequate IGA response (IGA ≥2) after 16 weeks of UST treatment than in those with adequate response (IGA=0/1). After randomization of inadequate responders to GUS or UST, incidence of anti-GUS ADA was lower than that of anti-UST ADA, and anti-GUS ADA were not associated with diminished PASI response.

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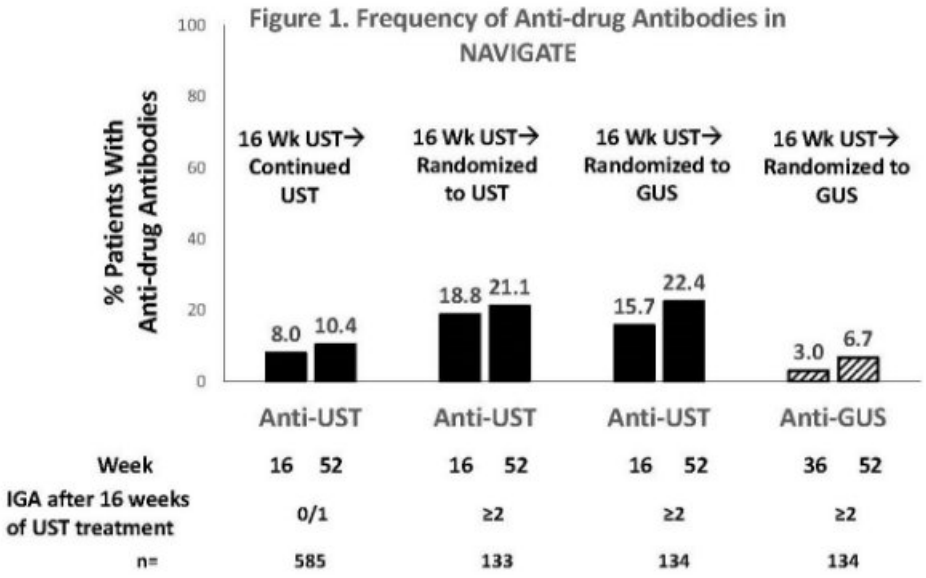


Figure 2. Association of Anti-Ustekinumab Antibodies with PASI Response at Week 52 in Patients Treated with Ustekinumab

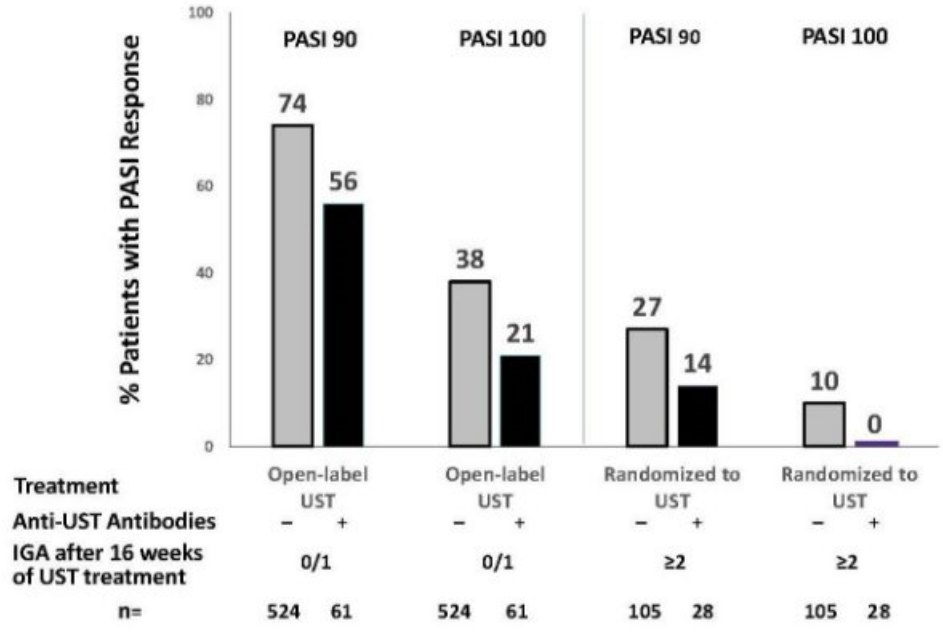
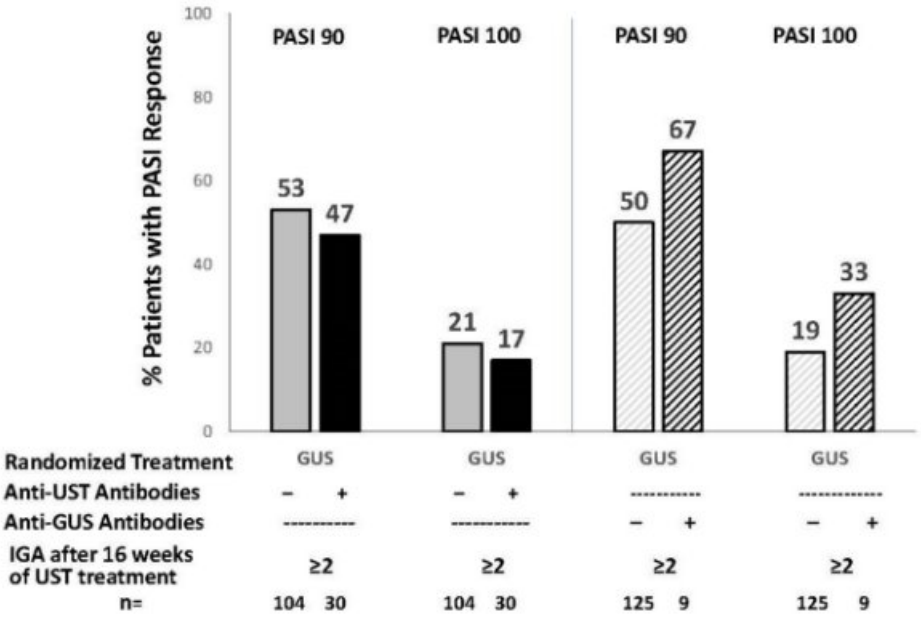


Figure 3. Association of Anti-Ustekinumab or Anti-Guselkumab Antibodies with PASI Response at Week 52 in Patients Treated with Guselkumab after 16 Weeks of UST Treatment



Randomized Treatment	GUS		GUS		GUS		GUS	
Anti-UST Antibodies	–	+	–	+	----------		----------	
Anti-GUS Antibodies	----------		----------		–	+	–	+
IGA after 16 weeks of UST treatment	≥2		≥2		≥2		≥2	
n=	104	30	104	30	125	9	125	9

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Abstract N°: 426

Efficacy and improvement in quality of life in patients treated with brodalumab in real clinical practice: a case series of 31 patients.

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Introduction & Objectives:

Psoriasis is a chronic inflammatory cutaneous disease with systemic manifestations and multiple comorbidities, including psoriatic arthritis, cardiovascular disease and obesity. Advances in the understanding of the pathogenesis of the disease have enabled new highly effective therapies targeting the IL-23/Th17 pathway.

Patients with moderate-to-severe plaque psoriasis are candidates for systemic treatments, including biologic therapies. Brodalumab is a fully human recombinant monoclonal antibody type IgG2 that binds with high affinity to IL-17RA and blocks the biological activity of the proinflammatory cytokines IL-17A, IL-17F, IL-17A/F, IL-17C and IL-17E, therefore inhibiting inflammation and clinical symptoms associated with psoriasis.

Materials & Methods:

The main objectives of this analysis are to determine the efficacy and safety of Brodalumab in the University Hospital Joan XXIII of Tarragona and compare these data with those observed in the Clinical Trials.

Baseline characteristics	
Number of patients	31
Mean age (years)	54,5
Men/Wowen n (%)	16 (52%) / 15 (48%)
Mean time of follow-up (years)	14,8
Mean BMI (Kg/m^2)	28,8
PASI (mean)	9,7
BSA (mean)	13,7
DLQI (mean)	20,6

Table 1. Description of the epidemiological data, follow-up time, PASI, BSA and DLQI scores of the sample of patients with psoriasis moderate-to-severe treated with brodalumab. BMI: Body Mass Index. PASI: Psoriasis Area and Severity Index. BSA: Body Surface Area. DLQI: Dermatology Life Quality Index.

A total of 31 patients with moderate to severe plaque psoriasis in treatment with brodalumab for at least 36 weeks (maximum 52 weeks of follow-up) were included.

Results:

Efficacy and quality of life were assessed by PASI and DLQI scores, respectively, at week 4, 12, 24, 36 and 52. Regarding the number of previous treatment lines before starting brodalumab, 83.9% (n=25) had received 1 single biological therapy previously.

A rapid improvement in absolute PASI was observed: 66% reduction of baseline PASI at week 4 and 90% at week

12. At week 12, 84%, 68% and 58% of patients achieved PASI 75, 90 and 100, respectively. This improvement was maintained over time until week 52.

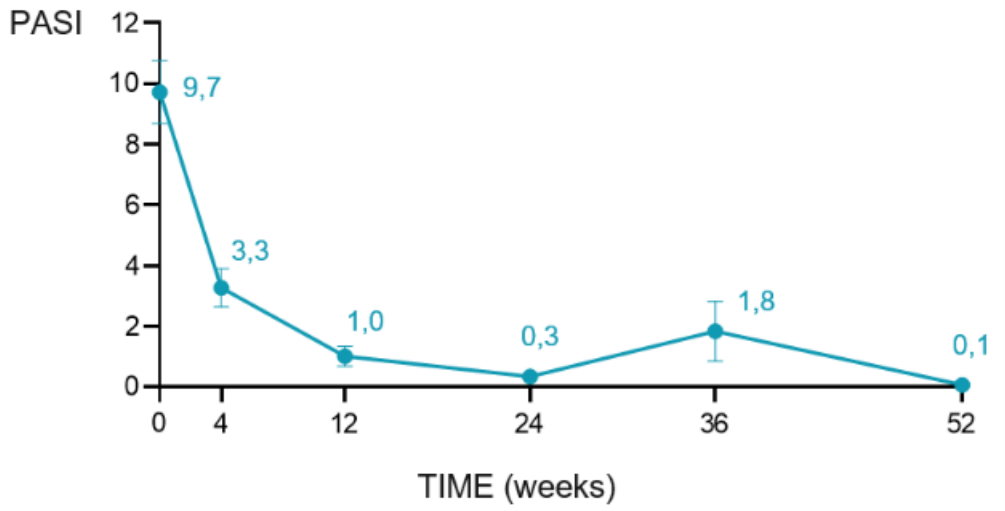

Figure 1: PASI score evolution over time, measured in weeks.

Rapid improvement in quality of life: a DLQI score reduction of 82% was observed as early as 4 weeks, reaching 93% at week 4 and maintained until week 52.

There were 6 discontinuations due to lack of efficacy, 3 due to remission of the disease at week 36 and 1 due to the appearance of joint involvement.

Efficacy data assessed by PASI scores were analyzed according to BMI and number of treatments received prior to brodalumab initiation. Regarding BMI, patients were divided into 2 cohorts: BMI<30 (n=13) and BMI ≥ 30 (n=18). No significant differences were observed in the different groups in terms of efficacy or fast onset of action. As for the number of previous treatment lines, no significant differences were observed either.

Conclusion:

In this case series, brodalumab has shown high effectiveness and fast onset of action, with a 90% reduction of baseline PASI at week 12. These results are similar to those obtained in the AMAGINE-2 and AMAGINE-3 clinical trials. Concurrent improvement in quality of life was observed. The population in this case series is mostly obese, and brodalumab appears to be a therapeutic alternative that offers a high efficacy regardless of the patient's BMI. Regarding the number of previous treatment lines, no conclusions can be drawn on efficacy, as most patients have received only one. Finally, there was only one discontinuation due to adverse effects, demonstrating a good safety profile.

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Abstract N°: 463

Sensory properties analysis of the main pharmaceutical forms used in the topical treatment of plaque psoriasis

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Introduction & Objectives: In psoriasis, poor treatment adherence is frequently related to low efficacy and limited cosmetic acceptability from patients' perspective. To potentially increase adherence and thus improve clinical outcomes, patient preferences should be considered. Some of the important attributes of topical medicines for psoriasis treatment in patients' view are good moisturizing properties, good absorption, not greasy and low skin shinning, amongst others. In order to evaluate these attributes of topical psoriasis treatment options, a study was conducted to characterize the sensorial properties of a calcipotriol (CAL) and betamethasone dipropionate (BDP) cream vehicle based on polyaphron dispersion (PAD) Technology and then compare them with those of a conventional ointment and gel (oleogel) formulations for psoriasis. In this new analysis, properties of the CAL/BDP PAD-cream vehicle are compared also with those of a non-aqueous foam formulation.

Materials & Methods: A panel of 16 experts assessed sensory properties of four different formulations similar to those used in the topical treatment in psoriasis (PAD-cream, oleogel, ointment and non-aqueous foam) at four different stages: appearance, pick-up, rub-out and after-feel. Descriptive sensory analysis was used to evaluate relevant attributes. Each attribute was rated on a line scale (range 0–100%). Active ingredients were not used because panellists were healthy volunteers, and comparable formulations were needed to be used instead.

Results: CAL/BDP PAD-cream vehicle was evaluated as having a low grease behaviour, good wetness, good spreadability and low after-feel stickiness, while the non-aqueous foam formulation showed a less desirable behaviour regarding these properties. Both cream vehicle and non-aqueous foam formulation showed similar behaviour during picking-up and immediate after-feel. However, after rubbing-out, the non-aqueous foam formulation showed an after-feel behaviour similar to the ointment, since the foam effect given by the propellants disappears, while CAL/BDP PAD-cream vehicle showed less gloss, lower stickiness and left a lower amount of residue on the skin.

Conclusion: Overall, CAL/BDP PAD-cream vehicle has the desirable requirements for a topical product for the treatment of psoriasis, with better sensory properties than the foam formulation, which may lead to greater acceptance and adherence, as it improves several attributes preferred by psoriasis patients.

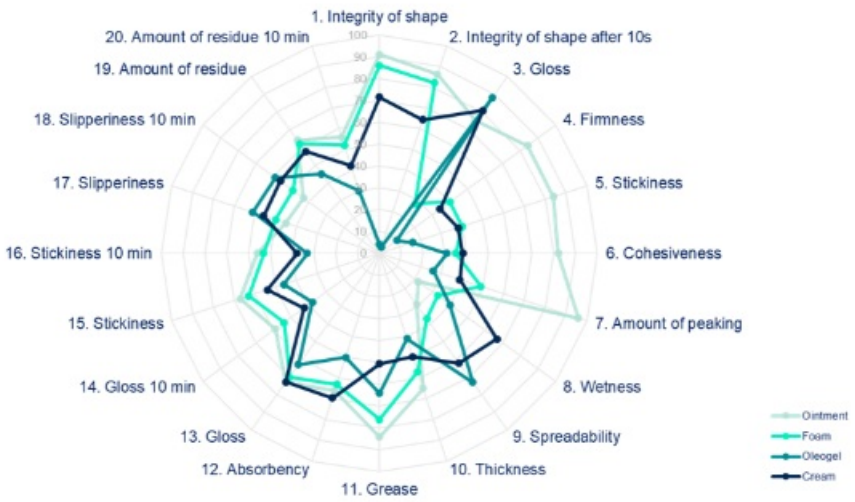

Figure 1. Radar diagram of the sensory evaluation of CAL/BDP PAD-cream vehicle versus petrolatum ointment, oleogel and foam formulations regarding parameters, including in the terms of appearance (1-3), pick-up (4-7), rub-out (8-12) and after-feel (13-20). BDP, betamethasone dipropionate; CAL, calcipotriol; PAD, polyaphron dispersion.

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Abstract N°: 475

Immunological memory of psoriatic lesions

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Introduction & Objectives:

The natural course of psoriasis is the appearance of new lesions in the place of previous ones, which disappeared after a successful therapy. Recent studies showed that after resolving of psoriatic plaques we can still find a trace of inflammation in the form of tissue resident memory cells (TRM): CD8+ T cells are abundantly present in epidermis and CD4+ in the dermis. Epidermal CD8+ TRM cells express CLA, CCR6, CD103 and IL-23R antigen and produce IL-17A during *ex vivo* stimulation, while CD4+ CD103+ TRM can produce IL-22 during stimulation. TRM in healed skin were still present and functioning after several years of disease remission.

Materials & Methods:

Systemic and topical therapy aims at constraining the inflammation, but also at inhibition of the TRM formation and reduction of its number. The recent study examining the lymphocete profile in psoriatic lesions after secukinumab and guselkumab treatment showed that both treatments reduced inflammatory DC and CD4+ CD49a-CD103-T. Interestingly, guselkumab reduced the number of TRM and promoted Treg, while secukinumab had the opposite effect. This is a very important conclusion from the study, because blocking IL-23 (a regulatory cytokine) TRM can be blocked effectively.

In own studies we assessed the occurrence of TRM in psoriatic lesions prior to and after 12 weeks of therapy in patients treated systemically with methotrexate or secukinumab or ixekizumab or adalimumab. The most rapid response was observed in case of therapy with anti-IL-17 at week 4 of treatment, while with MTX and anti- TNF the response was observable at week 12. On the other hand topical treatment with Cal/BD foam significantly decreased the expression of TRM markers mainly in the epidermis, and to a lesser extent in the dermis, during the 12-week observation period. It probably results from a worse penetration of the drug into the dermis and the effect of the preparation mainly on the epidermis. The persistence of a high expression of TRM markers in the dermis may result in the rapid recurrence of lesions after discontinuation of topical treatment.

Results:

A significant positive relationship was demonstrated between the expression of TRM markers in patients with plaque psoriasis and the duration of skin lesions, which obliges us to implement therapy as soon as possible.

Understanding the mechanisms of psoriatic inflammation and the role of TRM can help to explain the key issues related to the disease:

- the resistance of lesions to treatment and reactivation of lesions at the same location,

- isomorphic Koebner phenomenon,

- the proper time of patient treatment, longer than lesion remission, to suppress and reduce the amount of TRM.

Conclusion:

The presence of TRM explains the clinical phenomenon of tendency of psoriatic lesions to relapse in the same location and it allows to develop new therapeutic strategies in the future.

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Abstract N°: 498

Influence of guselkumab therapy on libido in patients with moderate to severe psoriasis in clinical routine: interim analysis of the non-interventional German G-EPOSS study after 28 weeks

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Introduction & Objectives:

According to the World Health Organization (WHO), sexual health is inseparably linked to overall health, well-being and quality of life1. In one psoriasis cohort, 40.8% of the patients reported sexual dysfunction **2**. Libido usually declines gradually with age. However, psoriasis can further exacerbate this natural trend and certain treatment options can even have a negative effect on sexual health3. G-EPOSS, a prospective, German multicentre, noninterventional study takes a holistic view of patient's well-being under guselkumab treatment, using patient-reported outcomes to examine sexual life (including libido) across age groups in routine clinical practice.

Materials & Methods:

The G-EPOSS study enrolled patients starting treatment with guselkumab from 10/2019 until 08/2021. Their sexual life was assessed using the Relationship and Sexuality Scale (RSS) questionnaire. This interim analysis describes outcomes for 293 patients through Week 28 (W28).

Results:

Sexual life improved among study participants overall and for all age groups with guselkumab treatment. At baseline, patients across different age groups indicated that their sex life had been negatively affected since the onset of their psoriasis.

From baseline to W28, RSS scores for impact on sexual life improved by 18% in the age group 18–<30 years, 20% in the group 30–<45 years, 17.1% in the group 45–<60 years, 11.1% in the group >60 years.

Treatment of psoriasis with guselkumab had a positive effect on sexual desire. From baseline to W28, RSS scores for sexual desire improved from 4.5% to 8.8% in the age group 18–<30 years, 6.2% to 22.7% in the group 30–<45 years, 7.0% to 14.1% in the group 45–<60 years, and 2.2% to 7.5% in the group >60 years.

Furthermore, the increase in libido was accompanied by improved satisfaction with frequency of sexual intercourse. From baseline to W28, RSS scores for satisfaction with sexual intercourse frequency increased from 59.1% to 91.1% in the age group 18–<45 years, 48.7% to 80.7% in the group 30–<45 years, 55% to 69.3% in the group 45–<60 years, and 55.5% to 57.5% in the group >60 years.

Conclusion:

The G-EPOSS study is the first to show an association between psoriasis treatment with guselkumab and an improvement of the sexual life of the patients. This manifests in an increased libido of patients as well as an

increase of sexual desire and satisfaction about the frequency of sexual intercourse until week 28 of treatment across all age groups. The increase in libido is even more pronounced in patients with psoriasis in the anogenital region at baseline. These results underscore the importance of focusing not only on treating the physical burden of psoriasis but also on the patient´s perspective on overall well-being.

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Abstract N°: 505

Kynurenine pathway in psoriasis-a promising link?

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Introduction & Objectives: Psoriasis is a common dermatosis which affects the patient's skin and also general well-being due to its link to diseases such as depression, kidney diseases or metabolic syndrome. Kynurenine pathway is one of the ways amino acid tryptophan is metabolised. In comorbidities typical for psoriasis such as chronic kidney disease, depression and atherosclerosis higher activity of the kynurenine pathway was observed when compared to the healthy individuals. The goal of this study is to explore the correlation between psoriasis, its comorbidities and their link to the kynurenine pathway as this subject has not been widely studied yet.

Materials & Methods: Researches included in the PubMed database in English, Polish and German were considered for this study. Medical Subject Headings used to investigate this top included: 'psoriasis'; 'kynurenine pathway'; 'kynurenine'; 'quinolinic acid'; 'indolamine 2,3-dioxygenase'; 'kynurenine in cardiovascular diseases'; 'kynurenine in depression'; 'kynurenine in kidney disease'; 'kynurenine in autoimmune diseases'; 'kynurenine in psoriasis'; 'kynurenine pathway in psoriasis'; 'kynurenine pathway in depression'; 'kynurenine pathway in kidney diseases'; 'kynurenine pathway in autoimmune diseases' and 'kynurenine pathway in cardiovascular diseases'.

Results: Tryptophan is an amino acid metabolised to serotonin, which regulates biological processes such as appetite, sleep or mood. However, approximately 99% of tryptophan is catabolised in the kynurenine pathway. The main product of the kynurenine pathway is nicotinamide adenine dinucleotide, however substances such as kynurenine and quinolinic acid that are by-products of this metabolic route are biologically active and believed to exhibit neurotoxic properties. In different studied it was noted that those metabolites negatively effect different organs and they were linked to the development of neurological, autoimmune and cardiovascular diseases among others. Abnormalities in the kynurenine pathway were also observed in acute kidney injury and chronic kidney disease. Patients suffering from psoriasis are at a greater risk of developing those diseases compared to a general population.** However, the kynurenine pathway has not been thoroughly studied among patients with psoriasis even though increased levels of L-kynurenine, one of an enzymes in the kynurenine pathway, were found in the psoriatic skin lesions.

Conclusion: Few reports show increased levels of metabolites and enzymes of the kynurenine pathway among patients with psoriasis and in psoriatic lesions but this connection has not been thoroughly researched yet. However, the alterations in kynurenine pathway in various psoriasis comorbidities point to the promising and a worth exploring new path that can help better understand the pathogenesis of psoriasis.

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Abstract N°: 507

Response of palmoplantar pustulosis to upadacitinib: a case series of 5 patients

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Introduction & Objectives:

Palmoplantar pustulosis (PPP) is a rare, chronic inflammatory skin disease and characterized by sterile pustules, erythema, and hyperkeratosis on the palms and soles. Recently, the first case of a successful therapy with the Janus kinase inhibitor (JAKi) upadacitinib in PPP has been published. Here, we report on five additional patients with PPP treated with upadacitinib.

Materials & Methods:

Retrospective analysis of the treatment effect of upadacitinib in five PPP patients treated in the dermatology departments of three German medical centers.

Results:

In this case series of five PPP patients, an average of 5.2 systemic therapies were used before upadacitinib therapy. In patient 1, good control by tofacitinib was maintained after switching to upadacitinib, in patient 2 and 3 there was a very good therapeutic response of PPP under upadacitinib, in patient 4, after a partial effect of guselkumab, PPP almost cleared after switching to upadacitinib, and in patient 5 there was a moderate improvement of PPP.

Conclusion:

To date, there are only small case series and few case reports on the therapy of PPP with tofacitinib, a JAKi that primarily inhibits JAK1 and JAK3, and one case report on the successful therapy of PPP with upadacitinib that has predominately a selectivity for JAK1. Our case series, together with the case already published, suggests that upadacitinib and possibly also other selective JAK1 inhibitors may be promising therapeutic options for PPP. Future studies are warranted to further investigate the role of JAKi in PPP.

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Abstract N°: 565

Secukinumab Demonstrates Sustained Retention and Favourable Safety in Patients With Moderate to Severe Plaque Psoriasis in a Real-world Setting: Long-term Results From an Interim Analysis of the SERENA Study

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Introduction & Objectives: Secukinumab has shown long-lasting efficacy and a favorable safety profile across multiple clinical trials across various domains of psoriatic disease1–7. Real-world evidence studies provide additional valuable data on the long-term retention and safety of secukinumab in routine clinical practice. This interim analysis of the SERENA study reports retention and safety data from patients with psoriasis (PsO) enrolled in the study between October 2016 and October 2018 who were observed for at least 3 years.

Materials & Methods: SERENA (CAIN457A3403) is a large, ongoing, longitudinal, observational study conducted at 438 sites across Europe for an expected duration of up to 5 years with a total intake of more than 2900 adult patients with moderate to severe PsO, psoriatic arthritis, and ankylosing spondylitis. Patients received ≥16 weeks of secukinumab treatment before enrolment in the study. Data were collected both retrospectively and prospectively. Retention rates of secukinumab were measured after the start of participation in the study, where retention rate is defined as the percentage of patients who have not discontinued secukinumab treatment.

Results: In total, 1755 patients with moderate to severe PsO (67.4% male) with a mean age of

48.4 years and a body mass index of 28.8 kg/m2 were included in the analysis. The secukinumab treatment retention rates after 1, 2 and 3 years in the study were 88.3%, 75.7%, and 68.2%, respectively. The time to treatment discontinuation of secukinumab after inclusion in the study is shown in Figure 1. In total, 755 patients discontinued the study and the most common reasons provided for discontinuation included lack of efficacy (43.6%), adverse event (15.8%), patient decision (13.4%), physician decision (12.1%) and lost to follow-up (7.7%). The safety profile of secukinumab was consistent with the known secukinumab safety profile, with no new safety signals reported. Low rates of inflammatory bowel disease (incidence rate per 100 subject-years [IR]: 0.13), candida infections (IR: 1.21) and MACE (IR: 0.34) were observed.

Conclusion: Secukinumab showed a high treatment persistence and a favorable safety profile in patients with moderate to severe PsO during long-term follow-up in a real-world population.

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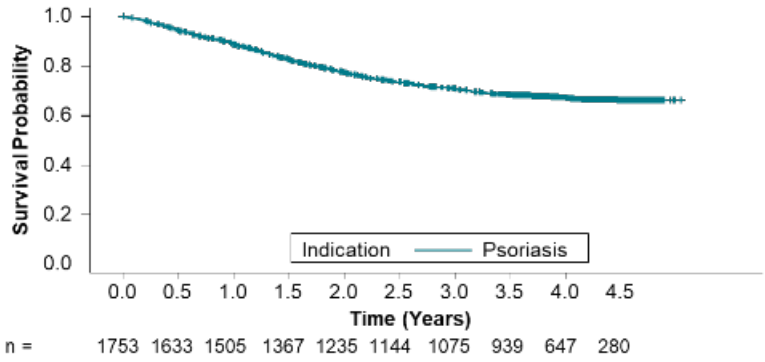
Figure 1: Time to treatment discontinuation of secukinumab



n, number of patients with evaluation (ie, with nonmissing data).

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Abstract N°: 570

Examining patterns and clusters of comorbidities in people with psoriasis

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Introduction & Objectives: Psoriasis is associated with several chronic diseases which can impact on physical and emotional health and mortality. Understanding patterns of comorbidity may prompt earlier and more targeted screening for these conditions and more appropriate treatment and management of psoriasis patients.

Materials & Methods: We obtained primary care data from English general practices from the Clinical Practice Research Datalink (CPRD) Aurum, linked with hospital and death records and Index of Multiple Deprivation data, to identify people diagnosed with psoriasis between 1998 and 2020. Crude and age-standardised prevalence of 30 chronic conditions were calculated at and after the psoriasis diagnosis. We used latent class analysis (LCA), incorporating patient characteristics (age, sex, ethnicity, deprivation, obesity), to empirically identify comorbidity clusters at baseline, and multinomial logistic regression to predict latent class membership.

Results: Our study population included 275,620 people with incident psoriasis; mean age 49±18 years, 51% female, with an ethnic composition of 81% White, 5% Asian, 1% Black, 1% other, and 12% unknown. Fifty-four percent of patients had at least one comorbidity present at diagnosis (58% of females, 49% of males, 58% of White patients, and 46% of Black and Asian patients). Common comorbidities were anxiety and depression (17%), osteoarthritis (15%), asthma (9%), sleep disorders (8%), type 2 diabetes (6%), thyroid disorders (6%), cancer (5%), chronic obstructive pulmonary disease (4%), inflammatory arthritis (4%), inflammatory bowel disease (3%), gout (3%), renal disease (3%), diverticular disease (3%) and stroke (3%). Women had a higher prevalence of anxiety/depression, osteoarthritis, inflammatory arthritis, asthma, and sleep disorders than men whereas type 2 diabetes, gout, and cardiovascular conditions were more prevalent in men. Most comorbidities were more prevalent in White patients compared with Asian or Black patients except for type 2 diabetes, renal disease, and liver disorders (non-alcoholic fatty liver disease, chronic liver disease, cirrhosis, hepatitis). Comorbidities were broadly similar across deprivation quintiles, except for anxiety/depression which increased as deprivation increased. LCA identified five distinct comorbidity classes including: 2.4% of patients in the "multiple comorbidities" class; 15.9% in the "type 2 diabetes & renal disease" class; 11.8% in the "sleep & mental health" class; 1.8% in the "respiratory & osteoarthritis" class; and 68.2% in the "low comorbidity" class. Relative to membership in the "low comorbidity" class: increasing age and deprivation levels were associated with higher probability of membership of all comorbidity classes, women had a higher probability of membership in the "multiple comorbidities" class (relative risk ratio [RRR] 1.48, 95% CI 1.38-1.58), "sleep & mental health" class (RRR 1.84 [1.79-1.89]) and "respiratory & osteoarthritis" class (RRR 1.04 [1.00-1.08]) compared to men and, Black and Asian patients had a higher probability of membership in the "type 2 diabetes & renal disease" class compared to White patients; RRR 1.06 (1.00-1.13) and RRR 1.25 (1.16-1.34), respectively.

Conclusion: We observed five distinct classes of comorbidities with differing patient profiles in people with psoriasis. Knowledge of these comorbidity patterns will assist clinicians in their management of people living with psoriasis.

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Abstract N°: 574

Real-World Patient Satisfaction and Quality of Life Among Ixekizumab Treated Patients with and without Nail Psoriasis

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Introduction & Objectives:

Psoriasis (PsO) involving special body sites increases disease severity,1 and carries a high burden of disease for patients.2 Involvement of special body sites, including nails, factors into therapeutic decision making in clinical practice.1 In clinical trials, ixekizumab (IXE) improved nail PsO at 24 weeks and in long term 5-year *post hoc* analyses.3-4 However, real-world data (RWD) on treatment satisfaction and quality of life (QoL) in IXE treated patients with PsO involving nails is lacking. This study evaluates RWD from the US IXE Customer Support Program (CSP) and describes patient-reported treatment satisfaction and QoL in IXE treated patients with PsO, with (w/) and without (w/o) nail involvement, from baseline (BL) to 24 weeks.

Materials & Methods:

In this 24-week prospective observational study, we analysed patient-reported treatment satisfaction and QoL in patients with PsO, w/ and w/o nail (fingernails and toenails) involvement at BL. Treatment satisfaction was assessed from the first 3 items of the patient satisfaction questionnaire (PSQ): PSQ1 (*i.e.*, my PsO is clear or almost clear), PSQ2 (*i.e.*, my PsO is clearing quickly), and PSQ3 (*i.e.*, my PsO is staying clear or almost clear while taking my medicine) starting at week 2. QoL was assessed from BL by the Dermatology Life Quality Index (DLQI). Here, we present percentages of patients reporting PSQ scores 4 (satisfied) or 5 (strongly satisfied), and DLQI (0,1). Descriptive statistics on observed data are reported, no data imputation was performed.

Results:

This analysis included 523 IXE treated patients with PsO: 140 w/ nail involvement and 383 w/o. At BL, patients w/ nail involvement had longer PsO duration *vs* those w/o (224.5 months *vs* 187.1), greater biologic treatment experience (54.3% *vs* 46.5%), and higher DLQI impact (mean (SD)): 11.6 (8.1) *vs* 9.2 (6.3) (Table 1). At BL, the proportions of patients reporting DLQI (0,1) were numerically similar between patients w/ nail involvement *vs* w/o: 8.0% *vs* 8.6%. These percentages increased steadily in both patient groups though week 24, when DLQI (0,1) was reached by half of the patients w/ nail involvement (50.5%) and w/o (55.1%) (Table 2). At week 2 (time of the PSQ first administration), the proportions of patients w/ nail involvement *vs* w/o reporting to be either satisfied or strongly satisfied were: 25.9% *vs* 32.4% for PSQ1, 47.2% *vs* 42.5% for PSQ2, and 34.3% *vs* 36.5% for PSQ3. These percentages increased steadily in both patient groups through week 24, when three-fourths of patients reported to be either satisfied or strongly satisfied, and percentages were numerically similar between patients w/ nail involvement *vs* w/o: 78.4% *vs* 75.6% for PSQ1, 74.2% *vs* 72.3% for PSQ2, and 76.3% *vs* 75.2% for PSQ3 (Table 2).

Conclusion:

This RWD analysis from the US IXE CSP demonstrated that the proportions of IXE treated patients with PsO who reported being satisfied or strongly satisfied with treatment and increases in DLQI (0,1) over time to week 24 were

similar for patients w/ *vs* w/o nail involvement at BL.

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3Dennehy E B, J Drugs Dermatol 2016;15(8):958-61. PMID: 27537996.

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Table 1. Demographics and baseline characteristics of IXE treated patients with PsO, w/ and w/o nail involvement at BL.

	W/ nail involvement at BL (N=140)	**W/o nail involvement at BL** (N=383)
Age, years	47.1 (12.0)	47.7 (12.1)
Female, n (%)	85 (60.7)	247 (64.5)
White, n (%)	124 (88.6)	327 (85.4)
BMI, kg/m^2	31.4 (7.7)	32.3 (7.9)
PsO duration time, months	224.5 (170.6)	187.1 (165.3)
Biologic experienced (previous 2 years), n (%)	76 (54.3)	178 (46.5)
BSA/PREPI	13.2 (20.9)	8.3 (12.3)
Itch NRS	5.3 (2.7)	5.2 (2.7)
Skin Pain NRS	4.6 (2.8)	4.1 (2.8)
DLQI	11.6 (8.1)	9.2 (6.3)
PatGA	3.3 (1.4)	3.2 (1.4)

Data are mean (standard deviation) unless stated otherwise.
Abbreviations: BL, baseline; BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; IXE, ixekizumab; N, number of patients with non-missing data at baseline; n=number of patients in the specified category; NRS, Numeric Rating Scale; PatGA, Patient's Global Assessment; PREPI, Patient-Reported Extent of Psoriasis Involvement; PsO, psoriasis; w/, with; w/o, without.

Table 2. Proportions of IXE treated patients with PsO, w/ and w/o nail involvement at BL, who reported DLQI (0,1), PSQ1 (4,5), PSQ2 (4,5), and PSQ3 (4,5) at BL and at week 24.

	W/ nail involvement at BL % (n/Nx)		W/o nail involvement at BL % (n/Nx)	
	BL*	**Week 24**	**BL***	**Week 24**
DLQI (0, 1)	8.0% (11/137)	50.5% (49/97)	8.6% (32/374)	55.1% (135/245)
PSQ 1 (4, 5)	25.9% (28/108)	78.4% (76/97)	32.4% (93/287)	75.6% (183/242)
PSQ 2 (4, 5)	47.2% (51/108)	74.2% (72/97)	42.5% (122/287)	72.3% (175/242)
PSQ 3 (4, 5)	34.3% (37/108)	76.3% (74/97)	36.5% (105/288)	75.2% (182/242)

**Baseline for PSQ starts at week 2, time of first administration.*
Scores 0 or 1 in the DLQI correspond to "not at all" or "a little" impact on QoL.
Scores 4 or 5 in the PSQ correspond to "satisfied" or "strongly satisfied" with the treatment.
PSQ1, My psoriasis is clear or almost clear; PSQ2, My psoriasis is clearing quickly; PSQ3, My psoriasis is staying clear or almost clear while taking my medicine.
Abbreviations: BL, baseline; DLQI, Dermatology Life Quality Index; IXE, ixekizumab; n=number of patients in the specified category; Nx, number of patients with non-missing data in the specified category; PsO, psoriasis; PSQ, Patient Satisfaction Questionnaire; QoL, quality of life; w/, with; w/o, without.

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Abstract N°: 661

Risk of uveitis in patients with psoriasis in Korea: A nationwide population-based cohort study

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Introduction & Objectives: Evidence for the association between psoriasis and uveitis according to the severity of psoriasis including psoriatic arthritis (PsA) and type of uveitis is lacking, and there are no data on the frequency or timing of recurrence of uveitis in patients with psoriasis. The objective of this study was evaluate the risk of first occurrence and recurrence of uveitis in patients with psoriasis in the Korean population. We further evaluated the risk of uveitis according to the severity of psoriasis, comorbidity of PsA and location of uveitis.

Materials & Methods: In a nationwide retrospective cohort study, we compared 317,940 adult patients who had psoriasis with 635,880 matched controls. Incidence rates (IRs) and estimated IR ratios of the first occurrence and recurrence of uveitis were calculated using survival analysis and Poisson regression, respectively.

Results: The rate of uveitis incidence and uveitis recurrence in patients with psoriasis was 1.18 and 2.31 per 1000 person-years, respectively. Compared to the controls, the IR ratios of development and recurrence of uveitis in patients with psoriasis were 1.14 (95% CI 1.08, 1.2) and 1.16 (95% CI 1.12, 1.21), respectively. The recurrence rate of uveitis was highest within 3 years after the onset of psoriasis. The corresponding IR ratios for uveitis recurrence in patients with mild psoriasis, severe psoriasis and PsA were 1.11 (1.06, 1.16), 1.24 (1.16, 1.33) and 1.49 (1.31, 1.7), respectively. Patients with psoriasis had an increased risk of recurrence of anterior uveitis, and patients with both psoriasis and PsA had an increased risk of recurrence of both anterior-uveitis and panuveitis.

Conclusion: Patients with psoriasis had a higher risk of both development and recurrence of uveitis, especially with severe psoriasis and PsA. The timing of uveitis recurrence was related to the onset of psoriasis, and patients who had psoriasis with PsA had an increased risk of vision-threatening panuveitis.

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Abstract N°: 716

Exploratory exposure–response analyses for skin responses from the randomized, double-blind, placebo-controlled phase 2b trial of the oral TYK2 inhibitor TAK-279 in moderate-to-severe psoriasis

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Introduction & Objectives:

TAK-279 is a highly selective, oral, allosteric inhibitor of tyrosine kinase 2 (TYK2) that mediates signaling from cytokines involved in the pathology of psoriasis and other immune-mediated diseases. The phase 2b study of TAK-279 met its primary endpoint; at the highest dose (30 mg; n=52), 67% of patients achieved a Psoriasis Area and Severity Index (PASI) 75 response at Week 12, with 46% and 33% achieving PASI 90 and PASI 100, respectively. Here, we report an exploratory exposure–response (E–R) analysis of this study to evaluate the impact of TAK-279 exposure on achievement of clinically relevant skin responses, including PASI 100 and body surface area (BSA) <1%.

Materials & Methods:

In this double-blind, placebo-controlled study (NCT04999839), patients with moderate to severe plaque psoriasis were randomized (1:1:1:1:1) to one of four doses of TAK-279 (2 mg, 5 mg, 15 mg, 30 mg) or placebo, given orally once daily for 12 weeks. Average concentration (Cavg) of TAK-279 was the primary exposure metric, calculated from individual patient pharmacokinetic (PK) parameters derived from a population PK model. Relationships between exposure and achievement of skin responses (PASI 75/90/100; BSA <1%) to Week 12 were assessed using exploratory plots. Cavg was divided into four groups (BINs; where CavgBIN=0 represents placebo) with increasing TAK-279 concentrations and proportion of patients with skin responses in each group plotted by time. We also report least squares (LS) mean change from baseline in BSA, analysed using a mixed model for repeated measures.

Results:

In total, 259 patients were randomized and received treatment (mean [standard deviation] baseline PASI and BSA: 17.7 [6.48] and 21.8% [13.35], respectively). LS mean (standard error) changes from baseline at Week 12 in BSA were: –4.0 (1.43), –7.6 (1.49), –11.9 (1.43), –14.7 (1.43) and –15.7 (1.43) for placebo, 2 mg, 5 mg, 15 mg and 30 mg groups, respectively ($p<0.001$ vs placebo except for 2 mg). A total of 250 patients with predicted Cavg were included in the post hoc E–R analysis. A positive E–R relationship was observed where higher exposures were associated with a greater proportion of patients achieving PASI 75/90/100 responses (Figure 1) and BSA <1% (Figure 2), with evidence of earlier onset of response with increasing exposure. Adverse events (AEs) were reported in 53–62% of patients in the TAK-279 groups versus 44% in the placebo group, without dose dependency. Changes in laboratory parameters consistent with TYK2 inhibition (e.g. creatine kinase elevations) were noted in TAK-279 groups. However, no dose- or exposure-dependent changes in laboratory parameters were noted in TAK-279 groups.

Conclusion:

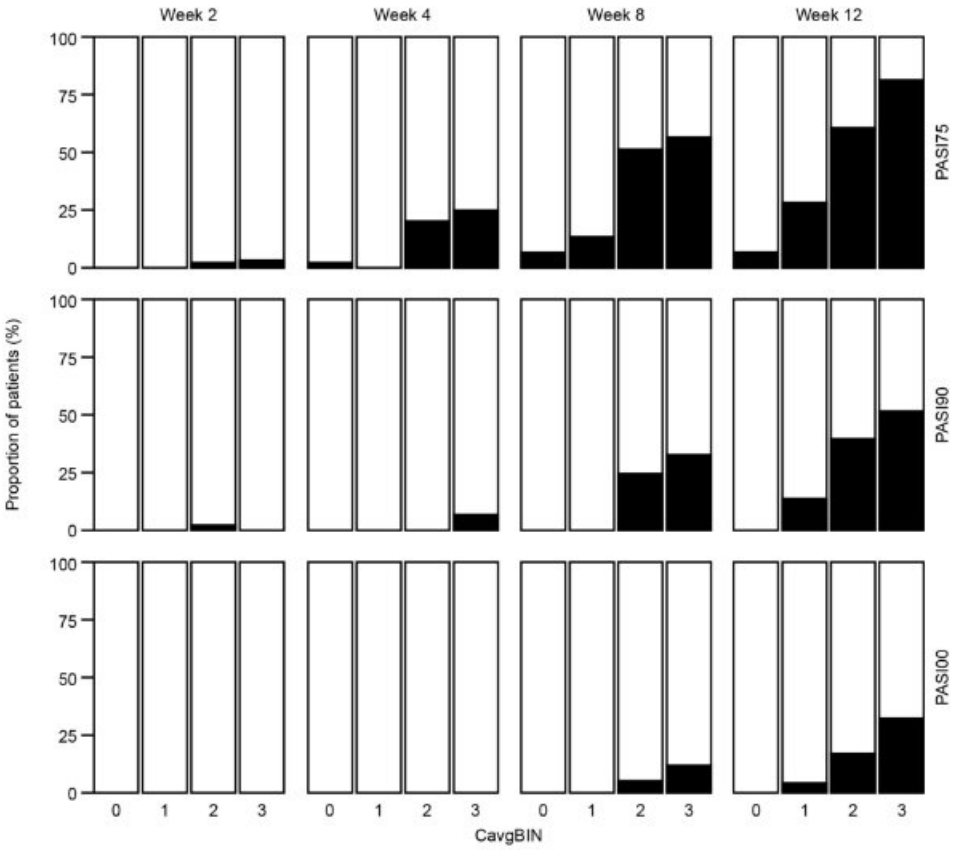
The highest dose of TAK-279 (30 mg) generated exposure levels associated with a greater proportion of patients

achieving earlier and maximal skin responses, including PASI 100 and BSA <1%.

Study/writing funding:

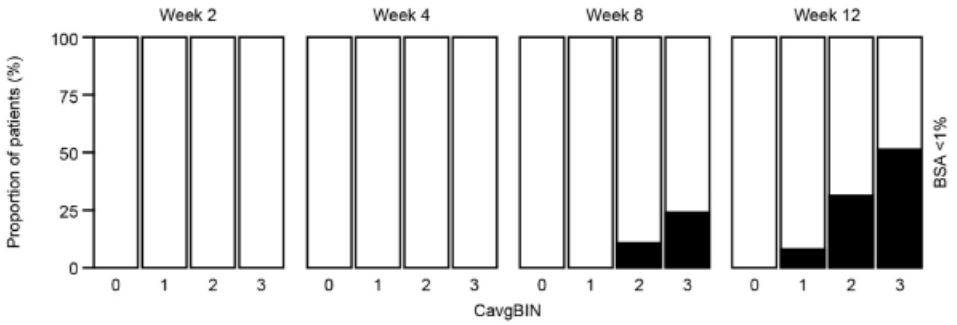
Nimbus Discovery, Inc./Takeda Development Center Americas, Inc.

Figure 1. Proportion of patients achieving PASI 75, 90 and 100 responses over time and by exposure (CavgBIN)



Positive PASI response shown by black bars for PASI 75 (top), PASI 90 (middle) and PASI 100 (bottom). CavgBIN 0 represents exposure in the placebo group. CavgBINs 1–3 represents exposure in the TAK-279 arms. CavgBIN 1: low exposure, median (range) 14.2 (3.37–24.7) ng/mL; CavgBIN 2: medium exposure, median (range) 49.7 (24.8–109) ng/mL; CavgBIN 3: high exposure, median (range) 177 (112–712) ng/mL. CavgBIN, average concentration group; PASI, Psoriasis Area and Severity Index.

Figure 2. Proportion of patients achieving a BSA <1% response over time and by exposure (CavgBIN)



Positive BSA response shown by black bars for BSA <1%. CavgBIN 0 represents exposure in the placebo group. CavgBINs 1–3 represents exposure in the TAK-279 arms. CavgBIN 1: low exposure, median (range) 14.2 (3.37–24.7) ng/mL; CavgBIN 2: medium exposure, median (range) 49.7 (24.8–109) ng/mL; CavgBIN 3: high exposure, median (range) 177 (112–712) ng/mL. BSA, body surface area; CavgBIN, average concentration group.

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Abstract N°: 717

Consistent Skin Clearance With Guselkumab Treatment for up to 5 Years in Patients With Moderate to Severe Psoriasis Irrespective of Baseline Disease Extent or Severity in the VOYAGE 1 and 2 Studies

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Introduction & Objectives: Guselkumab (GUS) is an interleukin-23p19 subunit inhibitor approved for the treatment of moderate-to-severe plaque psoriasis (PsO) and active psoriatic arthritis. The objective of this post-hoc analysis is to assess mean percentage and absolute improvement in Psoriasis Area and Severity Index (PASI) through 5 years of GUS treatment in patients with lower body surface area (BSA) vs. extensive BSA involvement, using pooled data from the phase 3 VOYAGE 1&2 studies.1,2

Materials & Methods: In VOYAGE 1&2, patients with moderate-to-severe PsO were randomized to GUS; placebo (PBO) with crossover to GUS at Week 16; or adalimumab. In VOYAGE 1, patients entered open-label GUS treatment from Weeks 52-252. VOYAGE 2 utilized a randomized withdrawal study design (Weeks 28-72), followed by open-label GUS treatment from Weeks 76-252. Mean percentage improvement from baseline in PASI and absolute PASI thresholds of 0, ≤1, and ≤3 were evaluated in PsO patients with lower BSA involvement (IGA 3, BSA 10%-15%, and PASI 12-15) and extensive BSA involvement (IGA 3 or 4, BSA >15%, and PASI >15) at baseline. Data are summarized for patients randomized at baseline to GUS or PBO, and for the combined GUS group (GUS and PBO→GUS); treatment failure rules were applied.

Results: At baseline, 9.5% (173/1829) of patients evaluable for efficacy had lower BSA involvement (GUS: IGA 3, mean BSA 12.6%, mean PASI 13.5; PBO: IGA 3, mean BSA 12.7%, mean PASI 13.6) and 58.6% (1072/1829) had extensive BSA involvement (GUS: IGA 3 73.1%, IGA 4 26.9%, mean BSA 30.9%, mean PASI 23.3; PBO: IGA 3 72.1%, IGA 4 27.9%, mean BSA 29.6%, mean PASI 22.4). As early as Week 4 in the GUS groups, mean percentage improvement from baseline in PASI was >50%, and at Week 16 was approximately 90%; these results were comparable by disease extent (lower vs. extensive BSA) and across disease severities (IGA 3 vs. 4). At Week 100, mean percentage improvement from baseline in PASI was approximately 93% and maintained through Week 252. Similarly, absolute PASI responses were comparable for patients in the GUS groups at Weeks 16 and 24, regardless of baseline disease extent or severity (Table 1). Comparable absolute PASI responses were achieved at Week 100 and were maintained through Week 252 (Table 2).

Conclusion: Regardless of baseline disease extent or severity, robust and durable skin responses were observed as early as Week 4; long-term responses were sustained over time with GUS treatment through 5 years.

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Table 1. Proportions of Patients Achieving Absolute PASI Thresholds at Weeks 16 and 24 by Psoriasis Extent and Severity at Baseline

	Lower BSA Involvement Moderate			Extensive BSA Involvement Moderate-Severe		
	Week 16		Week 24	Week 16		Week 24
	PBO (n=63)	GUS (n=110)	GUS (n=110)	PBO (n=359)	GUS (n=713)	GUS (n=713)
PASI 0	3.2%	37.3%	44.5%	0.3%	35.1%	44.2%
PASI ≤1	6.3%	53.6%	63.6%	0.6%	55.0%	63.1%
PASI ≤3	7.9%	86.4%	91.8%	3.3%	79.1%	83.7%

Moderate: IGA=3, BSA 10%-15%, and PASI 12-15; Moderate-Severe: IGA 3 or 4, BSA >15%, and PASI >15.

Table 2. Proportions of Patients Achieving Absolute PASI Thresholds at Weeks 100, 156, 204, 252 in the Combined GUS Group* by Psoriasis Extent and Severity at Baseline

	Lower BSA Involvement Moderate				Extensive BSA Involvement Moderate-Severe			
	Week 100 (n=157)	Week 156 (n=148)	Week 204 (n=142)	Week 252 (n=135)	Week 100 (n=947)	Week 156 (n=896)	Week 204 (n=865)	Week 252 (n=815)
PASI 0	51.0%	58.8%	60.6%	63.0%	49.3%	48.2%	51.7%	51.2%
PASI ≤1	72.6%	74.3%	74.6%	72.6%	66.0%	64.4%	66.7%	66.3%
PASI ≤3	95.5%	95.9%	92.3%	93.3%	87.8%	85.5%	86.5%	88.2%

Moderate: IGA=3, BSA 10%-15%, and PASI 12-15; Moderate-Severe: IGA 3 or 4, BSA >15%, and PASI >15.
*Includes patients randomized to GUS at baseline and those randomized to PBO at baseline who crossed over to GUS at Week 16.

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Abstract N°: 802

Impact of risankizumab compared with apremilast on improving health-related quality of life, treatment satisfaction, and work productivity in patients with moderate plaque psoriasis: results from the phase 4 IMMpulse trial

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Introduction & Objectives: Risankizumab (RZB) is a humanized immunoglobulin G1 monoclonal antibody that inhibits IL-23 by binding to its p19 subunit. This analysis evaluated the impact of RZB vs apremilast (APR) on health-related quality of life (HrQoL), psoriasis symptoms, treatment satisfaction, work productivity and activity impairment in adult patients (pts) with moderate plaque psoriasis (PsO) who were candidates for systemic therapy.

Materials & Methods: IMMpulse is a phase 4, multicenter, randomized, open-label, assessor-blinded, active comparator study comparing RZB to APR in adult pts with moderate plaque PsO. In Period A, pts were stratified by weight and prior systemic and/or biologic therapy and randomized 1:2 to receive subcutaneous RZB (150 mg; N=118) or oral APR (30 mg BID; N=234) for 16 weeks (wks). In Period B, all APR-treated pts were re-randomized 1:1 to RZB (N=102) or APR (N=97) stratified by PASI 75 response. Patient-reported outcomes (PROs) assessed were Psoriasis Symptoms Scale (PSS), Dermatology Life Quality Index (DLQI), Treatment Satisfaction Questionnaire for Medication version 9 (TSQM-9), and Work Productivity and Activity Impairment (WPAI) for PsO. For binary endpoints, non-responder imputation incorporating multiple imputations to handle missing data was used. For continuous endpoints, least squares mean changes from baseline (BL) at wk 16 were compared between RZB vs APR by mixed-effects repeated regression modeling.

Results: Mean PRO scores were similar between treatment arms at BL; mean PSS (RZB/APR) was 8.8/9.0, and mean DLQI was 12.6/12.7. At wk 16, a greater proportion of pts treated with RZB vs APR achieved PSS 0 (29.7%/3.0%), PSS 0/1 (44.9%/9.0%), DLQI 0/1 (54.2%/14.1%), and ≥ 4 points improvement in DLQI (minimally clinically important difference [MCID]; 82.4%/52.6%) (Table). In pts who continued Period A treatment beyond wk 16, a greater proportion of RZB-treated pts achieved PSS 0 (46.6%), PSS 0/1 (60.2%), DLQI 0/1 (66.1%) and DLQI MCID (76.9%), than pts treated with continuous APR from BL where pts achieved PSS 0 (0%), PSS 0/1 (4.5%), DLQI 0/1 (9.1%) and DLQI MCID (15.8%) at wk 52 (all nominal P<0.001). At wk 16, RZB- vs APR-treated pts reported greater overall treatment satisfaction (adjusted difference [Δ], 39.8; 95% CI, 34.2, 45.5), satisfaction with effectiveness (Δ, 34.3; 95% CI, 28.3, 40.3), and satisfaction with convenience (Δ, 16.3; 95% CI, 11.8, 20.7). RZB- vs APR-treated pts reported greater reductions in overall work impairment (Δ, -12.0%; 95% CI, -18.0%, -6.1%) and activity impairment (Δ, -15.1%; 95% CI, -20.1%, -10.1%) from BL. In pts who continued RZB through wk 52, all treatment satisfaction domain scores and improvements from BL in overall work and activity impairment were

maintained. Among pts not achieving PASI 75 with APR at wk 16, those who switched to RZB reported improvement of all PROs, including treatment satisfaction in Period B.

Conclusion: Treatment with RZB was associated with improved HrQoL compared to APR in adult pts with moderate plaque PsO. RZB-treated pts also demonstrated greater overall treatment satisfaction, satisfaction with effectiveness and convenience, and improvements in work productivity and activity impairment compared to APR-treated pts. The improvements in RZB-treated pts were observed out to wk 52. These results support the opportunity to enhance PROs with RZB in systemic-eligible patients with moderate plaque PsO.

Table. Summary of PSS, DLQI, TSQM-9, and WPAI results at week 16 in IMMpulse (NCT04908475)

			Adjusted difference (95% CI)	Nominal P-value[5]
	RZB N = 118	**APR N = 234**		
PSS 0, n (%)	35 (29.7)	7 (3.0)	26.6 (18.1, 35.1)	<0.001
PSS 0/1, n (%)	53 (44.9)	21 (9.0)	35.9 (26.2, 45.5)	<0.001
DLQI 0/1, n (%)	64 (54.2)	33 (14.1)	40.3 (30.5, 50.1)	<0.001
minimally clinically important difference (≥ 4 points improvement) in DLQI from baseline[1], n (%)	89 (82.4)	111 (52.6)	29.7 (20.0, 39.5)	<0.001
	RZB	**APR**	**LS mean between group difference (95% CI)**	
TSQM Global Satisfaction[2], mean	86.2	47.7	39.8 (34.2, 45.5)	<0.001
TSQM Effectiveness[2], mean	80.6	46.9	34.3 (28.3, 40.3)	<0.001
TSQM Convenience[2], mean	84.9	69.0	16.3 (11.8, 20.7)	<0.001
WPAI Overall Work Impairment[3], LS mean percent change from baseline (95% CI)	-18.2 (-23.1, -13.2)	-6.1 (-10.1, -2.2)	-12.0 (-18.0, -6.1)	<0.001
WPAI Activity Impairment[4], LS mean percent change from baseline (95% CI)	-22.7 (-27.0, -18.4)	-7.6 (-10.9, -4.3)	-15.1 (-20.1, -10.1)	<0.001

APR, apremilast; CI, confidence interval; DLQI, Dermatology Life Quality Index; LS mean, least squares mean; PSS, Psoriasis Symptoms Scale; RZB, risankizumab; TSQM, Treatment Satisfaction Questionnaire for Medication version 9; WPAI, Work Productivity and Activity Impairment.
[1]Patients with baseline DLQI ≥ 4, RZB N = 108, APR N = 211.
[2]RZB N = 110, APR N = 207.
[3]RZB N = 74, APR N = 123.
[4]RZB N = 101, APR N = 183.
[5]Nominal P-values were not multiplicity controlled.
For binary endpoints, non-responder imputation incorporating multiple imputations to handle missing data due to COVID-19 was used. For continuous endpoints, least squares mean changes from baseline at week 16 were compared between RZB vs APR by mixed-effects repeated regression modeling.

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Abstract N°: 803

Comparison of the efficacy and safety of risankizumab with apremilast in patients with moderate plaque psoriasis eligible for systemic therapy: results from the phase 4 IMMpulse trial

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Introduction & Objectives: Risankizumab (RZB) is a humanized IgG1 monoclonal antibody that inhibits IL-23 by binding to its p19 subunit. The IMMpulse trial compared the efficacy and safety of RZB with apremilast (APR) in systemic-eligible pts with moderate plaque psoriasis (PsO), and after switching to RZB vs continuing APR.

Materials & Methods: This phase 4, multicenter, randomized, open-label, assessor-blinded, active comparator study compared RZB to APR in adult pts with moderate plaque PsO (sPGA=3, BSA 10-15%, PASI > 12) who were candidates for systemic therapy. Prior APR exposure was not allowed.** In Period A, pts were stratified by weight and prior systemic and/or biologic therapy and randomized 1:2 to receive subcutaneous RZB (150 mg; N=118) or oral APR (30 mg BID; N=234) for 16 wks.** In Period B, all APR-treated pts were re-randomized 1:1 to RZB or APR stratified by PASI 75 response. For APR-treated pts not achieving PASI 75 at wk 16, 83 switched to RZB and 78 continued APR. All RZB pts in Period A continued treatment up to wk 52.** Co-primary endpoints for Period A were PASI 90 and sPGA 0/1 at wk 16. Primary endpoint for Period B was PASI 90 at wk 52 in pts not achieving PASI 75 response with APR at wk 16. Ranked secondary endpoints were PASI 75 (wk 16 and 52) and sPGA 0/1 (wk 52). Non-responder imputation incorporating multiple imputation to handle missing data due to COVID 19 was used.

Results: Baseline (BL) demographics and disease characteristics were similar between the treatment arms. Mean age was 46 years, 65.6% were male, and mean weight was 90.6 kg (27.3% >100 kg); 32.1% received prior systemic and/or biologic therapy. Mean BL PASI and BSA were 14.5 and 13.1% respectively, and mean BL DLQI was 12.7. All primary and ranked secondary endpoints were achieved in both study periods (P<0.001; **Table 1**). At wk 16, RZB-treated pts achieved significantly higher PASI 90 (55.9%) and sPGA 0/1 (75.4%) rates compared to APR-treated pts (5.1% and 18.4%, respectively). PASI 75 was achieved by 84.7% of RZB-treated pts and 18.8% of APR-treated pts. For pts not achieving PASI 75 with APR at wk 16, 72.3% who switched to RZB achieved PASI 90 at wk 52 compared to 2.6% continuing APR (P<0.001). PASI 75 non-responding pts who switched to RZB achieved significantly higher PASI 75 (83.1%) and sPGA 0/1 (77.1%) rates compared to pts continuing APR (11.5%, 7.7%; respectively). In pts who continued BL treatments for the duration of the study, RZB-treated pts achieved numerically higher (nominal P<0.001) PASI 90 (73.7%), PASI 75 (82.2%), and sPGA 0/1 (80.5%) response rates than APR-treated pts (4.5%, 19.1%, 14.5%, respectively) at wk 52. TEAEs and AEs leading to study drug discontinuation were numerically higher in APR-treated pts (**Table 2**). Most frequently observed TEAEs for RZB

were COVID-19 and nasopharyngitis, and for APR were diarrhea, nausea, and headache.

Conclusion: Treatment with RZB was associated with greater clinical response compared to APR in adult pts with moderate plaque PsO. In APR-treated pts not achieving PASI 75 at wk 16, switching to RZB resulted in superior efficacy compared to continued APR treatment. TEAEs and AEs leading to study drug discontinuation were more frequently observed with APR; discontinuation remained low and stable with RZB. No additional safety concerns were identified in pts who switched from APR to RZB without washout. These results support the opportunity to elevate treatment outcomes with RZB in systemic-eligible pts with moderate plaque PsO.

Table 1. Summary of efficacy results from the IMMpulse trial (NCT04908475)

Endpoints, n (%)		RZB N=118	APR N=234
Period A Week 16	**Co-Primary Endpoints**		
	PASI 90	66 (55.9%)***	12 (5.1%)
	sPGA clear or almost clear	89 (75.4%)***	43 (18.4%)
	Ranked Secondary Endpoint		
	PASI 75	100 (84.7%)***	44 (18.8%)
Endpoints, n (%)		**APR/RZB N=83**	**APR/APR N=78**
Period B Week 52	**Primary Endpoint**		
	PASI 90	60 (72.3%)***	2 (2.6%)
	Ranked Secondary Endpoints		
	PASI 75	69 (83.1%)***	9 (11.5%)
	sPGA clear or almost clear	64 (77.1%)***	6 (7.7%)

P-values for comparison versus apremilast: ***, P <0.001.
APR, apremilast; PASI 75 / 90, 75 / 90% improvement in Psoriasis Area and Severity Index; RZB, risankizumab; sPGA, static Physician's Global Assessment.
Non-responder imputation incorporating multiple imputation to handle missing data due to COVID-19 was used in the analysis.

Table 2. Overview of treatment-emergent adverse events in Period A and Period B

TEAEs, n (%)	Period A			
	RZB 150 mg n = 118 n (%)	RZB 150 mg n = 118 E (E/100 PY) PY = 35.8	APR 30 mg n = 234 n (%)	APR 30 mg n = 234 E (E/100 PY) PY = 66.7
Adverse Event (AE)	48 (40.7)	77 (215.7)	144 (61.5)	300 (451.8)
AE with reasonable possibility of being related to study treatment[a]	6 (5.1)	9 (25.1)	96 (41.0)	165 (248.5)
Severe AE	1 (0.8)	1 (2.8)	9 (3.8)	11 (16.6)
Serious AE	1 (0.8)	1 (2.8)	3 (1.3)	3 (4.5)
AE leading to discontinuation of study drug	0	0	12 (5.1)	22 (33.1)
AE leading to death	0	0	0	0
TEAEs reported in ≥5% of patients				
Diarrhea	1 (0.8)	1 (2.8)	46 (19.7)	49 (73.8)
Nausea	0	0	41 (17.5)	45 (67.5)
Headache	2 (1.7)	2 (5.6)	27 (11.5)	28 (42.0)
COVID 19	12 (10.2)	12 (33.6)	17 (7.3)	17 (25.6)
	Period B, all patients randomized to APR at baseline			
	APR / RZB n = 102 n (%)	APR / RZB n = 102 E (E/100 PY) PY = 82.0	APR / APR n = 97 n (%)	APR / APR n = 97 E (E/100 PY) PY = 40.0
Adverse Event (AE)	57 (55.9)	124 (151.2)	45 (46.4)	91 (227.5)
AE with reasonable possibility of being related to study treatment[a]	11 (10.8)	13 (15.9)	14 (14.4)	19 (47.5)
Severe AE	3 (2.9)	5 (6.1)	2 (2.1)	2 (5.0)
Serious AE	3 (2.9)	6 (7.3)	2 (2.1)	2 (5.0)
AE leading to discontinuation of study drug	0	0	5 (5.2)	5 (12.5)
AE leading to death	0	0	0	0
TEAEs reported in ≥5% of patients				
COVID 19	12 (11.8)	12 (14.6)	14 (14.4)	14 (35.0)
Nasopharyngitis	10 (9.8)	11 (13.4)	8 (8.2)	10 (25.0)
Upper respiratory tract infection	6 (5.9)	8 (9.8)	3 (3.1)	3 (7.5)

[a]Investigator assessed AEs possibly related to the study treatment
APR, apremilast; E, event; PY, patient-year; RZB, risankizumab; TEAE, treatment-emergent adverse event.

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Abstract N°: 810

JNJ-77242113 Treatment Induces a Strong Systemic Pharmacodynamic Response Versus Placebo in Serum Samples of Patients With Plaque Psoriasis: Results From the Phase 2, FRONTIER 1 Study

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Introduction & Objectives: JNJ-77242113, an orally administered interleukin-23 receptor (IL-23R) antagonist peptide, demonstrated significantly greater efficacy compared with placebo (PBO) in adults with moderate-to-severe plaque psoriasis in the phase 2, FRONTIER 1 study (NCT05223868). In this analysis, we evaluated the pharmacodynamic (PD) response to JNJ-77242113 and its relationship to clinical efficacy.

Materials & Methods: FRONTIER 1 was a randomized, double-blind, PBO-controlled, dose-ranging, phase 2 study of JNJ-77242113 in the treatment of moderate-to-severe plaque psoriasis. Patients were randomized 1:1:1:1:1:1 to receive JNJ-77242113 25 mg daily (QD), 50 mg QD, 25 mg twice daily (BID), 100 mg QD, 100 mg BID, or PBO through Week (W) 16. Clinically validated therapeutics that target the IL-23 pathway in psoriasis drive systemic PD changes in the serum levels of beta-defensin 2 (BD-2), IL-22, IL-17A, and IL-17F relative to baseline. We analyzed serum levels of these disease biomarkers in FRONTIER 1 patients who received PBO or JNJ-77242113. A linear mixed effect model was used to analyze the treatment over time interaction, baseline serum protein levels, and patient random effect.

Results: All doses of JNJ-77242113 significantly decreased serum levels of biomarkers relevant to psoriasis disease pathophysiology (BD-2, IL-22, IL-17A, and IL-17F), with the fold reduction relative to baseline significantly distinguished from PBO ($p < 0.05$ for all doses vs PBO). Interestingly, as previously observed with therapeutic blockade of the IL-23 pathway in psoriasis, reduction of these systemic biomarkers by JNJ-77242113 showed a strong correlation with clinical response. Importantly, JNJ-77242113 treatment did not increase serum levels of IL-23 in psoriasis patients as seen with some other cytokine receptor antagonist therapeutics.

Conclusion: We show for the first time that specific targeting of the IL-23 pathway through inhibition of IL-23R signaling with the novel oral IL-23 receptor antagonist JNJ-77242113 induces a strong systemic PD response in psoriasis patients that is significantly distinguished from PBO. We provide evidence supporting that the JNJ-77242113 PD response is comparable to other clinically validated therapeutics targeting IL-23 in psoriasis, and it corroborates the observed clinical efficacy of JNJ-77242113. Taken together, consistent with its mechanism of action, JNJ-77242113 dampens objective biomarkers of IL-23 pathway activation and psoriasis disease severity to drive disease improvement.

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Abstract N°: 821

Superoxide dismutase enzyme activity in patients with psoriasis

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Superoxide dismutase enzyme activity in patients with psoriasis

Introduction & Objectives: An important role in the pathogenesis of psoriasis is played by the body's antioxidant system, which provides protection against oxidative stress - a condition of impaired redox status of cells. It was found that psoriasis has signs of an autoimmune disease, which is confirmed by the production of catalytic antibodies.

Therefore, it is important to study the pathogenesis of psoriasis to analyze the relationships between clinical and laboratory indicators of disease activity.

Materials & Methods: To evaluate the state of the redox system in patients with various clinical forms of psoriasis. A total of 68 in-patients were evaluated.

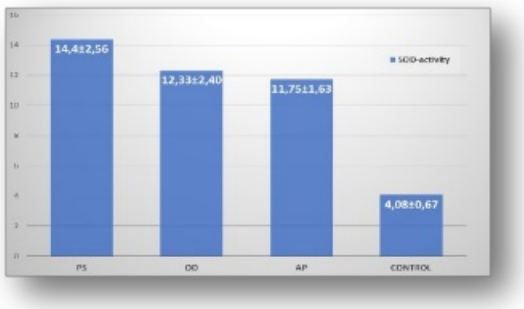
Clinical variants of psoriasis.

PS – patients with only skin affection (n=16, Mean age – 23.0 ± 1.77),

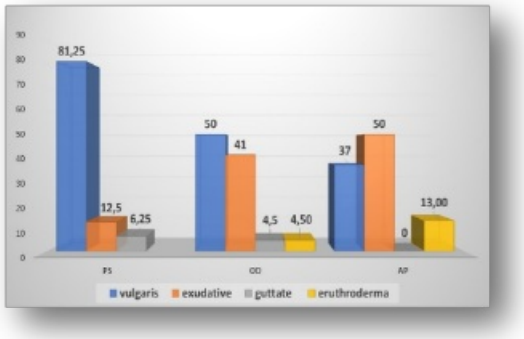
OD – patients with lesions on the skin and nails (n=22, av. age – 37.86 ± 2.75 years),

AP – patients with arthropathic psoriasis (n=30, av. age – 45.1 ± 1.8 years).

Results: ***SOD-activity of polyclonal IgG***



Distribution of patients into groups, %



Conclusion:

1. In the arthropathic form of psoriasis, more complicated forms of skin lesions were more often recorded.
2. In patients of all groups, an increase in the redox activity of polyclonal immunoglobulins was detected.
3. Levels of SOD-activity of polyclonal IgG in groups decrease with increasing severity of psoriasis.

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Abstract N°: 863

Impact and management of psoriasis in clinical practice in the Spanish National Health System: The SUMMER Project

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Introduction & Objectives: The SUMMER study is an ambispective, non-interventional, multicenter study aimed at knowing the impact and management of moderate to severe psoriasis in clinical practice in the Spanish National Health Service (NHS). The primary objective is to use Real-World Data (RWD) to provide information on the different patient profiles, disease characteristics and treatment patterns in patients with psoriasis in clinical practice in Spanish NHS.

Materials & Methods: Characteristics of the disease, pattern of treatment, and direct healthcare resources were recruited from the medical records of the patients (retrospective phase). Primary data (patient-reported outcome measures [PROMs] and direct non-healthcare and indirect costs) are still being collected as a 6-month follow-up period (prospective phase). Here we present an intermediate retrospective analysis of 3 Spanish hospitals including the sociodemographic and clinical characteristics of patients and treatment patterns.

Results: A total of 1,107 patients (mean age 50.9 [14.3] years, treated with biological drugs) were identified from the hospital databases between 2017 to 2019. The most common diagnosis was plaque psoriasis (90.9%), followed by psoriatic arthritis (35.7%), guttate psoriasis (7.7%), palmoplantar psoriasis (12.9%), pustular psoriasis (0.8%), erythrodermic psoriasis (0.1%), and inverse psoriasis (0.1%) being the least diagnosed. Plaque psoriasis was the first diagnosis for 896 (80.9%) patients. Of the total number of patients, 60.2% presented only one diagnosis of the above, while 30.2% presented two and 7.6% presented three dermatological diagnoses. The mean number of biological treatments was 1.3 (0.6), with psoriatic arthritis being the diagnosis with the highest number of treatments (1.4 [0.7]). Regarding the changes in treatment in the analysis period, 1.4% of the patients were treated with the same treatment during the 3 years of analysis, while 74.8% changed once and 23.8% made ≥2 changes.

Conclusion: The most prescribed biological drug in this period was anti-tumor necrosis factor (anti-TNF) (36.8%), followed by interleukin (IL)-12/23 (32.3%), IL-17 (26.3%), and IL-23 (4.3%).

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Abstract N°: 877

Effectiveness and safety of guselkumab in patients with moderate to severe psoriasis and facial and/or genital involvement: interim analysis of results up to week 28 from the GULLIVER Study

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Introduction & Objectives:

The GULLIVER study is an ongoing non-interventional study designed to evaluate, in a real-life setting, the effectiveness and safety of guselkumab in the treatment of adult patients with psoriasis and a significant involvement (defined as a static physician global assessment (sPGA) score ≥ 3) of genitals and/or facial area. Guselkumab is an interleukin-23 pathway inhibitor with proved efficacy in patients with moderate-to-severe plaque psoriasis. The objective of this subanalysis is to evaluate the effectiveness of guselkumab through to week 28 in patients with moderate to severe psoriasis (defined as PASI score >10) or special sites involvement (genital or face psoriasis) enrolled in the GULLIVER study.

Materials & Methods:

The effectiveness of guselkumab has been evaluated calculating the percentage of participants who achieved PASI 100/90/75 responses up to 28 weeks of treatment, and improvements by individual PASI components (erythema, thickness, and scaling) of each body region (head, trunk, upper extremities, and lower extremities). The interim analysis includes patients who have completed 12 weeks of treatment with guselkumab by 31 Dec 2022.

Results:

Overall, 351 patients were included in the study and 180 (51.3%) of them had a PASI score >10 at baseline. Of the total number of patients 40.8%, 19.0%, 24.0% and 16.2% had a head, trunk, upper extremities, and lower extremities initial localization of the disease, respectively. Most of the patients were males (57.8%) and the mean disease duration from diagnosis to first dose of guselkumab was 16.8±12.3 years. The percentage of patients who had previously received at least one biologic agent was 37.8%. Among patients with a PASI score > 10 at baseline, the percentage of subjects achieving PASI 100/90/75 at week 12 was 47.7% (n=84),

69.3% (n=122) and 86.4% (n=152), respectively; rates of PASI 100/90/75 at week 28 were 63.5% (n=101), 85.5% (n=136) and 97.5% (n=155), respectively. The overall mean value of PASI markedly decreased from baseline: the mean (±SD) change of total score was 17.0±8.2 at week 12 and 18.4±8.3 at week 28. Improvements from baseline to week 12 and week 28 in erythema, thickness and scaling were observed across all body regions. The percentage of patients with a moderate to very severe score at baseline who achieved a score 0/1 (none/slight) at week 12 for erythema, thickness, and scaling, respectively, was as follows: head (87.0%, 91.7% and 90.2%), trunk (85.1%, 87.7%, 90.0%), upper extremities (87.2%, 90.9%, 90.2%), and lower extremities (86.7%, 90.0%, 90.9%). The corresponding rates for erythema, thickness, and scaling at week 28 were, respectively: head (93.9%, 97.6% and 92.7%), trunk (92.7%, 95.1%, 98.1%), upper extremities (96.2%, 97.0%, 98.1%), and lower extremities (95.7%, 99.1%, 98.2%).

Conclusion:

In this sub-analysis, guselkumab was shown to be effective for the treatment of moderate to severe chronic plaque psoriasis in a real-life setting through 28 weeks of treatment. In general, PASI response rates were in line with the results observed for the pivotal VOYAGE 1, VOYAGE 2 and ECLIPSE trials although with a higher proportion of patients achieving higher % of PASI 100/90/75.

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Abstract N°: 914

Internet use in the context of psoriasis: A cross-sectional study among individuals with psoriasis in Germany

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Introduction & Objectives:

Psoriasis is a common chronic inflammatory skin disease leading to a substantial physical and psychological burden as well as impaired quality of life. Unmet needs often lead affected people to seek disease-related information online. To be able to provide adequate and target group-specific online information, this study aims to identify which online channels are used by those affected and to determine factors which influence the disease-related internet use among people affected by psoriasis.

Materials & Methods:

Participants aged 18 years and older with medical diagnosed psoriasis were recruited at the Department of Dermatology and Allergy at the Technical University of Munich, Germany in person and online via German support groups, patient organisations, and social media. Volunteers were asked to complete a standardized anonymous online or paper-based questionnaire between 09/2021 and 02/2022. The pilot-tested questionnaire asked for gender (male, female, diverse), age (year), education (leaving school with(out) university entrance), place of residency (urban, rural), disease severity and psychological burden (mild, moderate, severe), presence of psoriasis arthritis, current dermatological treatment, self-assessed psoriasis-related knowledge (less than good, good or very good), regular psoriasis-related internet use, and the online channels used. Data of complete cases were descriptively analysed and included in a binary logistic regression using the statistical analysis software IBM SPSS Statistics.

Results:

Overall, 321 participants were included (60.7% women, median age: 53.0 years interquartile range [41.0; 61.0], 54.2% regular psoriasis-related Internet users). More than half of the Internet-using participants stated to use psoriasis websites regularly to search online for psoriasis-related information (56.4%), followed by search engines (52.1%), and Facebook (36.7%), while Instagram and YouTube were rarely used (9.0% and 7.4%, respectively). Regular disease-related Internet users were more likely to be female (adjusted odds ratio (aOR)=1.72, confidence interval (CI)=[1.05-2.83]) and to have moderate and severe psychological burden (aOR=1.81, CI=[1.02-3.20]; aOR=2.05, CI=[1.01-4.13]). Having left school without university entrance, living in a rural area, having moderate and severe disease severity, being affected by psoriasis arthritis, not being in dermatological treatment, and good psoriasis-related knowledge (1.02 (CI=[0.43-2.43])≤aOR≤1.66 (CI=[0.74-3.74]) was associated with regular psoriasis-related Internet use.

Conclusion:

This study showed that evidence-based psoriasis information should be provided primarily through psoriasis websites, search engines, and Facebook, while misinformation on these online channels should be resolved. In addition, information on psychological support should be provided urgently not only online, but also physicians

should focus more on the psychological burden of psoriasis patients. Moreover, with the help of these results, online prevention campaigns for the quality of life of affected persons should be established and evaluated.

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Abstract N°: 944

The role of inflammation in Psoriasis Vulgaris

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Introduction & Objectives:

Continuous studies in the domain of molecular biology and immunology indicate psoriasis as a disease with very complex characteristics with respect to its pathogenesis. A large number of inflammatory cells are included in its pathogenesis where a major role is being played by lymphocytes-T cytokines and chemokines.

Materials & Methods:

There have been studied 2 groups. Psoriasis group patients (number of studied cases 199). In this group were included patients of both sexes hospitalized in the clinic of Dermatology-Venerology in the University Hospital Center "Mother Teresa". It was calculated PASI for all the patients and for how many years they have had psoriasis. The control group of nonpsoriasis individuals (the number of cases taken into the study was 199). The excluding criteria from the study were the same as in the first group. Samples have been taken for analyzing hs-CRP and TNF-alpha. There were excluded from both groups all individuals aged less than 18 years, having a current/or past history of acute myocardial infarction, peripheral artery disease or coronary arteries or, known of presence inflammatory diseases.

Spearman correlation coefficients (for –non parametric ordinary data) were applied for the evaluation of the linear relationship among numerical. The exact Fisher test was applied for the proportion comparison of categorical variables. The values of $P<0.05$ were considered statistically significant.

Results:

99.5% of psoriasis patients have a CRP value of >1.10mg/L versus 57.8% in the control group and this difference is statistically very significant (Fischer exact test: $P<0.001$).

32.7% of non-psoriasis patients have a TNF-alpha value >8.10pg/ml versus 65.3% in the psoriasis group and this difference was statistically highly significant (Fischer's exact test: $P<0.001$). There is a relatively strong correlation between PASI and alfa –TNF: Spearman correlation coefficient = 0.57, P= 0.034. There is a strong correlation between PASI and CRP: Spearman correlation coefficient =0.49, P=0.048

Conclusion:

The measurement of the seric level of the abovementioned mediators could be considered as an objective parameter of the psoriasis activity and clinical importance (PASI). These data confirm the hypothesis, that psoriasis could be considered a totally systemic disease with specific immunology mechanisms.

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Abstract N°: 947

Undertreatment and mistreatment in psoriasis therapy? - Quantification using registry and claims data in Germany

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Introduction & Objectives:

In the past decade, a multitude of treatment options has been introduced in psoriasis (PSO) care. However, it has not been sufficiently investigated to what extent health care follows treatment guidelines. The aim of this study was to quantify potential drug mis- and undertreatment for patients with PSO in Germany.

Materials & Methods:

The analyses were performed using data from the German national psoriasis registry PsoBest (records data of patients treated with dermatologists and receiving systemic therapy) from 2008 until 2018 and claims data (DAK-Gesundheit) from 2016 until 2020. Therapy prevalences (registry data) and incidences (claims data; first systemic therapy: 180 days wash-out) as well as time to change of therapy or to initiation of biologics (registry data) were calculated. Time-to-event analyses were conducted using Kaplan-Meier curves (registry data: within ongoing observation).

Results:

A total of 9,092 (registry data) and 62,063 (claims data) patients with PSO were analysed. In the registry, 70.6% of patients started with non-biologic systemic drugs (NBSD) in 2008-2014; in 2015-2018, this proportion decreased to 61.3%; more than 62% of patients had PASI>10 and 48% had DLQI>10. For the subset of available registry data (26%; 74% not yet observed, i.e., right-censored cases), median time on NBSDs was 4.3 years. Median time until initiation of the first biologic systemic drug (BSD) in the registry was 5.9 years. Of 2,246 patients who initiated NBSDs and had valid data at the one year visit, 1,913 did not reach 50% reduction of baseline severity (PASI) after one year. Nonetheless, 59.3% of these patients remained on NBSDs.

In the claims data of 2019, 80.7% of the patients started topical therapy and 30.6% systemic therapy. Within systemic therapies, BSD accounted for 11.2% and NBSD for 91.4%. Of the NBSD, 86.6% were oral or parenteral glucocorticosteroids. 45.8% of patients with NBSD discontinued, 5.6% switched to another therapy within one year. Among patients initiated with NBSD, 1.6% switched to BSD within one year.

Conclusion:

Registry data and claims data concordantly show that health care for psoriasis with systemic drugs in Germany is far from guideline recommendations. In particular, there is a markable overuse of systemic glucocorticosteroids in many patients and these patients tend to remain on NBSDs for long period of time despite limited response.

Higher usage of advanced targeted systemic treatments for PSO in registry data than in claims suggest that patients are more likely to receive treatment according to the guideline when treated with dermatologists. Further

measures for improving PSO care must include non-dermatologists who showed higher deviation from guidelines and recommendations.

As limitations, reasons for not switching could not be examined (e.g., contraindication, refundability, fear of injection) and relative PASI improvement but not absolute PASI was analysed as an outcome.

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Abstract N°: 979

The mystery of ulcerated psoriatic lesions: a case report

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Introduction & Objectives:

Psoriatic plaques have a relatively low incidence of secondary infections. Overactive innate immune response in psoriasis, which can effectively combat invading pathogens, and significantly increased production of antimicrobial peptides, such as cathelicidin and beta-defensins may play a role in limiting infections in psoriasis. However, mechanical trauma, compromised immune function, and immunosuppressive medications can increase the risk of secondary infections in psoriatic plaques. Ecthyma is a deep skin infection that penetrates the epidermis into the dermis and causes painful pustules or ulcers. It is more prevalent in individuals with compromised immune systems, such as those with psoriasis. Therefore, clinicians should be vigilant in identifying and treating such infections promptly to prevent potential complications.

The objective of this report is to present a rare case of ecthyma infection occurring within psoriasis plaques.

Materials & Methods:

A 51-year-old male with a two-year history of plaque psoriasis presented with multiple painful ulcerated lesions with cyanotic periphery on his calves. The patient had typical psoriatic erythrosquamous plaques on his scalp, torso, and limbs, with a Psoriasis Area Severity Index (PASI) score of 10.5 and a moderate score on the Dermatology Quality of Life Index (DLQI) of 10 points. The patient reported wearing pants with an elastic band that mechanically pressed his calf before the ulcers appeared.

Methods used in this case study included a physical examination of the patient's lesions, laboratory tests and microbiological cultures to identify the possible underlying infection.

Results:

Laboratory tests showed a slight elevation of C-reactive protein (CRP), liver enzymes and a marked elevation of Immunoglobulin E. No suggested immunosuppression was found, including a negative HIV test. The initial treatment included local antiseptics and hydrocolloid silver-containing dressings to the ulcers, narrowband UVB therapy and the application of emollients, keratolytics, and medium potency corticosteroid to the remaining psoriatic plaques. A microbiological culture from the ulcer identified *Streptococcus pyogenes*, which was susceptible to penicillin and macrolides.

The diagnosis of ecthyma occurring in psoriatic plaques was established. As a result, additional treatment of Amoxicillin/Clavulanic acid 1000/200 mg intravenous solution TID was administered, along with the introduction of an elastic band containing zinc and gelatine. The patient showed significant improvement with steady progress during follow-up.

Conclusion:

This case report emphasizes the importance of identifying possible underlying infections in psoriatic lesions and provides valuable insights into the effective comprehensive management of psoriasis with concurrent infection.

References upon request.

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Abstract N°: 983

The Role of Gut Microbiome in Psoriatic Arthritis—A Literature Review

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Introduction & Objectives:

Psoriatic arthritis is a heterogeneous chronic autoimmune disorder characterized principally by skin lesions, arthritis, dactylitis and enthesitis. The exact etiology of the disease is yet to be discovered, with genetic predisposition alongside environmental factors being a well-known theory. In recent years, new discoveries have emphasized the role of gut microbiome in perpetuating inflammation in spondylarthritis. The exact mechanism through which dysbiosis underlies the pathophysiology of psoriatic arthritis is not defined. One of the current areas of focus in rheumatic research with new studies emerging annually is the link between microbiome and psoriatic arthritis.

Materials & Methods:

In this review, we synthesized the recent knowledge on intestinal microbiome and psoriatic arthritis.

We screened two databases for articles, PubMed and Medline, using the following keywords: “microbiome”, “microbiota” and “psoriatic arthritis”.

Results & Conclusion:

We described the current expertise on diversity and composition of gut microbiome in psoriatic arthritis, comparing the results with other inflammatory diseases. In the future, preventing the dysbiosis process that leads to the development of psoriatic arthritis could open the door to new therapeutic modalities. Moreover, faecal microbiota transplantation and probiotics’ benefits in modulating the gut microbiome are being intensively researched at the moment.

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Abstract N°: 1011

Gasdermin D (GSDMD) and E (GSDME) – new potential players in the pathogenesis of psoriasis? The first study on human serum.

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Introduction & Objectives:

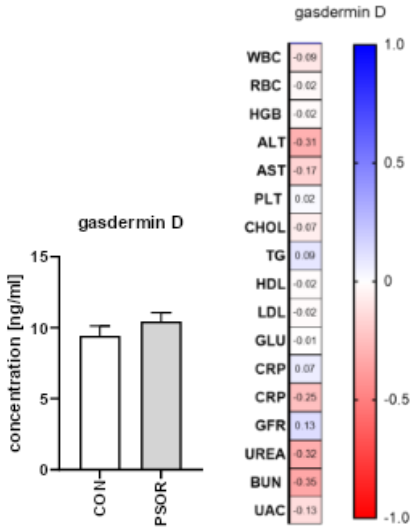
Psoriasis is a frequent and incurable skin disease whose pathogenesis is still not fully understood. It is characterized by immune disturbances, hyperproliferation and improper differentiation of keratinocytes. Gasdermins are a relatively recently described family of 6 proteins. Gasdermin D (GSDMD) and E (GSDME) are involved in the processes of inflammation, proliferation and death of cells, especially pyroptosis. GSDMD and GSDME have never been studied in psoriatics' sera before. Our aim was to determine their possible role in this dermatosis.

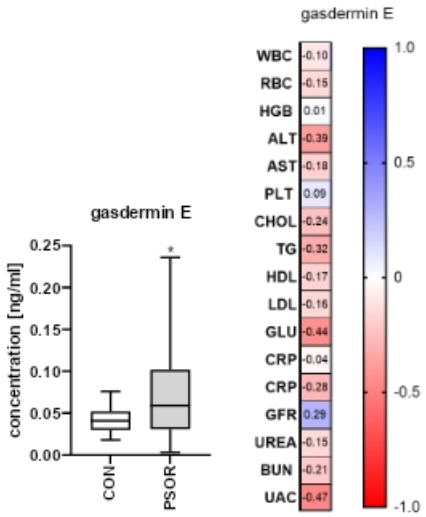
Materials & Methods:

The study enrolled 60 psoriatic patients and 30 volunteers without dermatoses as controls, who were age, sex-, and BMI-matched. GSDMD and GSDME concentrations were measured in serum of all participants by ELISA. Psoriasis severity was assessed using Psoriasis Activity and Severity Index (PASI). Moreover, basic laboratory parameters were examined.

Results:

Serum GSDME concentration was significantly higher in patients than controls ($p<0.05$), whereas GSDMD insignificantly higher ($p>0.05$). There was no correlation between serum GSDMD and GSDME concentrations and psoriasis severity in PASI, age or disease duration. GSDME concentration was significantly negatively correlated with BMI, triglycerides and glucose concentrations.





Conclusion:

We are the first to report on possible serum GSDMD and GSDME application in psoriatics. Understanding the role of gasdermins in the death and proliferation of cells, we propose their engagement in psoriasis pathogenesis based on the activation of caspases, which results in the cleavage of gasdermins, leading to the release of pro-inflammatory cytokines and epidermal hyperproliferation. Moreover, pyroptosis, in addition to inducing cell death, exacerbates inflammation, which, chronically sustained, is a feature of psoriatic epidermis. Gasdermins, especially GSDME, may become new non-invasive psoriasis markers, but not of its severity. They could also be tested as potential future drug targets. GSDME may perhaps exert a protective influence on the metabolic complications in psoriasis which requires further studies.

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Abstract N°: 1015

Apremilast Treatment is Associated with Weight Loss, Cardiometabolic and Inflammatory Marker Changes in Psoriasis and Psoriatic Arthritis Patients

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Introduction & Objectives

Psoriasis (PsO) and psoriatic arthritis (PsA) are chronic systemic inflammatory diseases associated with high rates of obesity and other cardiometabolic diseases. Phosphodiesterase 4 (PDE4) enzyme plays an important role in inflammation, lipolysis, and insulin homeostasis (Wu C & Rajagopalan S, 2016). Apremilast (APR) is an oral small-molecule inhibitor of PDE4, whose inhibition has been associated with weight loss in past APR studies and reported in product labeling. These findings, in complement with the increased prevalence of metabolic syndrome in psoriatic disease, prompts further interest in the better understanding of the impact of APR on markers of cardiometabolic disease. In this retrospective pooled analysis, we sought to explore and demonstrate the concurrent benefit of APR on weight loss and cardiometabolic markers.

Methods & Materials

Pooled samples of four legacy phase 3 and 4 clinical trials (PALACE-1 [NCT01172938]; MOSAIC [NCT03783026]; ADVANCE [NCT03721172]; DISCREET [NCT03777436]) for PsO and PsA, were analyzed without adjusting for disease indication. Patients treated with APR 30 mg BID and placebo (PBO) were included in this study. Patients received PBO or APR until Week 16, after which all patients received APR through Week 32. Outcomes measured included change from baseline in body weight, body-mass index (BMI), high-density lipoprotein (HDL), low-density lipoprotein (LDL), plasma glucose, hemoglobin A1c (HbA1c), and blood pressure at Weeks 16, 18, 24 and 32.

Results

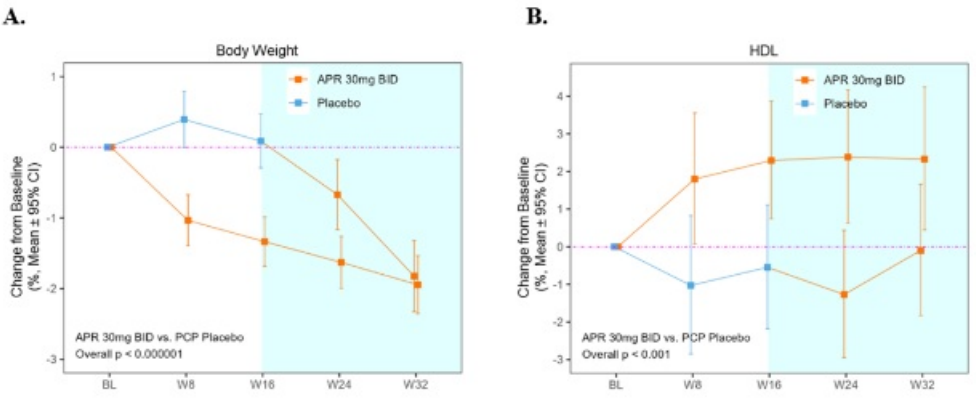
Baseline (BL) parameters were balanced between the APR (n=718) and the PBO groups (n=609) (**Table**). The BL BMI distribution showed that more than 80% of participants were overweight or obese. Across all timepoints, APR-treated patients showed significant weight loss compared to the PBO group (overall; $p < 0.000001$; **Fig A**). However, the subgroup analysis indicated the significant weight loss was observed only in the overweight or obese patients ($p < 0.000001$) not in the normal or leaner patients. Greater weight loss was seen with longer APR exposure. At Week 32, a quarter of APR-treated patients lost ≥5% body weight; a greater impact was observed in patients with higher BMI. At Week 16, mean HDL was increased by 2.3% and remained above 2% until Week 32 in the APR-treated group. No HDL increase was observed in the PBO group (**Fig B**). The HDL increase from BL exhibited associations with weight loss across all timepoints analyzed in the APR group. A trend in the reduction of diastolic blood pressure, but not systolic, was seen in the APR-treated group. No changes in LDL, plasma glucose, or HbA1c were observed.

Conclusion

These findings add to a growing body of evidence describing the impact of APR on weight loss, mainly in the overweight or obese patients. There was also no impact on LDL with potential minor benefit on HDL. Given the

high prevalence of the metabolic syndrome features of high BMI with low HDL in the psoriatic population, with current recommendations stating to manage cardiometabolic comorbidities, these data suggest APR (PDE4 inhibition) may provide benefit beyond skin and joint disease with weight reduction although prospective studies are needed to examine these findings further.

Figure



APR, apremilast; BID; twice a day; BL, baseline; CI, confidence interval; HDL, high-density lipoprotein; PCP, placebo-controlled period.

Table

Baseline characteristic	Placebo (N=609)	APR 30mg BID (N=718)
Age (years), median (range)	49 (18, 85)	49 (18, 85)
Sex, n (%)		
Female	268 (44)	320 (45)
Male	341 (56)	398 (55)
Race, n (%)		
White	539 (88.6)	640 (89.1)
Asian	34 (5.6)	31 (4.3)
Black or African American	19 (3.1)	21 (2.9)
Other	10 (1.6)	17 (2.4)
Unknown	7 (1.1)	9 (1.3)
Body weight, median (kg)	86	87
Body mass index, median, (kg/m^2)	30	30
High-density lipoprotein, median (mg/dL)	49.9	50.3

Normal range for adults: BMI, 18.5-24.9 kg/m^2; HDL >40mg/dL

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Abstract N°: 1036

Successful treatment of generalized pustular psoriasis with Guselkumab

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Successful treatment of generalized pustular psoriasis with Guselkumab

Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare, chronic, and potentially life-threatening disease that poses multiple diagnostic and management challenges to dermatologists. The monoclonal antibody Spesolimab blocking human IL36R has recently been approved for GPP flares as the first in class treatment option. However, consistent international treatment guidelines are missing. Our case shows that the IL23p19 inhibitor Guselkumab may also be a safe and effective treatment option for GPP.

Materials & Methods:

In July 2021, a 83-year-old patient presented with a severe pustular and painful rash since one day. He suffered from malaise and severe pruritus. A concomitant plaque psoriasis had been diagnosed two years ago and a similar flare was treated with Acitretin and topical steroids one year ago. No trigger factors (drugs, infections) were detected. His medical history revealed Diabetes mellitus, arterial hypertension, hypercholesterinemia, myocardial infarction and stroke.

Dermatological examination showed a deep dark red erythema with multiple pustules on the entire integument excluding the face. Laboratory results revealed neutrophilia, lymphocytopenia and eosinopenia as well as increased CRP and thrombocytosis. Other infectious foci were ruled out. Skin biopsies showed an irregular acanthosis of the epidermis with focally thinned stratum granulosum. Additionally, circumscribed parakeratosis and subcorneal pustules were seen as well as a superficial perivascular lymphocytic infiltrate in the upper dermis. Based on the clinical and histological findings the diagnosis of GPP was made.

The patient was hospitalized and treated with clobetasol cream twice daily. A biological therapy with Guselkumab 100mg s.c. was started.

Results:

After two days, no new pustules occurred and the skin started to scale. Pruritus and pain were relieved. Initially elevated lab results went back to normal range again. After five days the patient was discharged from the hospital and came for ambulant control visits three and six months later. He has not flared up again for two years.

Conclusion:

This case demonstrates that Guselkumab is a very effective and safe treatment option for GPP. Our findings go along with a Phase 3 Japanese study by Sano et al. which showed relevant clinical improvement of the skin condition in almost 45 % of patients treated with Guselkumab (n=9) after 16 weeks. In general, it must be noted that biological therapies are more effective in the treatment of GPP compared to non-biological therapies and that treatment adherence with biologic therapies is significantly higher, so that in severe forms of GPP a first-line biologic therapy should be evaluated. With the approval of Spesolimab we have the first in-label effective treatment option for acute flares. This case study shows a further possible treatment option. European guidelines

for immediate treatment of GPP flares and long-term management of patients should be established to ensure optimal and standardized care for patients.

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Abstract N°: 1046

Real-life experience with Tildrakizumab in our Clinical Practice

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Introduction & Objectives: Psoriasis is a chronic inflammatory disease with a great therapeutic arsenal regarding biological therapy. The latest drugs that have been incorporated belong to the family of IL-23 blockers. Tildrakizumab is a humanized monoclonal antibody of the humanized IgG1/j type that specifically binds to the p19 subunit of the cytokine interleukin 23 (IL-23), it has been approved for the treatment of moderate-to-severe plaque psoriasis in adults.

Materials & Methods: In our center a total of 26 patients with moderate-to-severe plaque psoriasis were treated. Among our study population 15/26 patients are bionaive and 11/26 are bioexperienced; 9/26 patients have a high mean BMI, entering on grade I obesity (31.71). Many of our patients show psoriatic lesions in "difficult sites": scalp is involved in 8/26 patients (30.97), nails in 8/26 patients (30.7%), genital area in 7/26 patients (26.9%) and palmoplantar zone in 6/26 (23%). Only 5 of our patients (9.09%) are affected by psoriatic arthropathy.

Results: No differences in response were found in terms of PASI or quality of life (DLQI) between bionaive and bioexperienced patients or when we consider comorbidities (hypertension, obesity, dyslipidemia and diabetes). We observed stability of clinical-radiological findings in patients with psoriatic arthropathy. No adverse events that caused interruption or therapeutical switch have been reported in the presented series. Regarding PASI values, our patients showed mean values of 9 at baseline which progressed to 0.4 at week 16 and to 1.7 at week 48 (1 year) of treatment; besides, an improvement in quality of life was observed, measured by the Dermatology Life Quality Index (DLQI), with a decrease from 8 at baseline to 1 at week 16 and 0.6 at week 48 (1 year). Nine (9) of our patients are in treatment from 2 years and their mean PASI value is 1.6 while mean DLQI value is 1. Three patients have been in treatment for 3 years with sustained complete response.

Conclusion: In our experience Tildrakizumab showed excellent results in the control of psoriasis in the short and medium term, with an excellent safety profile.

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Abstract N°: 1105

Effect of early Risankizumab treatment on quality of life –2 year real world data from the German cohort of the VALUE study

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Introduction & Objectives:

Risankizumab (RZB) is an IL-23 p19 inhibitor and biologic compound approved for the treatment of moderate-to-severe plaque psoriasis and psoriatic arthritis. Real world data of RZB on specific aspects in patients' reported outcomes in different areas of life are still limited. This real world study analyzes the effect of treatment with RZB beside disease activity on patient-relevant aspects such as quality of life, stigmatization, social support, loneliness and work productivity.

Materials & Methods:

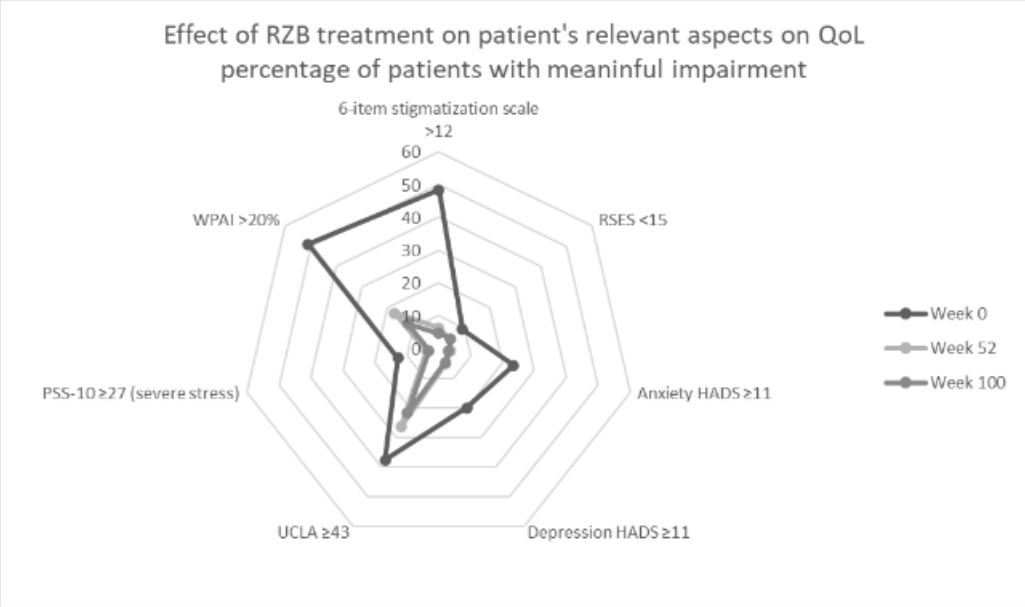
The aim of the VALUE study is to investigate durability of response and time to first treatment change for RZB compared to other biologic treatments. Treatment decisions were made at the physician's discretion, according to local label and clinical practice. Here, we report 104 weeks data from an interim analysis with a database lock on 26 Sep 2022 for the German cohort of a multi-country non-interventional observational study (VALUE). Patients with moderate-to-severe psoriasis (PsO) were asked about following psychosocial components: stigmatization (6-Items Stigmatization scale from ISDL), social support (UCLA Loneliness scale), impact of disease on profession (work productivity/activity impairment WPAI), mood/personality (hospital anxiety and depression score HADS-D, Rosenberg self-esteem RSE and fear of flare and loss of effectivity FFLE), coping strategies (HADS-A and perceived stress scale PSS), and health-related QoL (DLQI). Additionally, they were asked about itch.

Results:

This analysis comprised QoL-data of 422 (215 bio-naïve) patients at baseline and 126 (65 bio-naïve) patients at 104 weeks assigned to RZB arm. Comparing baseline with 52 weeks and 104 weeks RZB treatment in bio-naïve patients resulted in decrease of patients (%) with meaningful impairment: 6-Item stigmatization score >12, 48.3% to 6.3% and 4.6%; UCLA score ≥ 43, 37.7% to 26.6% and 21.9%; WPAI overall productivity impairment >20%, 51.0% to 17.3% and 12.1%; RSES score <15 (=low self-esteem), 9.2% to 4.4% and 4.7%; HADS-D score ≥ 11, 20.0% to 5.0% and 4.7%; HADS-A score ≥ 11, 23.4% to 3.7% and 3.1%; PSS-10 ≥ 27 (=severe stress), 12.8% to 3.8% and 3.1% (Figure 1). At baseline, 75.5% of patients reported very/rather often scratching with nails indicating a high itch. This number reduced to 6.4% at week 52 and 7.9% at week 104. FFLE question "how you would currently assess your fear of an illness flare up" was answered with 5.2 on a visual analogue scale (1-10) at baseline, with 2.1 at week 52 and 1.8 at week 104.

Conclusion:

Treatment of bio-naïve patients with moderate to severe psoriasis with RZB resulted in improvement of highly relevant psychosocial components and overall disease burden within 52 weeks that remained stable afterward. This indicates that patients should be treated as early as possible with RZB for the best patient outcome.



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Abstract N°: 1114

pulsed dye laser plus topical calcipotriol and crticosteroid combination vesus topical calcipotriol and corticosteroid combination alone in treatment of nail psoriasis

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Introduction & Objectives:

Psoriasis is a chronic, inflammatory skin disease that causes significant distress and morbidity.Nail involvement is more commonly found in patients with psoriatic arthropathy than in those with uncomplicated psoriasis. Nail psoriasis has a significant adverse influence on the quality of life of patients. The treatment of nail psoriasis largely depends on the severity of symptoms. Local or topical therapies along with Ultraviolet(UV) therapy should be attempted initially; however, the efficacy of these methods is limited, as penetration through the nail plate and nail matrix is difficult. The aim of this study is to compare the efficacy of Pulsed Dye Laser (PDL) plus topical calcipotriol and corticosteroid combination versus topical calcipotriol and corticosteroid combination in the treatment of nail psoriasis.

Materials & Methods:

This study is a comparative clinical trial including thirty patients aged 6-65 with bilateral fingernail psoriasis.. The diagnosis was based upon the clinical characteristics of nail psoriasis in patients known to have psoriasis vulgaris. Each patient received topical calcipotriol and corticosteroid(betamethasone valerate) combination daily for six months on both hands.One session of PDL (595nm) was applied on the right hand every month for six months. Modified NAPSI scores were calculated at baseline, 3 months, and 6 months of treatment then in the follow up period after 3 and 6 months. Digital photographs were taken every month during treatment period and then after 3 and 6 months in follow up period. Quality of life was also assessed before and after treatment using Nail Psoriasis Quality of life 10 (NPQ10).

Results:

The mean of mNAPSI score before treatment for the Rt.hand was 25.2 and for the Lt. hand was 21.7. After 3 sessions the mean for the Rt. hand was 17.6 and for the Lt. hand was 16.9($p<0.001$). After 6 sessions the mean for the Rt. hand was 15.03 and for the Lt. hand 16.4($p<0.001$). On the other hand there was no statistical significant difference between Rt. hand and Lt. hand . Also the the quality of life improved significantly at the end of the trial .

Conclusion:

PDL laser therapy has shown to be effective and safe for nail psoriasis. It could be used alone or combined with different therapeutic modalities, being especially beneficial with topical treatments.

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Abstract N°: 1149

A case of IgA pemphigus in a patient with a history of psoriasis

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Introduction & Objectives:

Immunoglobulin A (IgA) pemphigus is a rare chronic autoimmune skin disease with two major subtypes: subcorneal pustular dermatosis (SPD) and intraepidermal neutrophilic dermatosis (IEN). Diagnosis is made by clinical features with histopathologic findings showing intraepidermal neutrophilic pustules, direct immunofluorescence study detecting IgA autoantibodies and reactivity with autoantigens. The autoimmune etiology of pemphigus incurred a question of possible association with other autoimmune or inflammatory diseases, such as psoriasis. Herein, we report a case of IgA pemphigus in a patient with a history of psoriasis.

Materials & Methods:

A 27-year-old male patient presented with pruritic, multiple, variable-sized, yellowish annular pustules and bulla above erythematous patches on the trunk and extremities for 4 days. A year ago, he was diagnosed with psoriasis at another hospital and was undergoing oral cyclosporine, topical betamethasone/calcipotriol and tacrolimus treatment.

Results:

Histopathologic findings showed intraepidermal blister which contains neutrophils and eosinophils. Direct immunofluorescence study detected IgA deposition in the intercellular spaces of epidermis. Based on the clinical and histological findings, he was diagnosed with IgA pemphigus. Since he strongly refused steroid treatment, he was referred to another hospital for treatment of dapsone.

Conclusion:

Dermatologists managing patients with psoriasis should be aware of this epidemiological feature that bullous diseases can be associated with psoriasis, and prospective studies are required to further delineate their relation.

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Abstract N°: 1152

Assessment of the quality of life in patients with psoriatic arthritis based on a severity of psoriasis

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Introduction & Objectives: Psoriatic Arthritis Impact of Disease - 12 items (PsAID-12 score) has shown to be a reliable tool for assessing the impact of psoriatic arthritis (PsA) on the quality of life (QoL), including an assessment of pain, depression and skin problems. There is no data about the use of PsAID-12 to assess the factors associated with achieving a good QoL with a long course of PsA. The aim of study is to evaluate the factors associated with achieving a good quality of life in patients (pts) with PsA.

Materials & Methods: This study assessed 53 (M/F–25/28) PsA pts fulfilling CASPAR criteria. Mean age 45±12.1 yrs, median (Me) PsA duration 90 [72;99] month (mos), Me follow-up 81 [61;91] mos. At the early stage of PsA (up to 2 years) all pts received methotrexate (MT) 20-25 mg/week, if remission or MDA was not achieved after 3-6 mos, combined therapy with MT+ biological DMARDs was added. All pts underwent standard clinical examination: tender joint count (TJS), swollen joint count (SJC), patient global assessment disease activity (PtGA), CRP (mg/l), skin psoriasis by BSA (%), presence of nail psoriasis, DAPSA activity index, the number of patients (in %) who achieved minimal disease activity (MDA) and completed PsAID-12 questionnaire. A total PsAID score below 4 out of 10 is considered a 'patient-acceptable state' (PASS). Based on the achievement/non-achievement of the PASS, pts were divided into two groups: those who achieved the PASS (pts with a better, good QoL), and those who did not achieve the PASS (pts with a worse QoL in relation to those who achieved the index). By analysing the odds ratio, the factors associated with achieving a good quality of life are presented. Me [Q25-Q75], M±SD, were performed. All $p<0.05$ were considered to indicate statistical significance.

Results: Me PsAID-12 score 2,1 [0,95;4,6]. PASS was achieved in 38 out of 50 pts (76%). Remission by DAPSA activity index was detected in 15 (28,3%), low disease activity in 16 (30,2%), moderate in 13 (24,5%), high activity in 9 (17%) pts. The scale of skin problems was assessed: PASS group Me 2 [1;3], in the group not achieving the PASS Me 8 [4;9], p=0,001. Factors associated with achieving a good QoL in patients with PsA were identified: absence of nail psoriasis (odd ratio 5,262; 95% CI 1,041-26,595), low activity of skin psoriasis (BSA less 3%) (odd ratio 5,625; 95% CI 1,542-20,523).

Conclusion: Further research is needed to obtain a more complete and accurate understanding of the impact of PsA on the QoL of pts. As our study has shown, the absence of nail psoriasis and low severity of skin psoriasis are associated with achieving a good QoL in PsA pts.

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Abstract N°: 1170

Flare frequency and duration in patients with generalized pustular psoriasis (GPP)

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Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare, neutrophilic, chronic skin disease in which an overactivation of inflammatory pathways causes widespread erythema and eruption of sterile pustules that may coalesce into 'lakes of pus'. GPP flares are heterogeneous, and there is no standard clinical definition. Symptoms of GPP flares are painful; severe cases may require emergency treatment and can lead to life-threatening complications such as sepsis. The objective of this study was to characterize the frequency, number, and duration of flares in patients with GPP.

Materials & Methods:

We conducted a retrospective chart review including patients of all ages with a confirmed diagnosis of GPP after 2011 who were receiving care at 27 participating sites in France, Malaysia, and Tunisia.

Results:

Data from 175 patients were included (France: 58.9%, Malaysia: 31.4%, Tunisia: 9.7%), and mean (SD) duration of follow-up was 5.0 (3.1) years. Flare-related care was the second most common reason for patient visits, accounting for 200 of 1378 follow-up visits after GPP diagnosis and surpassed only by routine follow-up. The mean (SD) annual number of flare episodes experienced by patients was 2.3 (2.0); the total number of flare episodes since the initial flare leading to diagnosis ranged from 0 to 9. Eighty-three (47.4%) patients experienced at least one flare episode after diagnosis, though individual country data suggested a higher flare burden in Tunisia (70.6%) and Malaysia (54.5%) compared with France (39.8%). Twenty-eight patients (16.0%) had ≥2 flare episodes (60 visits); median (min, max) time between episodes was 11.6 (0.1, 52) months. The mean (SD) duration of flares was 34.3 (41.3) days during follow-up. Of 254 hospitalisations, 128 (50.4%) were flare-related inpatient admissions. Overall, 37.5% of GPP flares required inpatient care.* The mean (SD) duration of flare-related admissions was almost twice as long as non-flare admissions at 19.2 (23.1) days compared with 10.5 (8.1) days.* Mean (SD) time between flare-related hospitalisations among 66 patients (128 hospitalisations) was 14.1 (17.1) months, with a median of 9.5 months indicating a skew distribution.

Conclusion:

Flare episodes are a heavy burden for patients with GPP, with flares recurring as often as once a year and lasting up to 2 weeks or more. Additionally, flares account for >50% of hospitalisations for patients with GPP and are an important cause of follow-up care visits. The frequency of flares varied between patients, with some individuals

experiencing up to 10 episodes over the study period. The heterogeneity of flares and the rarity of GPP make diagnosis and clinical study challenging, while the severity of acute episodes and the burden of flare reoccurrence demonstrate the need for more effective treatment options than are currently available.

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Abstract N°: 1189

Efficacy and safety after 52 weeks in psoriasis patients switching to risankizumab after suboptimal response to secukinumab or ixekizumab

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Introduction & Objectives: Psoriasis is a chronic inflammatory skin disease often treated with biologics. Here we assess the safety and efficacy of risankizumab, an interleukin-23 inhibitor approved for treatment of moderate-to-severe plaque psoriasis, in patients with suboptimal responses to the interleukin-17 inhibitors secukinumab or ixekizumab, after 52 weeks of treatment.

Materials & Methods: In this open-label, single-arm study for patients with a suboptimal response (static Physician's Global Assessment (sPGA) score of 2 or 3 and body surface area of 3% to 10% after at least 6 months of treatment with secukinumab or ixekizumab) received 150mg RZB at weeks 0, 4, and q12w through week 40 without a washout period. sPGA 0/1, sPGA 0, Dermatology Life Quality Index (DLQI), and Psoriasis Symptom Scale (PSS) scores were assessed at week 52 by non-responder imputation. Safety was monitored throughout the study.

Results: At week 52, 63.0% (159/252, 95% CI [56.9, 68.8]) of patients that switched to risankizumab achieved sPGA of 0/1 and 26.2% (66/252, 95% CI [21.2, 32.0]) achieved sPGA 0. DLQI scores of 0/1 were achieved by 46.5% (117/252, 95% CI [40.4, 52.7]) of patient and 27.4% (69/252, 95% CI [22.3, 33.3]) of patients achieved a 0 score on PSS. No new safety signals were observed in this analysis.

Conclusion: In this difficult-to-treat patient population with a suboptimal response to secukinumab or ixekizumab without a washout period, treatment with RZB led to improved efficacy of signs and symptoms of psoriasis and improvement in health-related quality of life with no new safety signals.

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Abstract N°: 1196

A pilot genome-wide association study identifies novel markers of metabolic syndrome in patients with psoriasis

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A pilot genome-wide association study identifies novel markers of metabolic syndrome in patients with psoriasis

Introduction and objectives: Recent studies have reported that psoriasis is associated with the development of metabolic syndrome. Multiple inflammatory and cytokine-mediated pathways are reportedly shared between psoriasis and metabolic syndrome. However, the exact pathogenic mechanism of the association is complex and not fully understood. Genome wide association studies have been used to discover gene variant markers that occur frequently in case group in relation to specific diseases. The aim of the present study was to investigate the variants of specific genes involved in metabolic syndrome associated with psoriasis.

Materials and methods: 95 psoriasis patients were recruited and divided into two groups: one with metabolic syndrome (38 patients) and the other without (57 patients). After genotyping, imputation, and quality checking, the association between the several single nucleotide polymorphisms and metabolic syndrome in psoriasis was tested, followed by gene set enrichment analysis.

Results: We found 76 gene polymorphisms that conferred an increased risk for metabolic syndrome in patients with psoriasis. Four single nucleotide polymorphisms (rs17154774 of *FRMD4A*, rs77498336 of *GPR116*, rs75949580 and rs187682251 of *MAPK4*) showed the strongest association between metabolic syndrome and psoriasis. The epidermal growth factor receptor protein was located at the center of the protein interactions for the gene polymorphisms.

Conclusion: This study identified several previously unknown polymorphisms associated with metabolic syndrome in psoriasis. These results highlight the potential for future genetic studies to elucidate the development, and ultimately prevent the onset, of metabolic syndrome in patients with psoriasis.

Key Words: Genetic polymorphism, Genome-wide association study, Metabolic syndrome, Psoriasis

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Abstract N°: 1207

Baseline characteristics of UK patients with psoriasis initiating ixekizumab as captured in an observational cohort study (PSoHO) versus a large-scale ixekizumab cohort from the UK and Ireland national biologics register BADBIR

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Introduction:

The British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR), a prospective observational cohort study seeking to assess the long-term safety of biologic treatments for psoriasis (PsO), has been recording real-world outcomes for patients with PsO initiating ixekizumab (IXE), a monoclonal antibody selectively targeting interleukin (IL)-17A, in the UK and Republic of Ireland since 2016. Psoriasis Study of Health Outcomes (PSoHO) is a prospective, multicentre observational study, initiated in 2018, comparing IL-17A biologics with other biologics in 1981 enrolled patients with PsO. The objective of this study is to describe real-world characteristics of patients prescribed IXE in the UK as captured in PSoHO as of 2018–2021 versus the BADBIR cohort who initiated IXE during the 7 years 2016–2022.

Materials & Methods:

Patients in the UK were recruited into the IXE BADBIR cohort between November 2016 and September 2022 from 156 dermatology centres across the UK and Republic of Ireland. In the current BADBIR cohort, all patients had PsO diagnosed by a dermatologist and switched to European Medicines Agency approved dosages of IXE as a subsequent-line therapy within the 6 months prior to study entry. The PSoHO IXE cohort included biologic-naïve or -experienced adult patients with an established diagnosis (at least 6 months prior to baseline) of moderate-to-severe PsO for whom the treating physician initiated IXE for the first time between 2018 and 2021. Data collected included patient demographics, disease duration, Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), comorbidities and concomitant medication at study entry (baseline). As observed data were summarized descriptively with N (%) for categorical variables and mean and standard deviation (SD) for continuous variables.

Results:

Baseline characteristics are shown in Table 1. Although the BADBIR cohort included only biologic-experienced patients and the PSoHO cohort included patients receiving IXE as any line of therapy, both cohorts were similar with respect to being predominately male, with depression as a common comorbidity; mean (standard deviation; SD) body mass indices were 32.8 (7.7) and 32.4 (7.9) kg/m2, respectively, and mean (SD) age was 44.3 (12.7) and 46.0 (12.6) years, respectively. The BADBIR cohort had a mean (SD) of 2.1 (1.6) comorbidities and the PSoHO cohort had a mean of 0.8 (1.0) comorbidities.

Discussion:

Baseline characteristics of patients with PsO receiving IXE in the ongoing PSoHO study were broadly similar, albeit with a few exceptions, to those of the larger cohort of biologic-experienced patients enrolled in the BADBIR

registry since 2016. These findings suggest that it will be appropriate to compare and contrast effectiveness data obtained from these cohorts. A limitation is the small IXE cohort in the UK. In both the BADBIR and PSoHO cohorts, depression was a common comorbidity.

Table 1. Baseline Characteristics for UK psoriasis patients initiating ixekizumab in the BADBIR and PSoHO cohorts

Variable	**BADBIR cohort (N=780)**	**PSoHO cohort (N=20)**
Gender (female), n (%)	345 (44.2)	8 (40.0)
Age at registration, years	44.3 (12.7)	46.0 (12.6)
Age at disease onset, years	23.7 (13.4)	Not available
Body mass index, kg/m²	32.8 (7.7)	32.4 (7.9)
Duration of disease, years	20.6 (12.5)	21.1 (13.2)
Psoriatic arthritis	291 (37.3)	11 (55.0)
PASI Score	12.0 (7.9)	15.2 (6.1)
DLQI Score	15.5 (8.9)	18.5 (5.8)
Previous biologic treatment, n (%)	780 (100.0)	6 (30.0)
Number of comorbidities reported	2.1 (1.6)	0.8 (1.0)
Reported depression comorbidity, n (%)	198 (25.4)	Not available
Significant depression (HADS-D score >10), n (%)	Not available	5 (27.8)

All data presented are mean (SD) unless otherwise specified.

BADBIR, British Association of Dermatologists Biologics and Immunomodulators Register; DLQI, Dermatology Life Quality Index; HADS-D, Hospital Anxiety and Depression Scale – Depression; PASI, Psoriasis Area and Severity Index; PSoHO, Psoriasis Study of Health Outcomes; SD, Standard Deviation

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Abstract N°: 1209

The disturbances in bioactive lipids profile in the skin and serum of psoriatic patients.

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Introduction & Objectives: The aim of this study is to compare and correlate the content of ceramides and selected metabolites of the sphingolipid pathway in lesional skin, non-lesional skin, and serum in patients with psoriasis compared to those amount in the skin and serum of healthy people.

Materials & Methods: The study included 16 patients with exacerbated plaque-type psoriasis and 14 healthy subjects. The punch biopsy from lesional, and non-lesional skin and serum samples were collected from the psoriatic patients. Additionally, the serum samples were obtained and a biopsy was performed on the healthy skin from the control group. Using high-performance liquid chromatography (HPLC), the concentrations of sphingosine monophosphate (S1P), sphinganine (SFA), sphingosine (SFO), and sphinganine monophosphate (SFA1P) ceramides (CER), were analyzed both in the skin and serum samples.

Results: The median concentrations of SFO, SFA, S1P, SFA1P, and CER in the lesional skin of psoriatic patients were significantly higher ($p<0.05$) relative to both the non-lesional skin of psoriatic patients and the skin of healthy subjects. Additionally, the SFO and CER concentrations in the non-lesional psoriatic skin were significantly higher than in the healthy skin. The results are shown in Figure 1.** Psoriatic patients had also higher levels of serum SFO, SFA, S1P, and SFA1P than the control group. We did not observe a significant difference between the serum concentration of CER between psoriatic patients and the healthy group. The results are shown in Figure 2.

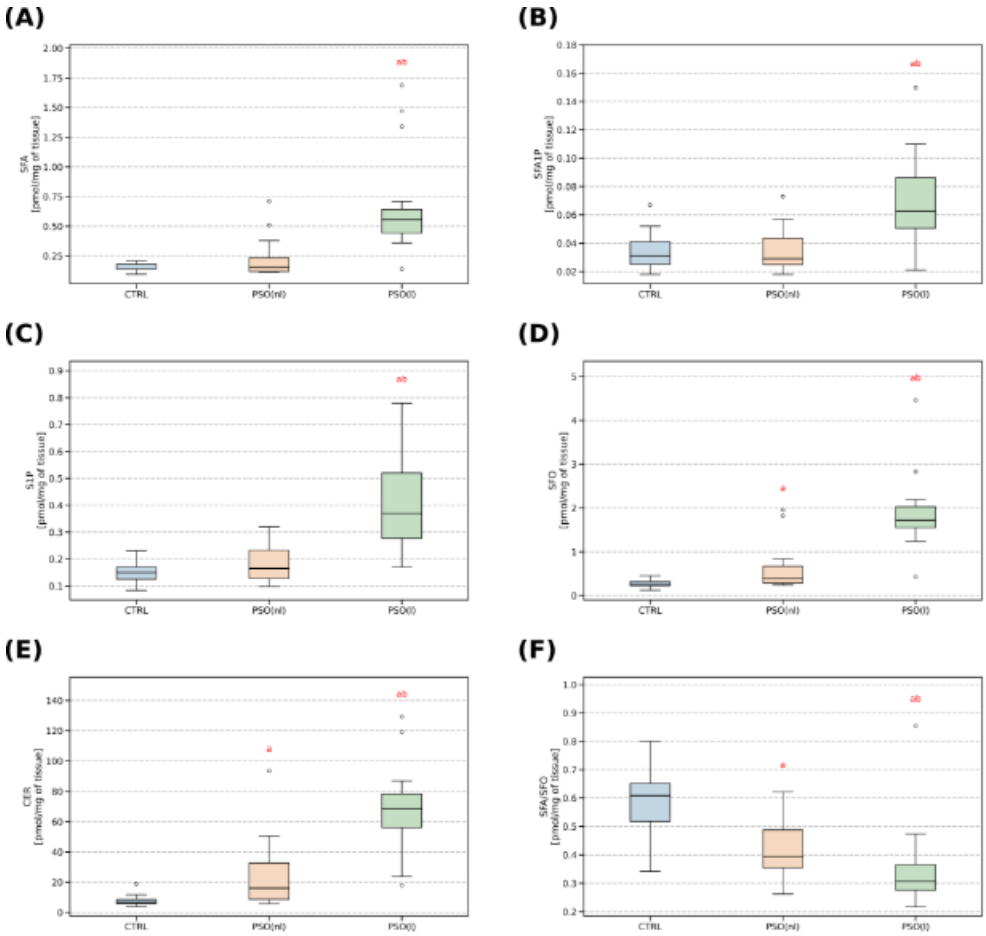

Figure 1. Comparison between the amount of sphingolipids [pmol/mg of tissue] in healthy (CTRL), psoriatic lesional [PSO (l)] and psoriatic non-lesional [PSO (nl)] skin. (A) Sphinganine (SFA) (B) sphinganine-1-phosphate (SFA1P), (C) sphingosine-1-phosphate (S1P), (D) Concentration of sphingosine (SFO), (E) ceramide (CER), (F) Ratio of sphinganine to sphingosine. Significance markers: a – difference vs. CTRL [$p < 0.05$], b – difference vs. PSO (nl) [$p < 0.05$].

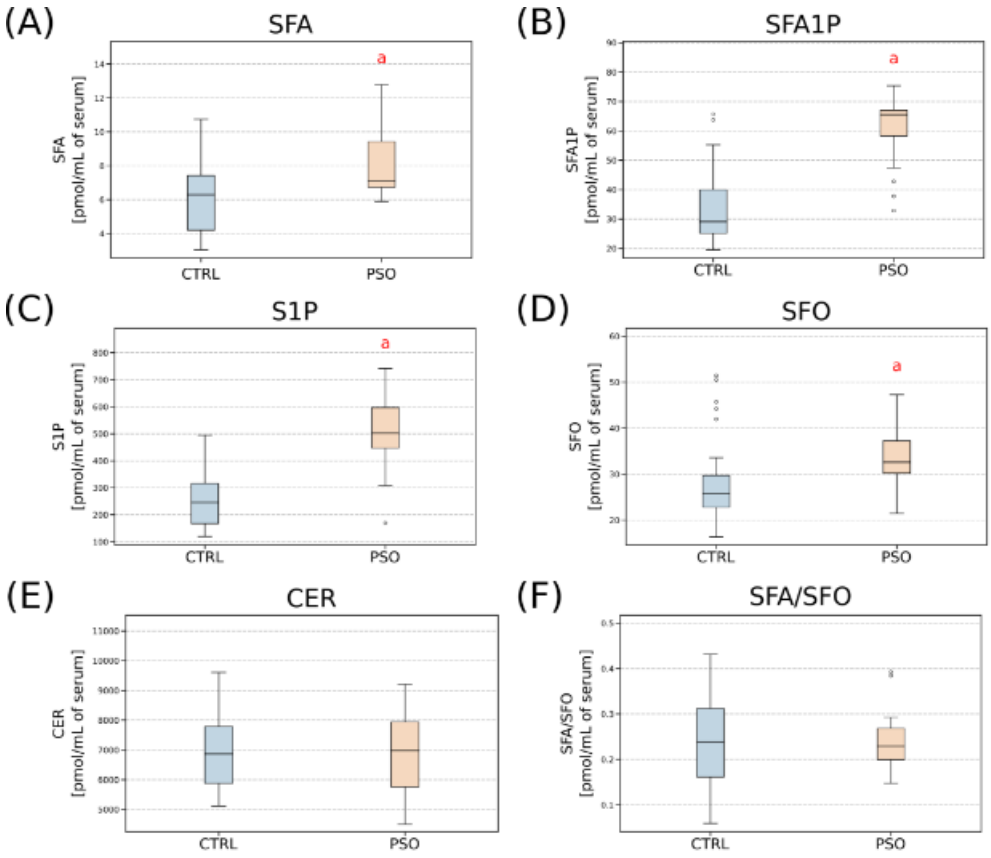

Figure 2. Comparison between serum sphingolipids [pmol/mL of serum] of psoriatic patients (PSO) and healthy controls (CTRL). (A) Sphinganine (SFA), (B) Sphinganine-1-phosphate (SFA1P), (C) Sphingosine-1-phosphate (S1P), (D) Sphingosine (SFO), (E) Ceramide (CER), (F) Ratio of sphinganine to sphingosine. Significance markers: a – difference vs. CTRL [$p < 0.05$]

Conclusion:

The profile of bioactive lipids in the skin and serum of patients with psoriasis shows significant differences from that in healthy subjects. These differences are more pronounced in lesional skin and serum, indirectly indicating the influence of the studied parameters on the development of inflammation. The study additionally reveals that lipid metabolism is also impaired in the clinically non-lesional skin of psoriatic patients.

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Abstract N°: 1213

Efficacy of cream containing pale ichthyol, juniper berry oil and canola oil on skin microbiota in patients with psoriasis

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Introduction & Objectives:

Psoriasis is a common chronic and recurrent skin disease that can have a considerable impact on patient's quality of life. Management of psoriasis involves intense pharmacotherapy during flare-ups, and suitable skin care to minimize the symptoms and extend remission period. Factors that can exacerbate the course of disease are infections, i.e. bacterial (*S. aureus* or *S. pyogenes*), viral (human papilloma virus and endogenous retroviruses), fungal (*Malassezia spp*. and *Candida albicans*) and parasitic. We performed Clinical trial of the cream no. 1464 (containing shea butter, juniper berry oil, canola oil and pale ichthyol) dedicated for patients with psoriasis, including microbiological study to check biodiversity of skin microbiota.

Materials & Methods:

Clinical trial was performed in a group of 20 adults (aged 24-69) with psoriasis of different severity. Dermatologist evaluation of the skin condition including psoriasis lesions (thickness/keratinization of the cuticle, exfoliation) was based on the analogue scale. The assessment of itch level was performed according to Numeric Rating Scale. After 4 weeks of product usage patients completed a satisfaction questionnaire. Microbiological study was performed in a group of 10 volunteers with visible psoriatic lesions or in remission period according to ISO 11133. The swabs were collected before and after 4 weeks of product usage from that same lesion/ place. Identification of microorganisms was carried out using RapID ONE, STAPH, CB, STR, NF, ANA (Oxoid), API 50CHB biochemical tests (BioMerieux).

Results:

Dermatological examination showed high skin tolerance of the tested cream. Scaling of psoriatic lesions was reduced by 47%, thickness by 31% and redness by 36%. Moreover decreasing of itch level (by 74%) was observed. All patients confirmed, that the tested cream soothes itchy skin, supports skin regeneration and softens psoriatic lesions as well as soothing skin redness. The microbiological tests confirmed that cream supports the commensal microbiota of the skin. After application of the cream no. 1464, in the majority (>50%) of the tested samples, commensal microbiota constituted a higher percentage among all isolated microorganisms. No additional growth of pathogens was observed after application of the tested product.

Conclusion:

The obtained results demonstrate that systematic application of the tested cream supports the commensal microbiota of the skin, reduced psoriasis symptoms and could extend the remission phase. Cream no. 1464 containing pale ichthyol,** juniper berry oil and canola oil** was efficacious and well tolerated in adult patients with mild to moderate psoriasis lesions. It can be used as regular skin care to minimize the psoriatic symptoms and prevents recurrence of lesions.

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Abstract N°: 1259

Effects of Apremilast on Quality of Life and Skin Clearance in Men and Women With Genital Psoriasis: Subgroup Analysis From the Phase 3 DISCREET Study

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Introduction & Objectives: Genital psoriasis (PsO) affects up to 63% of patients over the course of their disease. It is highly stigmatizing, and often overlooked and undertreated. In addition to painful and bothersome symptoms, genital PsO can severely affect quality of life (QoL) and sexual health; yet, there are limited treatment options. Women often report more intense symptoms than men, are less likely to engage in sexual activity, and may be less frequently diagnosed with or treated for genital PsO. Apremilast (APR) is a unique oral immunomodulating phosphodiesterase 4 inhibitor approved for the treatment of plaque PsO. The objective of this analysis was to evaluate the efficacy of APR in men and women with genital PsO from DISCREET.

Materials & Methods: DISCREET (NCT03777436) was a phase 3, randomized, placebo (PBO)-controlled, double-blind study evaluating APR 30 mg BID in patients with moderate to severe genital PsO (defined as a modified static Physician Global Assessment of Genitalia [sPGA-G] score ≥3). Patients were randomized 1:1 to APR or PBO for 16 weeks. We previously reported APR significantly improved genital PsO, including skin, itch, and QoL, in patients with moderate to severe genital PsO inadequately controlled by or intolerant to topical therapies. In this post hoc analysis, male and female subgroups were analyzed. Key endpoints for this analysis were change from baseline in Dermatology Life Quality Index (DLQI) question 9 (Q9) score (sexual difficulties), change from baseline in DLQI total score, achievement of modified sPGA-G response (score of 0 [clear] or 1 [almost clear] with ≥2-point reduction from baseline), and achievement of overall sPGA response (score of 0 [clear] or 1 [almost clear] with ≥2-point reduction from baseline). Week 16 results are shown.

Results: Overall, 289 patients were enrolled and treated in DISCREET: 202 men (APR, n=100; PBO, n=102) and 87 women (APR, n=43; PBO, n=44). Demographics and baseline disease characteristics are summarized in **Table 1**. Twice as many men vs women were enrolled, which was not a specific enrollment criterion. A greater proportion of men vs women had severe disease. The mean baseline DLQI score was higher in women, though mean scores for men and women indicate a very largely affected quality of life. At Week 16, there was a treatment difference favoring APR in least-squares (LS) mean change from baseline in DLQI-Q9 score of −0.27 (95% CI: −0.52, −0.02) in men and −0.41 (95% CI: −0.82, 0.01) in women (**Figure 1**). Similarly, there was a greater improvement from baseline in total DLQI score among male and female APR patients; treatment differences of LS mean change from baseline were −2.62 (95% CI: −4.49, −0.76) for men and −2.78 (95% CI: −5.66, 0.10) for women (**Figure 2**). Greater proportions of men and women treated with APR achieved a modified sPGA-G response and an overall sPGA response at Week 16 (**Figure 3**). Modified sPGA-G response at Week 16 was achieved by 35.7% of men treated with APR vs 18.6% of men who received PBO. Nearly half of women treated with APR achieved a modified sPGA-G response (48.7%) vs 21.6% of women who received PBO.

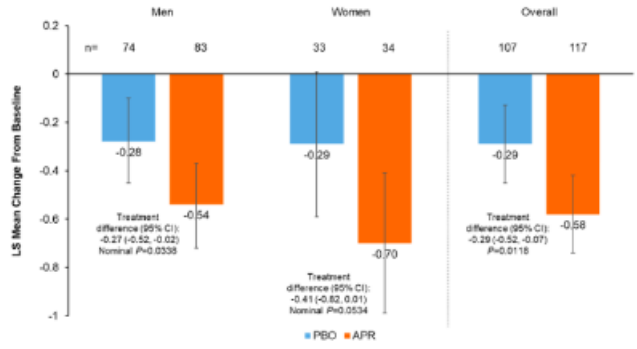
Conclusion: Men and women treated with APR, the first oral systemic treatment studied for genital PsO, experienced consistent treatment benefits, including improved sexual health and QoL, and achievement of genital PsO clearance and overall skin clearance. While sample size for female patients was lower, results are notable as women with genital PsO often experience higher burden of disease.

Table 1. Demographics and Baseline Disease Characteristics

	Men		Women	
	PBO n=102	APR n=100	PBO n=44	APR n=43
Age, mean (SD), years	47.4 (14.97)	42.5 (11.74)	44.2 (12.78)	46.0 (16.41)
Duration of genital PsO, mean (SD), years	13.3 (13.19)	10.8 (10.49)	8.7 (9.87)	11.5 (11.98)
sPGA-G score, n (%)				
3 (Moderate)	86 (84.3)	86 (86.0)	42 (95.5)	37 (86.0)
4 (Severe)	16 (15.7)	14 (14.0)	2 (4.5)	6 (14.0)
sPGA score, n (%)				
3 (Moderate)	89 (87.3)	88 (88.0)	41 (93.2)	38 (88.4)
4 (Severe)	12 (11.8)	12 (12.0)	3 (6.8)	5 (11.6)
BSA, mean (SD), %	8.9 (4.92)	10.9 (12.73)	7.7 (5.02)	10.4 (14.00)
DLQI[a] total score, mean (SD)	12.0 (6.87)	12.6 (7.22)	14.5 (6.60)	14.8 (6.58)
DLQI-Q9 (sexual difficulties)[b] score, mean (SD)	1.3 (1.1)	1.3 (1.1)	1.6 (1.2)	1.5 (1.2)

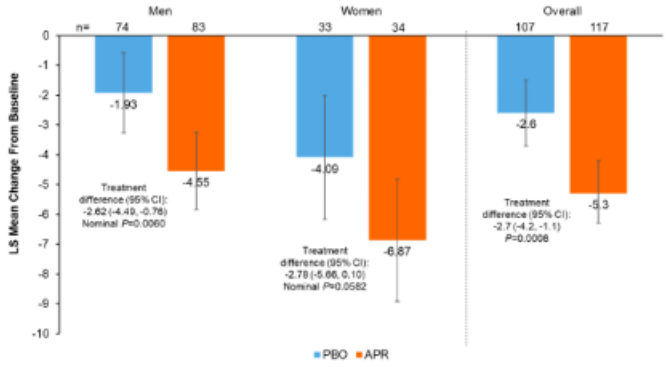
APR=apremilast; BSA=body surface area; DLQI=Dermatology Life Quality Index; sPGA-G=static Physician Global Assessment of Genitalia.
[a]The DLQI total score ranges from 0 (best quality of life) to 30 (worst quality of life).
[b]DLQI-Q9 asks, "Over the last week, how much has your skin caused any sexual difficulties?" It is scored on a scale from 0 (not relevant or not at all) to 3 (very much).

Figure 1. Change From Baseline in DLQI-Q9 (Sexual Difficulties) at Week 16



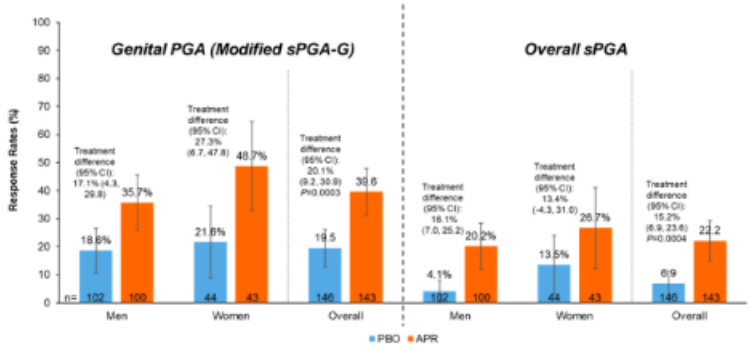
Intent-to-treat population.
Error bars represent 95% CI.
Mixed-effect model for repeated measures used for missing values.
DLQI-Q9 asks, "Over the last week, how much has your skin caused any sexual difficulties?" It is scored on a scale from 0 (not relevant or not at all) to 3 (very much).
APR=apremilast; CI=confidence interval; DLQI=Dermatology Life Quality Index; LS=least squares; PBO=placebo.

Figure 2. Change From Baseline in DLQI Total Score at Week 16



Intent-to-treat population.
Error bars represent 95% CI.
Mixed-effect model for repeated measures used for missing values.
The DLQI total score ranges from 0 (best quality of life) to 30 (worst quality of life).
APR=apremilast; CI=confidence interval; DLQI=Dermatology Life Quality Index; LS=least squares; PBO=placebo.

Figure 3. Modified sPGA-G and Overall sPGA Response at Week 16



Intent-to-treat population.
Error bars represent 95% CI.
Multiple imputation used for missing values.
Modified sPGA-G response defined as a score of 0 (clear) or 1 (almost clear) with ≥2-point reduction from baseline.
sPGA response defined as a score of 0 (clear) or 1 (almost clear) with ≥2-point reduction from baseline.
APR=apremilast; CI=confidence interval; sPGA=static Physicians Global Assessment; sPGA-G=static Physician Global Assessment of Genitalia; LS=least squares; PBO=placebo.

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Abstract N°: 1274

PsoPlus: an Integrated Practice Unit for Psoriasis

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Introduction & Objectives:

There is a need to revise the current healthcare organization due to the ever-rising costs and variation in quality of delivered care. Over the past decades there have been several strategic frameworks attempting to tackle this problem. Value-based healthcare (VBHC) is one those frameworks which has gained increasing popularity the last years. The framework is formulated on the premise that the healthcare sector should deliver integrated care, using integrated practice units (IPUs), and strive to maximize the value created. Value in this context is defined as the health outcomes achieved per costs made.

Materials & Methods:

We have designed a lean IPU called PsoPlus in which psoriasis patients are managed by a multidisciplinary team which has all the expertise and skill to manage psoriasis and its associated conditions. In addition, we have developed and implemented guidelines for the management of psoriasis associated comorbidities enabling us to deliver integrated care in the Belgian healthcare setting. Finally, we have designed a supporting information technology platform, called PsoSmart, that brings data from patients and healthcare providers together and provides actionable insights for clinical decision making. The created value is documented and captured using a value-based outcome set. Cost assessments at the individual patient level are also performed.

Results:

The PsoPlus clinic was set up at the end of 2012 and over the years, the format has continuously evolved, with a major change in 2019 where VBHC was introduced. Since January 2023, costs on the individual patient level are collected every consultation and outcomes are measured every six months. Comorbidities are screened every six months and laboratory tests are performed annually. If needed, patients are referred to actor(s) in our multidisciplinary team. All data is captured and brought together on a supporting information technology platform, this includes all data around patient and provider-reported outcomes, costs, medical interventions or treatments and comorbidities. Baseline findings of the impact of our IPU are expected in the final quarter of 2023.

Conclusion:

We describe a comprehensive IPU setting for psoriasis which incorporates the VBHC principles. This IPU goes further and delivers a higher level of integrated care than other multidisciplinary psoriasis clinics. Monitoring outcomes and costs provides us with further insights to optimize psoriasis care. In addition, a software program designed to enhance psoriasis care is being developed further, however, advances in healthcare technology are needed.

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Abstract N°: 1278

Guselkumab in patients with scalp psoriasis: A post hoc analysis of the VOYAGE 2 trial

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Introduction & Objectives: Scalp involvement is common in patients with psoriasis. It is often associated with itching which significantly impacts quality of life. The Phase III VOYAGE 2 trial compared guselkumab, an interleukin-23(p19) inhibitor, with placebo and with adalimumab in patients with moderate-to-severe plaque psoriasis.

Materials & Methods: This *post hoc* analysis explored scalp responses during guselkumab treatment and withdrawal in patients with scalp involvement (as indicated at screening) who were randomised to guselkumab 100 mg at Week (W)0 and W4, then every 8 weeks. At W28, Psoriasis Area and Severity Index (PASI) 90 responders were re-randomised to continue (n=159) or discontinue (n=164) guselkumab; non-responders continued guselkumab (n=84).

Results: Among guselkumab responders remaining on treatment, mean scalp-specific Investigator Global Assessment (ss-IGA) score rapidly declined from 2.9 at W0 to 0.2 at W24, and 0.3 at W48; mean PASI head scores were 2.0, 0.1 and 0.1, respectively, and were consistent with total PASI score improvements (21.9, 0.6 and 1.0, respectively). Changes in ss-IGA and PASI scores were less marked in non-responders than responders, but also showed improvements. Guselkumab responders who had treatment withdrawn showed an increase in mean ss-IGA score from 0.2 (W24) to 1.3 (W48) and mean PASI head score (0.1 to 0.6, respectively). Changes in mean Psoriasis Symptoms and Signs Diary itch scores and Dermatology Life Quality Index scores paralleled changes in mean ss-IGA scores for all cohorts.

Conclusion: Guselkumab demonstrated rapid and durable clinical efficacy, itch relief and quality-of-life improvements in patients with scalp psoriasis. Further investigation is required to understand predictors of scalp response.

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Abstract N°: 1297

Living with psoriasis: Patient profiles characterization based on the impact of psoriasis on their lives

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Introduction & Objectives: The impact of psoriasis (PSO) on patient lives due to an accumulation of negative effects (on quality of life, stress, sleep, even life plans) is often underestimated. This study therefore intended to better assess the different aspects of the impact of PSO on patient lives from their own point of view and to characterise the patients most impacted by this form of dermatosis.

Materials & Methods: This study was conducted using data from a transversal 2021 study of adult PSO patients recruited via the patient association "France Psoriasis". An online questionnaire asked patients to assess the impact of PSO on their quality of life [Dermatology Life Quality Index (DLQI, primary criterion) and 12-item Short Form (SF-12)], stress [Perceived stress scale-10 (PSS-10), sleep (Epworth Sleepness Scale (ESS)], life plans (Major Life Changing Decision Profile, MLCDP, which was recently validated in French), and the severity of the disease [Simplified Psoriasis Severity – severity (SaSPI-s)]. The results were analysed via a hierarchical grouping to define homogeneous patient profiles based on the impact of PSO on their quality of life, with descriptions of patient characteristics for each profile.

Results: The 1219 patients analysed had a mean age of 46.1±14.2, were predominantly female (60.0%), working (71.0%) and had a long-term illness per the French social security in 34.0% of cases. The hierarchical analysis allowed 3 patient profiles to be identified based on the impact of PSO on their lives (with significantly different DLQI, SF-12, PSS-10, ESS and MLCDP scores). Among the 275 patients whose lives were most affected (profile 3, 22.6%), there were many negative effects of PSO. These patients were significantly younger, working, had a long-term illness, had more severe PSO with a current outbreak, had prolonged therapeutic care, more common psychological care, and worse MLCDP subscores (social and job/career in particular).

Conclusion: This study based on patient viewpoints allowed those patients most impacted by psoriasis to be identified and characterised. The accumulation of negative effects on these patients' lives, particularly in terms of their life plans which were assessed for the first time as part of this study, must be taken into account in their care.

|**Parameters**|
Profile 3

N=275

Impact of psoriasis on patient lives	
DLQI (0-30)	14 [11; 19]
SF-12 *	
Physical (0-100)	44.2 [40.2-48.2]
Mental (0-100)	43.1 [39.0-46.4]
PSS-10 (0-40)	21 [19-23]
ESS (0-24)	12 [8-14]
MLCDP – graded score (0-128)	54 [32.5-66.5]
Psoriasis characteristics	
SaSPI-s (0-50)	5 [2-10]
Severe psoriasis per the patient	54 (19.6%)
Current outbreak per the patient	158 (57.5%)
Age (years)	37 [30-46.5]
Female	137 (49.8%)
Working	228 (82.9%)
Long-term illness	137 (49.8%)
Type of treatment	
Oral without injection ± topical	40 (14.6%
Injection ± oral ± topical	71 (25.8%)
Psychological support	86 (31.3%)
MLCDP subscores	
Education (0-12)	5 [2-7]
Job/career (0-36)	15 [9-20]
Family/relationships (0-20)	8 [3-11]
Social (0-40)	16 [10-20]
Physical (0-20)	9 [6-11]

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Abstract N°: 1374

Apremilast Benefits Patients Irrespective of Prior Conventional Systemic Treatment Use: Results from the Phase 4 EMBRACE Trial

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Introduction & Objectives: Management of chronic plaque psoriasis (PsO) often involves conventional systemic (CS) therapies. Patients (pts) may discontinue CS treatments for a variety of reasons, including long-term safety concerns, development of contraindications, reproductive risks, treatment burden, and lack of effectiveness. Apremilast is a unique oral immunomodulating phosphodiesterase 4 inhibitor approved in adults with moderate to severe chronic plaque PsO in the European Union, and in the United States regardless of disease severity. EMBRACE (NCT03774875), a phase 4, multicenter, randomized, double-blind, placebo (PBO)-controlled trial in Western Europe, demonstrated that apremilast 30 mg BID (APR) improved skin-related quality of life in pts with limited skin involvement with chronic plaque PsO in special areas. The present post hoc subgroup analyses of APR are based on prior CS-therapy history from EMBRACE.

Materials & Methods: Pts had chronic plaque PsO (≥6 months) inadequately controlled by topical therapy and a lack of response, contraindication, or intolerance to first-line or later CS therapies. Subgroup analyses were based on number of prior CS therapies (0, 1, 2, or ≥3). Key endpoints were percent change from baseline (BL) in body surface area (BSA), Psoriasis Area and Severity Index (PASI) response (PASI <3), change from BL in Dermatology Life Quality Index (DLQI) response (≥4-point reduction from BL), Itch Numeric Rating Scale, and Skin Discomfort/Pain Visual Analog Scale, and achievement of Patient Benefit Index (PBI) ≥1, ≥2, or ≥3. All endpoints were assessed at Week 16.

Results: Of 277 pts treated in EMBRACE, 92 were randomized to PBO and 185 randomized to APR. Pts had been treated with either 0 (PBO: n=18; APR: n=55), 1 (PBO: n=34; APR: n=63), 2 (PBO: n=22; APR: n=32), or ≥3 (PBO: n=18; APR: n=35) prior CS therapies. Demographics and baseline disease characteristics of each CS subgroup are shown in **Table 1**. The most common prior CS therapies were methotrexate (1 and 2 prior CS) and dimethyl fumarate (≥3 prior CS). Percent change from BL in BSA showed consistent benefit in APR pts across subgroups; percent changes ranged from −11.8% to −29.5% among APR pts, while percent changes ranged from 4.9% to 36.8% among PBO pts. A greater proportion of APR pts achieved a DLQI response, regardless of number of prior CS therapies (**Figure 1**). Similarly, a greater proportion of APR pts had a PASI response versus PBO pts in all subgroups with prior CS therapy; the difference was minimal for pts with no prior CS therapies . Mean (SD) DLQI total score change from BL was greater among APR pts, irrespective of number of prior CS therapies: −4.8 (4.8) for PBO and −9.0 (7.2) for APR, 0 prior CS; −2.2 (6.5) for PBO and −9.0 (7.2) for APR, 1 prior CS; −4.9 (7.7) for PBO and −7.7 (6.9) for APR, 2 prior CS; −3.0 (5.2) for PBO and −8.0 (6.3) for APR, ≥3 prior CS. APR pts in all prior CS subgroups experienced greater improvement in skin discomfort/pain and itch versus PBO (**Figure 2**). Greater proportions of APR pts across prior CS subgroups experienced patient benefit versus PBO, with the majority of pts achieving a PBI ≥1 and many achieving a PBI ≥2 or ≥3 (**Figure 3**). Small sample sizes may limit interpretation of

this analysis.

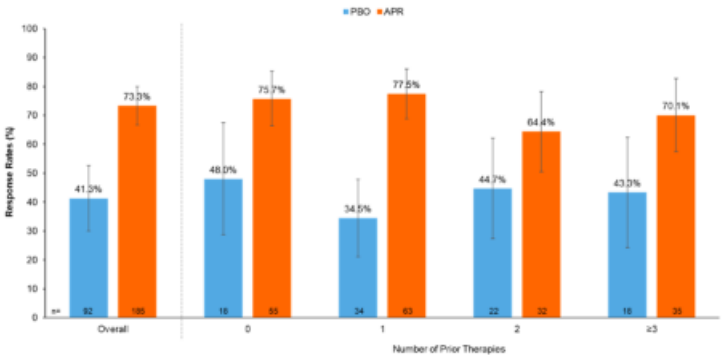
Discussion: APR demonstrated a consistent treatment benefit versus PBO in the phase 4 EMBRACE trial, irrespective of the number of prior CS therapies used.

Table 1. Patient Demographics and Baseline Characteristics

	PBO (n=92)	APR (n=185)
0 Prior CS	n=18	n=55
Age, mean (SD), years	53.3 (14.6)	49.1 (14.8)
Duration of plaque psoriasis, mean (SD), years	19.8 (15.6)	16.5 (14.1)
DLQI score, mean (SD)	17.7 (5.4)	18.8 (5.1)
PASI score, mean (SD)	6.6 (2.1)	7.1 (1.8)
BSA, mean (SD), %	6.6 (4.1)	6.3 (2.6)
1 Prior CS	n=34	n=63
Age, mean (SD), years	49.4 (13.6)	43.9 (12.9)
Duration of plaque psoriasis, mean (SD), years	15.6 (12.9)	15.1 (12.3)
DLQI score, mean (SD)	18.5 (4.9)	18.6 (5.0)
PASI score, mean (SD)	6.9 (2.1)	6.8 (2.0)
BSA, mean (SD), %	7.3 (4.8)	7.5 (3.8)
2 Prior CS	n=22	n=32
Age, mean (SD), years	54.0 (13.7)	51.5 (15.7)
Duration of plaque psoriasis, mean (SD), years	22.7 (13.4)	18.4 (15.5)
DLQI score, mean (SD)	18.9 (5.2)	16.8 (5.0)
PASI score, mean (SD)	6.7 (1.9)	6.0 (1.6)
BSA, mean (SD), %	7.6 (4.3)	5.7 (3.0)
≥3 Prior CS	n=18	n=35
Age, mean (SD), years	47.6 (12.6)	47.5 (13.6)
Duration of plaque psoriasis, mean (SD), years	17.2 (11.1)	16.2 (10.7)
DLQI score, mean (SD)	18.9 (4.5)	17.3 (4.0)
PASI score, mean (SD)	6.8 (2.0)	7.1 (1.9)
BSA, mean (SD), %	7.8 (3.8)	8.5 (4.1)

APR, apremilast 30 mg BID; BSA, body surface area; CS, conventional systemic therapy; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; SD, standard deviation.

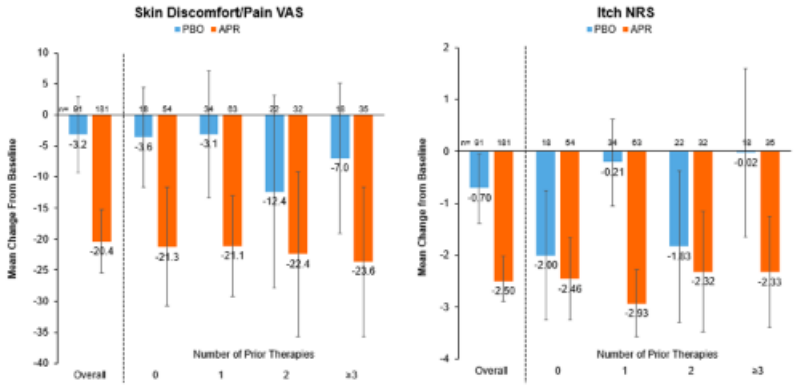
Figure 1. Achievement of DLQI Response at Week 16



Intent-to-treat population. Error bars represent 95% CI. DLQI total scores range from 0 to 30. Higher scores correspond to poorer quality of life. DLQI response was defined as a ≥4-point reduction in DLQI from baseline. Multiple imputation was used to impute missing scores at the scheduled analysis visits in the PBO-controlled phase (Weeks 0–16) to create M=25 complete data sets. The Markov Chain Monte Carlo method was used to impute missing scores by treatment and stratification factor to create M=25 imputed data sets with monotone missing patterns. The predictive mean matching method including treatment arm and stratification factor was used to impute the remaining missing scores for the 25 data sets. The responses at Week 16 were derived based on both observed and imputed scores.

APR, apremilast 30 mg BID; DLQI, Dermatology Life Quality Index; PBO, placebo.

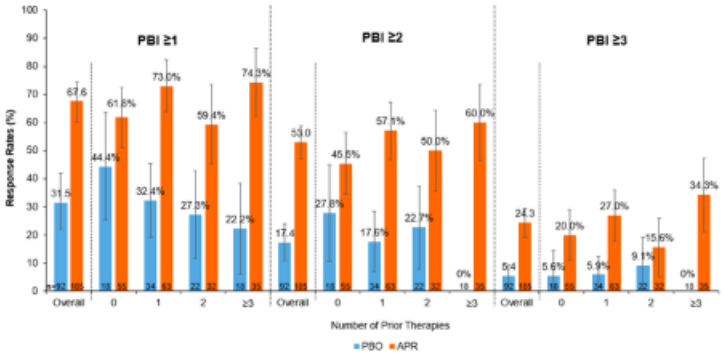
Figure 2. Change from Baseline in Skin Discomfort/Pain VAS and Itch NRS at Week 16



Intent-to-treat population. Error bars represent 95% CI. VAS ranges from 0 (no pain at all) to 100 (worst possible pain). NRS scores range from 0 (no itch) to 10 (worst itch imaginable). Error bars represent 95% CI. Multiple imputation was used to impute missing scores at the scheduled analysis visits in the PBO-controlled phase (Weeks 0–16) to create M=25 complete data sets. The Markov Chain Monte Carlo method was used to impute missing scores by treatment and stratification factor to create M=25 imputed data sets with monotone missing patterns. The predictive mean matching method including treatment arm and stratification factor was used to impute the remaining missing scores for the 25 data sets. The total score at Week 16 was derived based on both observed and imputed scores.

APR, apremilast 30 mg BID; NRS, numeric rating scale; PBO, placebo; VAS, visual analog scale.

Figure 3. Achievement of PBI ≥1, ≥2, and ≥3 at Week 16



Intent-to-treat population. Error bars represent 95% CI. The PBI score ranges from 0 (no benefit) to 4 (maximum benefit). NRI used for missing scores. Results from the primary analysis of PBI response (PBI ≥1) at Week 16 using MI were a 39.9% response rate for PBO (95% CI: 28.8, 51.0) and 76.6% (95% CI: 70.2, 83.1) for APR.

APR, apremilast 30 mg BID; MI, multiple imputation; NRI, nonresponder imputation; PBI, Patient Benefit Index; PBO, placebo.

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Abstract N°: 1395

fractional laser-assisted delivery versus intralesional injection of methotrexate in nail psoriasis

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Introduction & Objectives:

The treatment of nail psoriasis is often unsatisfactory due to poor penetration of topical therapeutics through the nail plate. Intralesional injection of corticosteroid or methotrexate has been used for many years in nail psoriasis with good results. However, pain is still the major side effect of this method, especially in patients with multiple digits involvement. Fractional lasers have been used in combination with topical agents in the treatment of onychomycosis and traumatic onychodystrophy leading to marked improvement of the dystrophic nails. Drug delivery of the topical treatment into the nail bed or matrix is enhanced through the holes created by the laser into the nail plate. In this study, we aim to compare the efficacy of intralesional methotrexate injection versus its topical application after fractional CO2 laser in the treatment of fingernail psoriasis.

Materials & Methods:

Twenty-eight patients with fingernail psoriasis were divided into 2 groups, each containing 14 patients. Group A was treated with intralesional injection of methotrexate while Group B received fractional CO2 laser followed by topical application of methotrexate on the psoriatic nails. The treatment was given at a 2-week interval for 6 sessions. The improvement of nail psoriasis was assessed by clinical and dermoscopic evaluation.

Results:

At the end of treatment, both laser-assisted delivery and intralesional injection of methotrexate were associated with statistically significant improvement of psoriatic signs. No statistically significant difference was found between the 2 groups regarding total NAPSI (nail psoriasis severity Index) (P=0.18), NAPSI matrix score (P=0.38), NAPSI bed score (P=0.23), and dermoscopic score (P=0.78). However, the pain and subungual hematoma were significantly less in the laser group (P=0.001 and P=0.03, respectively) compared to intralesional injection group.

Conclusion:

Fractional CO2 laser-assisted delivery of methotrexate can be an effective and well-tolerated alternative to intralesional injection in nail psoriasis. Targeting the nail plate and folds by fractional laser led to accumulation of the drug into the nail matrix and bed which subsequently improved the psoriatic signs in both structures. In addition, the continuous vaporization followed by re-epithelialization of the nail tissue was associated with remodeling of the nail plate.

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Abstract N°: 1413

Treatment with il-23 inhibitors in palmoplantar psoriasis. A case series.

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Introduction & Objectives:

Psoriasis affecting palms and soles represents a special localization with difficult therapeutic management, with heterogeneous response to the approved treatments. Our objective was to asses therapeutic response in patients with plaque psoriasis and pustular palmoplantar psoriasis receiving treatment with IL-23 inhibitors.

Materials & Methods:

We conducted a retrospective study with patients with plaque psoriasis and lesions on palms and soles, as well as pustular palmoplantar psoriasis receiving treatment with anti-IL-23 drugs, initiated between 2019 and 2022, and collected data evaluating response with PGA at weeks 12-16, 24-28 and 52, previous and simultaneous treatments, comorbidities and adverse events.

Results:

10 patients were included, 5 with Guselkumab and 5 with Risankizumab. 8 women and 2 men. Median age was 56,3 years and 4 patients were active smokers. Two cases had pustular forms of psoriasis. The following comorbidities were present: 3 had dyslipidemia, 2 had hypertension, 1 suffered from type 2 diabetes, 1 had had a previous cardiovascular event, 1 had an incomplete SAPTHO, 4 had psychiatric diseases and 2 had a history of a previous neoplasia. All cases had plaque psoriasis, 7 had arthritis, 5 with onychopathy, 4 in the scalp and 2 had inverted psoriasis. They had received on average 3,1 previous treatments, including classical immunosuppressants and other biologic treatments. 9 had done previous biologic treatment, only one case was naïve, 3 cases were second line, 3 third line and 3 as fourth line or more. Change of treatment was due to lack of response. In all cases, improvement was seen at week 12-16, maintaining response on later evaluation. In 4 cases complete resolution was observed. In others, the affected surface diminished: 2 cases persisted only on fingertips and the rest improved in approximately 50% the affected area. Two cases received concomitantly apremilast or acitretine. All patients applied topical treatment with corticosteroids only or combined with vitamin D analogues. Only one case of injection site reaction was reported. No patient did intensification or deintensification.

Conclusion:

In our case series, all patients improved with IL-23 inhibitors, with a good safety profile. As limitations to this study, only 10 patients were reported and data were obtained retrospectively. It would be interesting to conduct a prospective study with a larger number of patients in order to establish the role of IL-23 inhibitors in palmoplantar psoriasis.

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Abstract N°: 1430

investigation of fecal calprotectin levels in psoriasis patients

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Introduction & Objectives: Psoriasis is a chronic immune-mediated systemic disease characterized by papulosquamous skin lesions. It is associated with comorbid conditions such as psoriatic arthritis and inflammatory bowel disease (IBD). The association of IBD and psoriasis has been confirmed at the genetic level. The cytokines that drive disease are also quite similar. Significant similarities in pathogenesis are reflected in their overlap in therapeutic approaches. Many biological therapies, such as anti-tumor necrosis factor (TNF) and anti-interleukin 23, are effective in both conditions, highlighting common immunological mechanisms. However, IBD exacerbations have been reported in anti-IL-17 trials. Therefore, it is stated that caution should be exercised in prescribing these drugs in patients with a personal history suggestive of IBD. Fecal calprotectin has been adopted as a standard marker in IBD screening and monitoring practices. In our study, we aimed to evaluate the relationship between psoriasis and intestines through the fecal calprotectin level, which is considered a very sensitive marker of intestinal inflammation.

Materials & Methods: 45 psoriasis patients between the ages of 18-65, who were newly admitted to the Department of Dermatology and Venereal Diseases of Atatürk University Faculty of Medicine, were included in the case group, and 45 healthy volunteers between the ages of 18-65 were included in the control group. Patients and volunteers with inflammatory bowel disease or bowel complaints, who had a history of using anti-inflammatory drugs or proton pump inhibitors in the last 2 weeks and who received systemic therapy, were not included in the study because it may affect fecal calprotectin levels. Fecal calprotectin levels in the case and control groups were measured simultaneously with the ELISA method, quantitatively.

Results: : Mean fecal calprotectin level was 97.59±20.3 pg/mL in the psoriasis case group and13.05±14.3pg/mL in the control group. The fecal calprotectin level of the case group was statistically significant compared to the control group ($p<0.007$).

Conclusion: In our study, fecal calprotectin levels in patients with psoriasis were found to be significantly higher when compared with the control group ($p=0.007$). This result reveals that patients with psoriasis have varying degrees of subclinical intestinal inflammation. Demonstrating the known comorbidity between intestinal and psoriasis through fecal calprotectin levels allows objective analysis of this related condition in psoriasis patients. At the same time, demonstrating subclinical inflammation through fecal calprotectin levels may provide an opportunity to be an objective guide in patient selection, especially at the beginning of anti-IL17 therapy. No correlation was found between fecal calprotectin level and PASI, age at onset of disease in psoriasis patients ($p=0.489$ for rust, $p=0.836$ for disease onset age). However, a positive correlation was found between fecal calprotectin levels and disease duration ($p=0.0026$). This result may guide us to be more careful in terms of intestinal-related comorbidities in patients with prolonged disease duration.

Keywords: fecal calprotectin, psoriasis, subclinical intestinal inflammation

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Abstract N°: 1489

Improvements in Skin Clearance and Patient-Reported Outcomes were Greater with Guselkumab Compared with Ustekinumab Among Patients with Persistent Mild Psoriasis After 16-Weeks of Treatment with Ustekinumab

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Introduction & Objectives: Managing clinical symptoms is key to patients achieving freedom from plaque-psoriasis. For patients whose symptoms are not adequately controlled, switching to another therapy with a different mechanism of action may be warranted. In the Phase 3 NAVIGATE trial, patients with moderate-to-severe psoriasis were initially treated with ustekinumab (anti-interleukin-12/23p40 subunit antibody). Patients with inadequate response to ustekinumab (Investigator's Global Assessment [IGA] ≥2) were randomized to either switch to guselkumab (anti-interleukin-23p19 subunit antibody) or continue ustekinumab. This post-hoc analysis evaluated the subgroup of patients with residual psoriasis of mild severity (IGA=2) after initial ustekinumab treatment.

Materials & Methods: Assessments included Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), and Psoriasis Symptom and Sign Diary (PSSD).

Results: Initially, 871 patients received ustekinumab. At Week 16, 268 patients with IGA≥2 were randomized; of these, 161 had residual psoriasis of mild severity (IGA=2). At Week 28, among guselkumab versus ustekinumab treated patients in this mild subgroup, 59% versus 28% achieved PASI 90; mean changes from baseline (Week 0) in PSSD symptom and sign scores were -44 versus -28 and -50 versus -32, respectively; and DLQI was 0/1 for 50% versus 21% (all nominal p-values <0.001). At Week 52, 54% versus 20% of patients receiving guselkumab versus ustekinumab achieved DLQI 0/1 (nominal p value <0.001). Complete resolution of symptoms or signs based on PSSD outcomes was more common with guselkumab versus ustekinumab, even among patients who had clear or almost clear skin.

Conclusion: Among patients with residual psoriasis of mild severity switching to guselkumab after 16 weeks of ustekinumab treatment had greater improvements in skin clearance and patient-reported quality of life compared with those continuing with ustekinumab.

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Abstract N°: 1574

Psoriasis increases retinal vein occlusion risk in diabetic patients : A nationwide population-based study

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Introduction & Objectives:

Recent studies have shown that approximately 10% of psoriasis patients have ophthalmic complications including blepharitis, dry eye, conjunctivitis, and uveitis, and those with pustular psoriasis and psoriatic arthritis have the highest risk for these complications. Retinal vein occlusion is the second most common retinal vascular disorder after diabetic retinopathy and is an important cause of vision loss. Both psoriasis and retinal vein occlusion are related to diabetes mellitus. To explore the association between psoriasis and retinal vein occlusion, the researchers analyzed the association between retinal vein occlusion and psoriasis in a diabetic population to minimize the confounding effects of diabetes mellitus. This study used a population-based cohort database of Korean individuals with type 2 diabetes mellitus based on the Korean Health Insurance Review and Assessment Service data from 2009 to 2018.

Materials & Methods:

This was a retrospective, nationwide, population-based, retrospective cohort study. Records from January 2009 to December 2012 were analyzed for patients ≥ 20 years of age who had been diagnosed with type 2 diabetes mellitus. We compared the incidence rate of retinal vein occlusion between a group of patients with psoriasis and a control group of patients without psoriasis until December 2018 in all subjects. Cox proportional hazards regression analysis was used to assess the association between psoriasis and newly developed retinal vein occlusion in diabetes mellitus patients. The incidence probability of retinal vein occlusion with the presence of psoriasis in diabetes mellitus patients was presented using the Kaplan-Meier curve. A log-rank test was also performed to analyze the differences between the psoriasis and control groups. Statistical significance was defined as a two-sided P-value lesser than 0.05.

Results:

Of 2,745,689 type 2 diabetes mellitus patients, 23,725 patients were classified in the psoriasis group, and the other 2,547,121 individuals in the control group. A total of 497 retinal vein occlusion cases occurred in psoriasis group (3.14 per 1000 person-years) and 42,388 retinal vein occlusion cases in controls (2.44 per 1000 person-years). According to multivariable Cox proportional hazard models, individuals with psoriasis had a significantly higher risk for retinal vein occlusion compared to controls (hazard ratio: 1.216, 95% confidence interval: 1.11–1.33) after adjustments for covariates.

Conclusion:

This study demonstrated that psoriasis was an independent risk factor for developing retinal vein occlusion in diabetes mellitus patients. Therefore, physicians should be alert to the development of retinal vein occlusion in diabetes mellitus patients who also have psoriasis.

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Abstract N°: 1578

How happy are psoriasis patients in Europe? A multicenter cross-sectional study (HAPPY SKIN EUROPE)

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Introduction & Objectives:

Psoriasis is typically characterized by disfiguring and stigmatizing skin lesions, resulting in a high psychosocial burden and impaired subjective well-being of affected patients. Previous studies have focused on well-being and happiness of patients with chronic skin disease, predominantly in one country. No comparable data are available at European level and a comparison between different European countries is still pending. The study aims to investigate subjective well-being of psoriasis patients and the relationship between well-being and disease characteristics in different European countries.

Materials & Methods:

Psoriasis patients were recruited for a cross-sectional study between 10/2021 and 02/2023 in eight European countries: Austria, Germany, Italy, Malta, Poland, Portugal, Romania, and Ukraine. As part of a more comprehensive study, patients filled in a paper-based questionnaire including age, gender, years since disease onset, and subjective severity, as well as validated scales measuring well-being namely heuristic happiness, satisfaction with life scale (SWLS), positive and negative affect (SPANE), and quality of life in dermatological diseases (DLQI). The treating physician ensured the diagnosis and documented the Psoriasis Area and Severity Index (PASI). Data were analyzed descriptively and using Kruskal-Wallis tests and Spearman's correlation (r).

Results:

Overall, 723 psoriasis patients were included for analysis (median age of 44 years (range: 18-86), 58.8% men): 165

from Austria, 57 Germany, 79 Italy, 86 Malta, 158 Poland, 75 Portugal, 16 Romania, and 87 Ukraine. The patients showed country-specific differences in age, years since initial psoriasis diagnosis, treatment, severity, and happiness scales ($p \leq 0.013$). For example, patients from Ukraine and Poland, also having the highest median PASI, were unhappier, less satisfied with their lives, and had more negative emotions compared with patients from other countries, whereas patients from Austria seemed to be the happiest, most satisfied and positive patients. The relationship between severity and the rating of well-being was also supported by correlations in almost all countries, particularly between severity and DLQI ($0.25 \leq r \leq 0.65$). For the majority of countries, severity also increased with increasing disease duration ($-0.02 \leq r \leq 0.42$), whereas the correlations between disease duration and happiness showed country-specific differences in direction.

Conclusion:

The study highlights the differences in disease status and the impact of psoriasis on the patients' happiness in different European countries. Despite efficient treatment options, the study may indicate an insufficient treatment, as several countries showed high correlation between disease duration and severity. Clinicians, researcher, and policy makers should be aware of these country-specific differences when treating psoriasis patients, planning studies, and implementing health policies in the future.

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Abstract N°: 1582

Бремя псориаза ногтей у пациентов с псориатическим артритом: значительное ухудшение состояния болезни и качества жизни

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Introduction & Objectives:

limited data are available regarding the burden of nail disease in psoriatic arthritis (PsA). The latest data shows that nail involvement in PsA patients (pts) is associated with significantly more severe disease status. To analyze, in clinical practice, the association of nail psoriasis with disease activity, quality of life, and work productivity in PsA pts.

Materials & Methods:

588 pts (M/F–277 /311) with PsA according to CASPAR criteria were included in the study. Pts' age 48.6±0.5 years (yrs), disease duration 7.0±0.3 yrs. Pts underwent standard clinical examination of PsA activity. Pts were split into two groups (gr.): those with nail psoriasis – gr.1, and those without it – gr.2. Demographics, disease activity, quality of life, and work productivity were compared between pts with and without nail psoriasis using Pearson's chi-square test and Mann–Whitney U test.

Results:

gr.1 includes 312 (53.1%) cases, gr.2 – 276 (46.9%) cases. More pts in gr.1 were males (51.9% vs 44.1%, p=0.013), disabled at work (37.20% vs 26.40%, p=0.000), chronic smokers (18.9% vs 8.7%, p=0.000) and with axial PsA disease signs according to physician (35.0% vs 26.4%, p=0.025) compared to pts in gr.2. Pts in gr.1 had higher tender and swollen joint counts: 8 [4-15] vs 5 [2-12] (p=0.002) and 5 [1-9] vs 2 [0-7] (p=0.003) respectively. Gr.1 pts had higher disease activity measured by DAPSA 25 [15-39] vs 20 [12-33] (p= 0.001), higher frequency of dactylitis (24.4% vs 16.7% p=0.022) and heel enthesitis (17.0% vs 10.1% p=0.016) respectively, higher frequency of erosive radiographic arthritis of feet (45.0% vs 31.2% p=0.003) compared to gr.2 pts. Pts in gr.1 had worse skin psoriasis measured by Psoriasis Area Severity Index – 6 [2-14] vs 3 [1-6] (p=0.000). Less pts in gr.1 than in gr.2 (27.0% vs 52.0% p=0.004) achieved minimal disease activity (MDA). Pts' reported outcomes (PRO's) in gr.1 were worse than in gr.2 in regard to reduced health-related quality of life according to PsAID (4.9±2.3 vs 4.0±2.3, p=0.040) and to EQ-5D (0.56±0.19 vs 0.64 ±0.21, p=0.024) questionnaires, overall work impairment (0.0 [0.0-0.3] vs 0.0 [0.0-0.2], p=0.034) and overall activity impairment (0.4 [0.1-0.7] vs 0.3 [0.0-0.5], p=0.006) according to WPAI.

Conclusion:

nail involvement in PsA pts is associated with male gender and axial disease. PsA pts with nail involvement are more often disabled, more often are chronic smokers, have significantly worse disease status as measured by disease activity; they are more likely to have more severe (erosive) peripheral arthritis of feet, higher frequency of heel enthesitis and dactylitis, higher psoriasis disease severity, lower frequency of MDA achievement, and worse quality of life and work productivity according to PRO's. Detection of nail involvement is critical for choice of treatment approach and better outcomes.

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Abstract N°: 1588

Nail psoriasis as a predictor of the development of erosive arthritis

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Introduction & Objectives:

it has been detected that the presence of psoriatic nail dystrophy is associated with erosive damage at distal interphalangeal joints in psoriatic arthritis (PsA) patients (pts). Predictors of erosive arthritis hadn't been sufficiently studied. To identify predictors of erosive peripheral arthritis in PsA pts.

Materials & Methods:

588 pts with PsA according to CASPAR criteria were examined. Pts underwent standard clinical examination of PsA activity including hands and feet x-ray at baseline and at end of study. Among them, 155 (26.4%) pts (M/F 73/82), without erosive radiographic arthritis at baseline were included in the study. Pts' age 47.4±12.45 years (yrs), disease duration 8.6±5.13 yrs. The study lasted 4.6±1.92 yrs. In order to identify predictors of erosive arthritis the analysis included the following features: pts' gender, age, disease duration, disability, smoking habit, tender and swollen joint counts (SJC), disease activity measured by DAPSA, DAS, DAS 28 and BASDAI, frequency of enthesitis and dactylitis, skin lesion severity (body surface area affected and Psoriasis Area Severity Index), presence of nail psoriasis, CRP and ESR, patient reported outcome (PRO) measures. Descriptive statistics and logistic regression methods were used.

Results:

among the 150 pts without erosive radiographic arthritis at baseline were 25 pts with nail psoriasis and 130 pts without nail psoriasis. At baseline SJC, in the pts group (gr.) with nail psoriasis was 4.7±0.8, while in the pts gr. without nail psoriasis 2.7±0.29 (p=0.025). At end of study, erosive radiographic arthritis developed in 9 of 25 (36.0%) pts with nail psoriasis and in 31 of 130 (23.8%) pts without nail psoriasis (p=0.204). In the logistic regression model, the combination of features – nail psoriasis (p = 0.049) and the number of swollen joints (p = 0.005) – proved to be prognostically significant for the development of erosive arthritis. The area under the ROC curve for the model is 0.65. Specificity 97%.

Conclusion:

it is a combination of features – nail psoriasis and the number of swollen joints – that constitute a clinical predictor for the development of erosive peripheral arthritis in PsA patients.

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Abstract N°: 1610

Sex Differences in Drug Toxicity in Systemic Psoriasis Treatments: A Decade of Insights from the Swiss Psoriasis Registry (SDNTT)

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Introduction & Objectives:

Psoriasis often requires prolonged systemic treatment, making it critical to assess the safety and efficacy of these therapies. Understanding the sex-specific variances is essential for personalizing treatment plans.

To investigate the real-world, long-term safety of systemic psoriasis therapies with sex stratification in drug toxicity.

Materials & Methods:

10-year data from patients with moderate-to-severe psoriasis requiring conventional systemic therapies (CSTs) and/or biologics were obtained from the Swiss psoriasis registry SDNTT. Safety was assessed by calculating drug-related adverse event (ADR) rates per 100 patient-years (PY). We used descriptive statistics for patient and disease characteristics, and binomial and t-test compared treatment groups and sex.

Results:

791 patients (290 females, 501 males) with a mean age of 46 years were included. 358 (45%) received CSTs and 433 (55%) biological therapy. CSTs led to a 2.2-fold higher ADR rate (40.43/100 PY vs. 18.22/100 PY, $p < 0.0001$) and 8.0-fold higher treatment discontinuation rate than biologics (0.16/PY vs 0.02/PY, $p < 0.0001$). Sex analysis revealed a significantly higher cumulative ADR rate for all treatments in females (1.8-fold for CSTs [57.30/100 PY vs 31.69/100 PY] and 2.0-fold for biologics [27.36/100 PY vs 13.9/100 PY], $p < 0.0001$), and drug-related discontinuation rates for most CSTs in females.

Conclusion:

CSTs lead to significantly more ADRs than biologics. The female sex is associated with a significantly higher rate of ADRs, except for apremilast, cyclosporine and anti-IL-17 as well as drug-related discontinuation rates. We suggest integrating sex stratification in future therapeutic decision-making in the patient-tailored management of psoriasis.

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Abstract N°: 1630

The burden of nail psoriasis in psoriatic arthritis patients: significantly worse disease status and quality of life

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Introduction & Objectives:

limited data are available regarding the burden of nail disease in psoriatic arthritis (PsA). The latest data shows that nail involvement in PsA patients (pts) is associated with significantly more severe disease status. To analyze, in clinical practice, the association of nail psoriasis with disease activity, quality of life, and work productivity in PsA pts.

Materials & Methods:

588 pts (M/F–277 /311) with PsA according to CASPAR criteria were included in the study. Pts' age 48.6±0.5 years (yrs), disease duration 7.0±0.3 yrs. Pts underwent standard clinical examination of PsA activity. Pts were split into two groups (gr.): those with nail psoriasis – gr.1, and those without it – gr.2. Demographics, disease activity, quality of life, and work productivity were compared between pts with and without nail psoriasis using Pearson's chi-square test and Mann–Whitney U test.

Results:

gr.1 includes 312 (53.1%) cases, gr.2 – 276 (46.9%) cases. More pts in gr.1 were males (51.9% vs 44.1%, p=0.013), disabled at work (37.20% vs 26.40%, p=0.000), chronic smokers (18.9% vs 8.7%, p=0.000) and with axial PsA disease signs according to physician (35.0% vs 26.4%, p=0.025) compared to pts in gr.2. Pts in gr.1 had higher tender and swollen joint counts: 8 [4-15] vs 5 [2-12] (p=0.002) and 5 [1-9] vs 2 [0-7] (p=0.003) respectively. Gr.1 pts had higher disease activity measured by DAPSA 25 [15-39] vs 20 [12-33] (p= 0.001), higher frequency of dactylitis (24.4% vs 16.7% p=0.022) and heel enthesitis (17.0% vs 10.1% p=0.016) respectively, higher frequency of erosive radiographic arthritis of feet (45.0% vs 31.2% p=0.003) compared to gr.2 pts. Pts in gr.1 had worse skin psoriasis measured by Psoriasis Area Severity Index – 6 [2-14] vs 3 [1-6] (p=0.000). Less pts in gr.1 than in gr.2 (27.0% vs 52.0% p=0.004) achieved minimal disease activity (MDA). Pts' reported outcomes (PRO's) in gr.1 were worse than in gr.2 in regard to reduced health-related quality of life according to PsAID (4.9±2.3 vs 4.0±2.3, p=0.040) and to EQ-5D (0.56±0.19 vs 0.64 ±0.21, p=0.024) questionnaires, overall work impairment (0.0 [0.0-0.3] vs 0.0 [0.0-0.2], p=0.034) and overall activity impairment (0.4 [0.1-0.7] vs 0.3 [0.0-0.5], p=0.006) according to WPAI.

Conclusion:

nail involvement in PsA pts is associated with male gender and axial disease. PsA pts with nail involvement are more often disabled, more often are chronic smokers, have significantly worse disease status as measured by disease activity; they are more likely to have more severe (erosive) peripheral arthritis of feet, higher frequency of heel enthesitis and dactylitis, higher psoriasis disease severity, lower frequency of MDA achievement, and worse quality of life and work productivity according to PRO's. Detection of nail involvement is critical for choice of treatment approach and better outcomes.

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Abstract N°: 1633

Effectiveness of Secukinumab in Patients With Moderate to Severe Plaque Psoriasis in Real-world Practice in Malaysia

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Introduction & Objectives:

Psoriasis is an immune-mediated chronic inflammatory disease affecting around 125 million people worldwide.1 Secukinumab is a fully human anti–interleukin-17A monoclonal antibody approved for the treatment of moderate to severe plaque psoriasis.2 In routine clinical care, patients with moderate to severe plaque psoriasis have shown to have different treatment outcomes depending on their demographics and disease characteristics.3 Asian population were underrepresented in majority of randomized controlled trials of biologic treatments for psoriasis.4 Limited data is available on the treatment outcomes of secukinumab from Asia. This retrospective study was conducted to assess the effectiveness of secukinumab in patients with moderate to severe plaque psoriasis in real-world practice in Malaysia.

Materials & Methods:

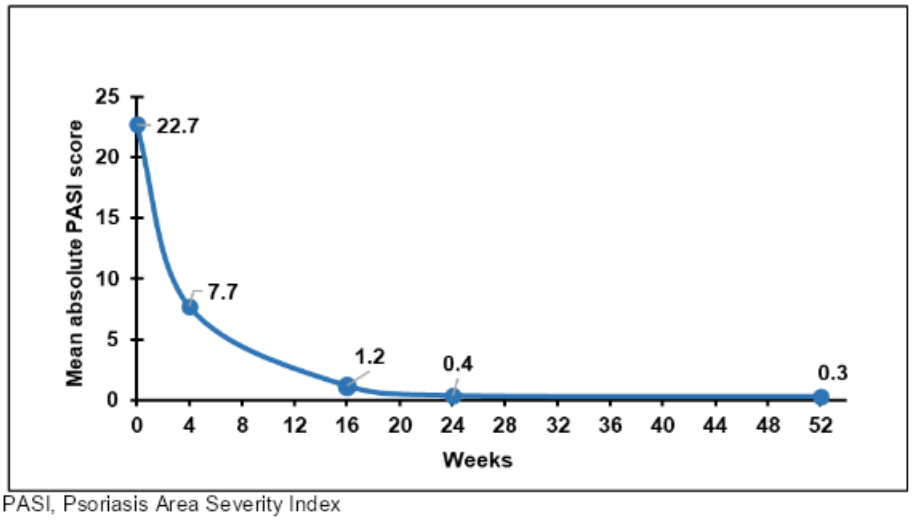
Data from two dermatology centres, Cohort A and Cohort B, were extracted from the medical chart of the patients. Adult patients who received at least 12 weeks of secukinumab between 01 June 2016 and 31 August 2020 were included in the study. The study assessed the effectiveness of secukinumab using Psoriasis Area Severity Index (PASI) score improvement rate from baseline to Week 16 and PASI 75/90/100 response from baseline to Week 4, 16, 24 and 52. The improvement in the mean PASI score was also analysed. Data for patients with available PASI scores and no off-label dose who were biologic naive were presented. Due to the inherent non-interventional nature of the study, there were some limitations, which include incomplete and missing data, small sample size, and the generalizability of results.

Results:

This study included 48 patients from both cohorts (Cohort A, n=20; Cohort B, n=28). Here we analyse and report 38 biologic naive patients with available PASI scores and no off-label dose. The mean age was 37.3 years and mean disease duration was 7 years. Patient demographics and baseline characteristics are presented in **Table 1**. At Week 16, the mean absolute PASI score decreased from baseline (22.7) to 1.2,** demonstrating 96.8% improvement rate in the** mean PASI score. The mean absolute PASI scores (the corresponding PASI score improvement rate) at Weeks 4, 24 and 52 were 7.7 (75.0%), 0.4 (99.5%) and 0.3 (98.4%), respectively **(Fig 1).** The proportion of patients achieving PASI 75, PASI 90 and PASI 100 responses at Week 16 were 100%, 88.0% and 59.0%, respectively (Week 4, 68.0%/36.0%/29.0%; Week 24, 100%/100%/83.0%; Week 52, 100%/100%/80.0%**; Fig 2)**. ###### **Table 1. Patient demographics and baseline characteristics of biologic-naive patients**

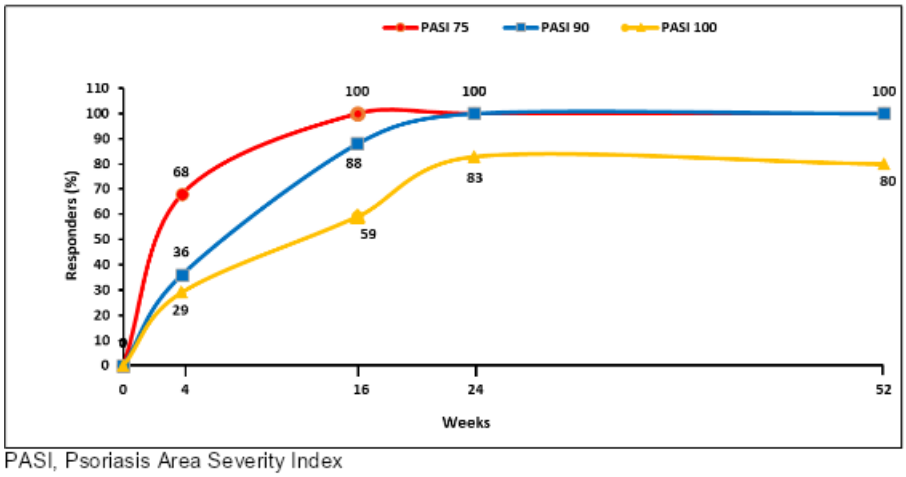
Demographics and baseline characteristics	Biologic naïve (N=38)
Age (years), mean (SD)	37.3 (12.30)
Males, n (%)	23 (60.5)
Weight (kg), mean (SD) [N=35]	74.9 (17.69)
BMI (kg/m2) [N=33]	26.8 (5.94)
Duration of psoriasis (years), mean (SD) [N=32]	7.0 (6.41)
Presence of psoriatic arthritis – n/N (%)	7/29 (24.1%)
Presence of scalp psoriasis – n/N (%)	13/30 (43.3%)
Presence of nail psoriasis – n/N (%)	2/28 (7.1%)
N, total no of patients in group; n, number of patients with outcome; SD, standard deviation	

Figure 1. Mean absolute PASI scores over time



PASI, Psoriasis Area Severity Index

Figure 2. Percentage of patients with PASI 75/90/100 over time at Week4/16/24/52



PASI, Psoriasis Area Severity Index

Conclusion:

This analysis of real-world data from Malaysia showed that treatment with secukinumab demonstrated rapid clinical improvement and sustained efficacy up to Week 52. The results complement the existing reports for the long-term use of secukinumab in the treatment of moderate-to-severe psoriasis.

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Abstract N°: 1635

Effect of disease duration on drug survival and efficacy of guselkumab and ustekinumab in patients with psoriasis: Week 104 results from the non-interventional, prospective, German multicentre PERSIST study

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Introduction & Objectives: PERSIST1 was a prospective, non-interventional, real-world study of guselkumab and ustekinumab in adult patients with moderate-to-severe plaque psoriasis in Germany. In the present analysis, we investigate drug survival and efficacy of guselkumab and ustekinumab, stratified by patients' disease duration (DD), over 104 weeks of treatment.

Materials & Methods: Patients (≥18 years of age, with a diagnosis of psoriasis for at least 2 years) received guselkumab or ustekinumab as per routine clinical practice. Concomitant medications other than biologics for the treatment of psoriasis were permitted. Patient enrolment in the ustekinumab and guselkumab cohorts began in April 2016 and January 2018, respectively, and final doses were given in February 2020 and April 2021, respectively. Outcomes to Week 104 were examined separately for guselkumab and ustekinumab patients. A *post-hoc* exploratory analysis of outcomes with guselkumab versus ustekinumab, stratified by patients' DD (<10 years versus ≥10 years since psoriasis diagnosis at the time of study initiation), was performed following propensity score matching of guselkumab and ustekinumab patients based on their baseline characteristics.

Results: Overall, 294 patients received guselkumab (DD <10 years, n=65; ≥10 years, n=229) and 294 patients received ustekinumab (DD <10 years, n=73; ≥10 years, n=221) at Week 0. Guselkumab patients with DD <10 years showed numerically greater drug survival than guselkumab patients with DD ≥10 years. However, this effect was not seen in the ustekinumab cohort (**Fig. 1**). Independent of DD, higher proportions of guselkumab patients achieved PASI90 (DD <10 years: 69%; DD ≥10 years: 64%) and PASI100 (DD <10 years: 51%; DD ≥10 years: 42%) outcomes relative to ustekinumab patients (DD <10 years: 56%, DD ≥10 years: 56%; and DD <10 years: 40%, DD ≥10 years: 25%, respectively); no difference in PASI75 response was observed (**Fig. 2**). In addition, guselkumab patients were able to achieve responses faster than ustekinumab patients, with higher proportions of guselkumab patients achieving PASI90 and PASI100 responses at Week 12/16. When analysing the potential effect of DD, patients with shorter DD (<10 years), generally achieved better PASI outcomes than patients with longer DD (≥10 years), for both the guselkumab and ustekinumab cohorts.

Conclusion: These real-world data are consistent with the well-established efficacy profiles for guselkumab and ustekinumab. Relative to ustekinumab, higher proportions of guselkumab patients achieved better efficacy outcomes (PASI90 and PASI100) among both patients with shorter (<10 years) or longer DD (≥10 years). In addition, guselkumab patients with shorter DD (<10 years) demonstrated greater drug survival and PASI response rates, highlighting the value of early intervention with guselkumab.

References

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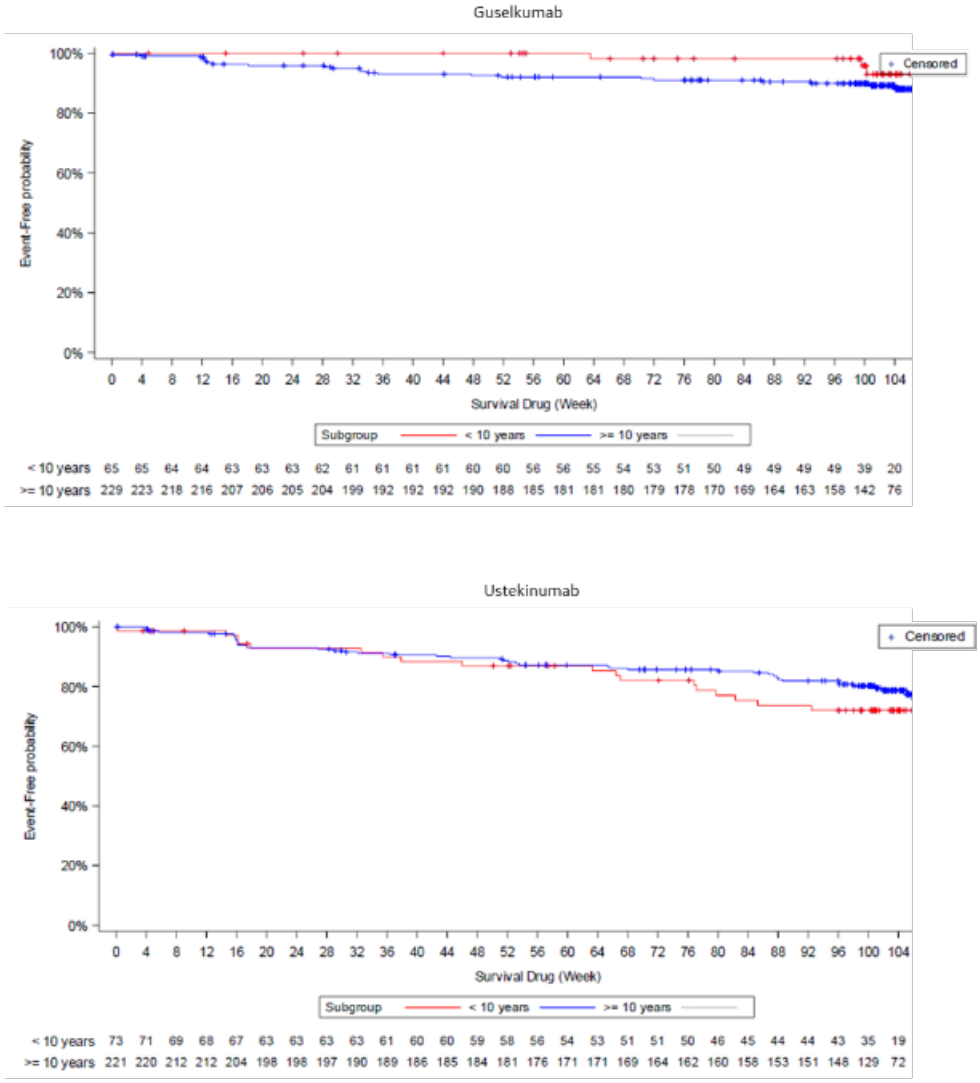
doi:10.1111/jdv.18218

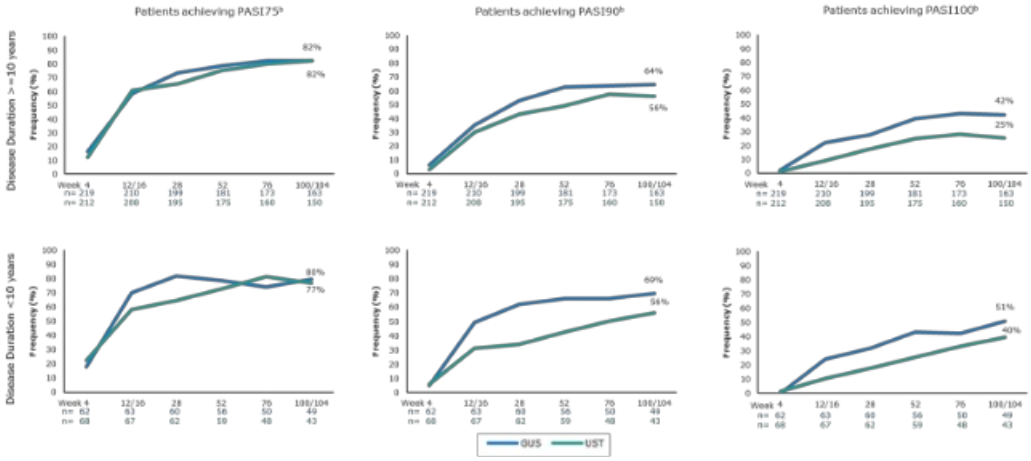
Figure 1. Treatment persistence of guselkumab and ustekinumab[a] patients by disease duration.



[a]A propensity-score-based method was employed to match patients in both cohorts based on their baseline characteristics. Propensity scores were calculated using logistic regression with treatment as the dependent variable, and sex, age, weight, disease duration, and baseline PASI, DLQI, and psoriatic arthritis as matching covariates.

DLQI, dermatology life quality index; PASI, Psoriasis Area and Severity Index

Figure 2. Proportion of guselkumab and ustekinumab[a] patients achieving different PASI outcomes by disease duration.



[a]A propensity-score-based method was employed to match patients in both cohorts based on their baseline characteristics. Propensity scores were calculated using logistic regression with treatment as the dependent variable, and sex, age, weight, disease duration, and baseline PASI, DLQI, and psoriatic arthritis as matching covariates.

[b]PASI75/90/100 represents a ≥75%/90%/100% improvement in PASI score from baseline.

DLQI, dermatology life quality index; GUS, guselkumab; PASI, Psoriasis Area and Severity Index; UST, ustekinumab

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Abstract N°: 1671

Real-world effectiveness of risankizumab in a multi-country post-marketing observational setting: 100-week analysis from the VALUE study

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Introduction & Objectives: Risankizumab (RZB) is an optimized IL-23 inhibitor targeting the p19 subunit with high affinity and specificity and is approved for the treatment of moderate-to-severe plaque psoriasis (PsO), psoriatic arthritis (PsA) and Crohn's disease. VALUE is investigating the effectiveness of RZB per label in real world practice with a greater proportion of RZB-treated patients (pts) achieving ≥90% improvement in Psoriasis Area and Severity Index (PASI 90) compared to those treated with other approved biologics (OtherBios) [77.3% vs 67.5%; P=0.0071] at week 52 (Thaci et al. EADV 2022, Abstract #1350). Here, we assessed the long-term effectiveness of RZB vs OtherBios in VALUE through week 100.

Materials & Methods: VALUE (NCT03982394) is an on-going, multi-country, prospective observational cohort study evaluating the real-world durability of response and time to first treatment change for RZB compared to OtherBios in PsO. Pts (≥18 years) with confirmed PsO receiving RZB or OtherBios as prescribed by a physician per label were enrolled in a 2:1 ratio. Effectiveness was assessed as absolute PASI and Dermatology Life Quality Index (DLQI), as well as proportions of pts achieving ≥90%/100% PASI improvement (PASI 90/100) compared to baseline. Treatment Satisfaction Questionnaire for Medication (TSQM), and changes to treatment were collected at baseline, week 4, and every 12 weeks. Descriptive statistics were summarized for both continuous and categorical variables from an interim database lock on 26 September 2022. Results are reported by modified non-responder imputation (mNRI) where pts who switched or discontinued the initiated biologic due to ineffectiveness or intolerability were judged as treatment failure for subsequent visits. Propensity score match (PSM) with 1:1 ratio using greedy algorithm and exact match for bio-naive/bio-experienced status was employed to account for imbalance between comparison groups.

Results: Among 1532 (RZB) and 764 (OtherBios) pts enrolled in this study, baseline demographics and characteristics were mostly comparable with a few exceptions. The RZB group enrolled fewer pts with a history of PsA (224 [14.6%] vs 208 [27.2%]; P<0.0001) and more pts who were bio-experienced (729 [47.6%] vs 268 [35.1%]; P<0.0001).

At week 100, pts receiving RZB achieved a significantly lower absolute PASI (1.1 vs 2.0; P = 0.0108) and DLQI (1.9 vs 3.1; P = 0.0202) compared to OtherBios (Table). Pts treated with RZB also had significantly higher rates of PASI 90 (73.9% vs 61.6%; P = 0.0071) at week 100 and a numerically higher rate of PASI 100 (55.4% vs 48.9%; P = 0.1947). Significantly higher TSQM global satisfaction scores (87.6 vs 80.8 P = 0.0012) were reported for pts receiving RZB at week 100. All effectiveness endpoints improved from week 16 to 52 and were sustained through week 100 in RZB-treated pts. Additionally, significantly fewer pts receiving RZB had any change in treatment within

the first 25 months (12.8% vs 20.3%; P<0.0001) than those receiving OtherBios. PSM confirmed these results and all effectiveness endpoints are shown (Table).

Conclusion: This longer-term analysis from the VALUE study demonstrated that pts treated with RZB in real-world practice achieve and maintain a significant reduction in PsO symptoms compared to OtherBios. Through 100 weeks, these results demonstrated a durable response with significant improvement in health-related quality of life, pt satisfaction and fewer treatment changes in pts treated with RZB.

Table. Patient outcomes in the VALUE study

Responses	Week 16			Week 52			Week 100		
	RZB	OtherBio	P-value	RZB	OtherBio	P-value	RZB	OtherBio	P-value
PASI									
mNRI									
mean (SD)	2.0 (5.19)	2.6 (4.17)	0.0308	1.1 (2.90)	2.0 (4.18)	<0.0001	1.1 (2.40)	2.0 (5.59)	0.0108
n	1261	630		975	444		363	139	
PSM									
mean (SD)	1.9 (2.89)	2.6 (4.24)	0.0002	1.1 (2.37)	2.0 (4.28)	<0.0001	0.8 (1.69)	2.0 (3.67)	0.0004
n	599	592		466	420		171	132	
DLQI									
mNRI									
mean (SD)	2.8 (4.25)	3.8 (5.32)	<0.0001	1.9 (3.43)	2.9 (4.69)	<0.0001	1.9 (3.84)	3.1 (5.42)	0.0202
n	1264	630		953	457		335	157	
PSM									
mean (SD)	2.8 (4.44)	3.8 (5.32)	0.0002	1.9 (3.57)	2.9 (4.67)	0.0008	1.6 (3.41)	3.1 (5.54)	0.0075
n	595	591		468	418		166	150	
PASI 50									
mNRI									
%	57.6	51.4	0.0110	75.6	63.9	<0.0001	73.9	61.6	0.0071
n/N	720/1240	320/622		730/966	281/440		266/360	85/138	
PSM									
%	58.2	51.7	0.0260	76.2	65.2	0.0008	76.6	61.8	0.0054
n/N	346/595	303/586		353/463	272/417		131/171	81/131	
PASI 100									
mNRI									
%	35.5	32.9	0.2900	55.2	45.0	0.0004	55.4	48.9	0.1947
n/N	448/1261	217/630		538/975	200/444		201/363	68/139	
PSM									
%	35.6	32.9	0.3408	55.6	45.2	0.0021	58.5	49.2	0.1094
n/N	213/599	195/592		259/466	190/420		100/171	65/132	
TSQM (Global)									
mNRI									
mean (SD)	81.2 (20.2)	76.3 (23.0)	<0.0001	85.6 (18.0)	78.3 (23.4)	<0.0001	87.6 (17.4)	80.8 (23.4)	0.0012
n	1227	608		944	429		352	155	
PSM									
mean (SD)	81.8 (19.6)	76.6 (22.7)	<0.0001	86.1 (17.4)	79.3 (25.2)	<0.0001	89.1 (15.8)	81.0 (21.8)	0.0008
N	571	570		449	404		166	128	

PASI, Psoriasis Area and Severity Index; DLQI, Dermatology Life Quality Index; TSQM, Treatment Satisfaction Questionnaire for Medication n, number; SD, standard deviation; mNRI, modified non responder imputation; PSM, Propensity Score Matched

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Abstract N°: 1683

Long-term Durability of Efficacy, High Disease Control and State of Remission of Risankizumab in Patients with Moderate to Severe Psoriasis

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Introduction & Objectives: Moderate-to-severe plaque psoriasis (PsO) is a chronic systemic inflammatory disease which causes significant distress to those affected. Therefore, treatment goals including high levels of skin clearance and long-term maintenance of response are critical for patients; particularly in preventing cumulative life course impairment. Risankizumab (RZB), which is approved for the treatment of moderate-to-severe psoriasis, is an optimized IL-23 inhibitor targeting the p19 subunit with high affinity and specificity. An ongoing phase 3 open-label extension (OLE) study, LIMMitless (NCT03047395), is investigating the long-term safety and tolerability of RZB in pts with PsO. This analysis was conducted within LIMMitless to evaluate the long-term durability of response and the ability to achieve and maintain uninterrupted high disease control in pts with moderate-to-severe PsO.

Materials & Methods: LIMMitless (NCT03047395) is a phase 3, single-arm, multicenter, OLE study investigating the long-term safety and efficacy of RZB in adults with moderate-to-severe PsO. Pts with a history of moderate to severe PsO who completed a preceding phase 2/3 randomized clinical trial (UltIMMa1/NCT02684370, UltIMMa2/NCT02684357, SustaIMM/NCT03000075, NCT03255382, or IMMvent/NCT02694523) were enrolled and administered RZB at 150 mg every 12 weeks (Q12W) for up to 5 years. Durability of efficacy (data cut-off date: Nov 23, 2022) was assessed by the proportion of pts who maintained ≥ 90% & 100% improvement in Psoriasis Area and Severity Index (PASI 90/PASI 100) and Dermatology Life Quality Index of no effect on patient's life (DLQI 0/1), at year 1/2/3/4 following achievement of the corresponding efficacy endpoints at week 52. The proportion of pts who demonstrated high disease control (defined as no loss of PASI 90 and DLQI0/1 at any following visit once achieved in year 1) and a state of remission (defined as no loss of PASI 100 at any following visit once achieved in year 1) for >1/>2/>3/>4 years was assessed. Observed cases (OC) analysis was conducted. Safety for the RZB PsO population was previously reported.

Results: A total of 897 pts randomized to RZB were included in this analysis. On average, pts were 46.9 years with a majority being male (70.6%) and white (73.8%). Pts had a mean PASI of 20.5, DLQI of 13.9 and body surface area involvement of 26.7%. 766 pts achieved PASI 90 at week 52 and 91.0% maintained PASI 90 at week 256 (Table). PASI 100 was achieved by 518 pts at week 52 with 76.9% maintaining the response at week 256 (Table). 680 pts achieved DLQI 0/1 at week 52 and 91.2% remained at DLQI 0/1 at week 256 (Table).

We further assessed high disease control in pts as no loss of PASI 90 and DLQI 0/1 (once achieved in year 1) at any following visit. The proportion of pts maintaining high disease control for >1/>2/>3/>4 years was 89.4/80.5/74.9/72.1/% (PASI 90) and 93.8/88.5/81.8/78.4% (DLQI 0/1) [Table]. State of remission was defined as no loss of PASI 100 at any following visit (once achieved in year 1). The proportion of pts maintaining a state of

remission for >1/>2/>3/>4 years was 71.9/55.6/47.2/42.5% (Table). Results were comparable between bio-naïve and bio-experienced pts.

Conclusion: This analysis demonstrates that pts with moderate-to-severe PsO treated with RZB who achieve treatment goals by week 52 can maintain a high level of long-term durability, high disease control and a state of remission for up to an additional 4 years.

Table. Long-term response rates of patients treated with RZB

Response (OC)	Week 52	Week 100	Week 160	Week 208	Week 256
PASI 90, n (%)					
All	766 (100)	685 (93.7)	630 (92.5)	464 (93.4)	558 (91.0)
Bio-exp	260 (100)	234 (92.9)	209 (89.3)	153 (91.1)	190 (89.6)
Bio-naive	453 (100)	405 (94.4)	376 (94.2)	267 (94.3)	330 (92.7)
PASI 100, n (%)					
All	518 (100)	411 (82.9)	373 (80.9)	274 (81.1)	319 (76.9)
Bio-exp	170 (100)	130 (79.3)	113 (73.4)	78 (68.4)	99 (71.7)
Bio-naive	311 (100)	251 (84.2)	234 (85.7)	167 (87.4)	197 (80.7)
DLQI 0/1, n (%)					
All	680 (100)	602 (92.3)		409 (90.9)	496 (91.2)
Bio-exp	225 (100)	204 (92.3)		133 (91.7)	167 (90.8)
Bio-naive	409 (100)	361 (93.0)		240 (90.9)	294 (92.2)

PATIENTS WITH NO LOSS OF RESPONSE AT ANY VISIT*				
Response (OC)	> 1 year	> 2 years	> 3 years	> 4 years
PASI 90, n (%)				
All	513 (89.4)	462 (80.5)	430 (74.9)	414 (72.1)
Bio-exp	184 (87.2)	165 (78.2)	153 (72.5)	145 (68.7)
Bio-naive	329 (90.6)	297 (81.8)	277 (76.3)	269 (74.1)
PASI 100, n (%)				
All	274 (71.9)	212 (55.6)	180 (47.2)	162 (42.5)
Bio-exp	95 (67.9)	78 (55.7)	63 (45.0)	54 (38.6)
Bio-naive	179 (74.3)	134 (55.6)	117 (48.6)	108 (44.8)
DLQI 0/1, n (%)				
All	408 (93.8)	385 (88.5)	356 (81.8)	341 (78.4)
Bio-exp	150 (95.5)	140 (89.2)	129 (82.2)	120 (76.4)
Bio-naive	258 (92.8)	245 (88.1)	227 (81.7)	221 (79.5)

PASI, Psoriasis Area and Severity Index; DLQI, Dermatology Life Quality Index; n, number; exp, experienced; OC, observed cases

*Patients must have achieved Year 4 and have <=10% missing data. If a patient has a missing record at one visit but has achieved the response before and after the visit, the patient will be considered as no loss of response at that visit.

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Abstract N°: 1696

Psoriasis And Mental Health Comorbidities: A Multinational Analysis Using the Global Healthcare Study on Psoriasis (GHSP)

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Introduction & Objectives: Psoriasis is associated with psychosocial comorbidities; however, worldwide prevalence of psychiatric disease in psoriasis patients worldwide remain unknown. This study compares the prevalence of depression and anxiety in Brazil, Chile, China, Singapore, Switzerland, and the United States (US), as part of the Global Healthcare Study on Psoriasis (GHSP). This study aims to compare the prevalence of psychiatric comorbidities among psoriasis patients in different countries and to examine the association between psychiatric comorbidities and psoriasis disease severity in different countries.

Materials & Methods: Adults with psoriasis in Brazil, Chile, China, Singapore, Switzerland, and the US completed questionnaires including depression and anxiety queries. Multivariable logistic regression analyses adjusted for age, sex, psoriasis severity, and treatment type.

Results: Among 2,323 psoriasis patients globally, 306 reported current/prior depression and/or anxiety. Depression rates were: US 16.9%, Brazil 15.6%, Chile 13.9%, Switzerland 6.8%, Singapore 1.6%, China 0%. Based on multivariable analyses evaluating depression in psoriasis patients globally, patients from the following countries are more likely to have depression: Brazil (aOR 1.66), Chile (aOR 1.52), and the US (aOR 1.21). Compared to other countries, patients from the following countries are less likely to have depression: Switzerland (aOR 0.47) and Singapore (aOR 0.13). Anxiety rates were: US 12.4%, Switzerland 2.7%, Singapore 1.6%, Chile 0.2%, Brazil 0%, China 0%. Based on multivariable analyses evaluating anxiety in psoriasis patients globally, compared to other countries, patients from the following countries are more likely to have anxiety: US (aOR 12.01), Switzerland (aOR 2.88), and Singapore (aOR 1.14). Compared to other countries, Chilean patients are less likely to have anxiety (aOR 0.27).

Conclusion: Psychiatric comorbidity prevalence varies worldwide; the US reported the highest depression and anxiety rates. Cultural norms may influence psychiatric comorbidity disclosure.

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Abstract N°: 1708

Severe scalp psoriasis showed increased biodiversity and relative abundance of Malassezia globosa compared to mild scalp psoriasis

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease mediated by predisposing genetic and environmental factors. Recently, alterations in the skin microbiome have been shown to interact with host immunity, affect skin barrier function, and play a role in the development and progression of psoriasis. The scalp is one of the most commonly involved sites in psoriasis, yet it often shows resistance to therapy.

Materials & Methods:

We investigated the scalp microbiome of 11 patients with psoriasis who had scalp lesions and calculated Psoriasis Area Severity Index of the scalp. Among them, sampling was repeated in 1 patient. We then analyzed the bacterial and fungal data. For the identification of bacteria, we used the QIIME2 software. To identify bacteria, we used the QIIME2 software, and to identify fungi, we utilized the UNITE database.

Results:

A total of 12 samples were analyzed. They were divided into mild (n=2), moderate (n=4), and severe (n=6) group. The mean Shannon index was 0.97±0.15 in the mild group, 1.38±0.19 in the moderate group, and 1.70±0.43 in the severe group. The relative abundance of *Malassezia restricta* in the mild group (0.90±0.01) was higher than the severe group (0.73±0.13) (p=0.29).

Conclusion:

Although further studies are needed to evaluate the associations between cutaneous mycobiome and psoriasis, this study suggests that the scalp microbiome is associated with disease severity in patients with psoriasis. Controlling Malassezia spp., especially M. globosa, could be a new therapeutic target in managing scalp psoriasis.

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Anti-interleukin biologics and tuberculosis: a narrative review

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Introduction & Objectives:

Screening for Latent *Mycobacterium Tuberculosis* Infection (LTBI) is an established procedure in clinical practice for psoriatic patients who require therapy with biological drugs. To reduce the risk of drug-induced tuberculosis reactivation, prophylactic therapy is mandatory before the initiation of biologic therapy. The use of the most recent anti-interleukin (IL) biological drugs, such as anti-IL-17, anti-IL-23, and anti-IL-12/23, has questioned the need for LTBI screening and consequent prophylaxis for positive patients, given the numerous clinical trials showing significantly lower rates of development or reactivation of active tuberculosis (aTB) than with anti-TNF-alpha biologics. The aim of our study is to evaluate the risk of tuberculous disease in psoriatic patients treated with anti-IL-17, anti-IL-23, and anti-IL-12/23 drugs in *real-life s*ettings, differentiating between LTBI positive and LTBI negative patients at the biological pre-treatment screening and among patients who received or did not take anti-tuberculosis prophylaxis before starting therapy.

Materials & Methods:

A narrative review of the scientific literature was conducted, including*real-life* reports of psoriatic patients treated with one of the following drugs: Brodalumab, Ixekizumab, Secukinumab, Guselkumab, Risankizumab, Tildrakizumab, Ustekinumab. Data were collected regarding patient demographics, positivity for LTBI at pre-treatment screenings, and any modification of the ongoing biological treatment.

Results:

Our study includes the analysis of 24 articles, with the collection of data from 1202 psoriatic patients, of which 1065 were LTBI-negative (88.6%) and 137 were LTBI-positive (11.4 %) at pre-therapy screening. During treatment, a seroconversion condition occurred in 33 patients (3.1%), while an aTB condition occurred in 5 patients (0.4%). In particular, out of the 137 LTBI-positive patients, 3 developed aTB (2.19%), while out of the 1065 LTBI-negative patients, 2 developed aTB (0.19%). In addition, of the 99 LTBI-positive patients who received tuberculosis prophylaxis, 3 developed aTB, while of the 38 LTBI-positive patients who did not receive tuberculosis prophylaxis, none developed aTB; the remaining 2 cases of aTB concern LTBI-negative patients of whom 50% had received anti-tuberculosis prophylaxis.

Conclusion:

The overview offered by this literature review strengthens the safety data of anti-IL drugs for this patient population and offers critical insights on the evaluation of the risk/benefit ratio of anti-tuberculosis prophylaxis.

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Abstract N°: 1718

Case series of bimekizumab for psoriasis treatment in real-world setting

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Introduction & Objectives:

Bimekizumab is the first and only dual selective inhibitor of isoforms A and F of IL-17 approved for the treatment of moderate to severe plaque psoriasis. Its novel mechanism of action results in high levels of complete skin clearance that have shown superiority in head-to-head clinical trials versus adalimumab, ustekinumab and secukinumab. Besides the superiority in direct comparisons, in the network meta-analysis published by Armstrong et al. 2022, bimekizumab was ranked as the drug with the highest probability of achieving PASI 75, PASI 90 and PASI 100 response among all approved treatments for psoriasis. Due to the recent approval of bimekizumab by regulatory agencies, the evidence of the drug in real-world clinical practice is limited and based on case reports. The objective of this study is to assess the effectiveness and safety of bimekizumab in our series of psoriasis patients from our routine clinical practice.

Materials & Methods:

Retrospective follow-up study of 6 patients treated with bimekizumab for their psoriasis in our hospital. Patients were followed as per current clinical practice. Psoriasis activity scores were assessed at baseline, at week 4, week 16, and week 24. Safety information was reported.

Results:

We present a series of patients with moderate to severe psoriasis treated with bimekizumab in routine clinical practice conditions. Our experience includes 6 patients that were treated according to bimekizumab summary of product characteristics. All 6 patients showed a rapid and sustained skin clearance, with good tolerability and no remarkable adverse events (only two of them presented mild oral candidiasis that did not lead to treatment discontinuation and was managed with standard antifungal therapy). Resolution of psoriasis was observed in all our patients regardless of the patient profile and psoriasis location.

Conclusion:

Bimekizumab effectiveness observed in our patients is similar to that reported in pivotal clinical trials, with no new safety alerts. The combination of efficacy, speed, durability, convenient posology, and safety of bimekizumab translates into better outcomes for the patient, which have been reported in clinical trials and are reproduced in our routine clinical practice.

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Abstract N°: 1737

Early intervention with secukinumab may affect the establishment of tissue memory in psoriasis: Results from a DNA methylation analysis

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Introduction & Objectives:

Biologics targeting the interleukin (IL)-17A pathway are efficacious in the treatment of plaque psoriasis (PsO).1 However, psoriatic skin lesions often recur after treatment cessation, potentially driven by a tissue memory.2 We hypothesize that early intervention with secukinumab (SEC) in new-onset PsO may lead to sustained skin clearance by preventing the establishment of a tissue memory.

Materials & Methods:

The Mechanistic Sub-study of the STEPIn trial assessed molecular changes in the skin of patients with new-onset (≤1 year) and chronic (≥5 years) moderate to severe plaque PsO treated with SEC 300 mg by profiling lesional (LS) biopsies collected at baseline (BL), week (Wk) 16, and Wk 52, with non-lesional (NL) skin biopsies collected at Wk 52 as reference.3 Previously published results showed that LS transcriptomes at BL were relatively similar between cohorts, but SEC treatment-induced normalization to NL levels of global gene expression and IL-17 pathway signatures occurred faster in patients with new-onset vs chronic PsO.4

Results:

Epigenetic analysis now revealed that differences in DNA methylation observed in LS skin were normalized only in the new-onset cohort at Wk 52, while in the chronic cohort, residual differential DNA methylation remained, suggesting a “molecular scar”. Intersecting these non-resolved differentially methylated regions with gene expression, known PsO genetic risk loci, and enrichment for transcription factor binding site motifs provided functional annotation and first insights into the molecular mechanisms underlying the hypothesized tissue memory.

Conclusion:

In summary, early intervention with SEC may lead to sustained skin clearance in patients with PsO by preventing the establishment of a tissue memory in psoriatic skin.

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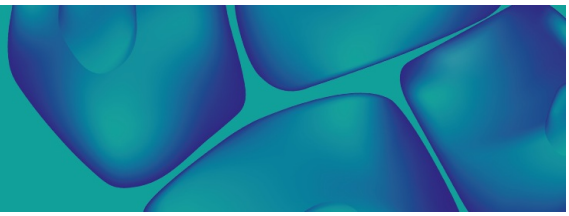

Abstract N°: 1750

Long-Term Efficacy and Safety of Risankizumab for csDMARD-IR Patients with Active Psoriatic Arthritis: 148-Week Results from the KEEPsAKE 1 Trial

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Introduction & Objectives: Risankizumab (RZB), a humanized immunoglobulin G1 monoclonal antibody that inhibits interleukin-23 by targeting its p19 subunit with high affinity and specificity, is approved for the treatment of adult patients with active psoriatic arthritis (PsA). Patients in the KEEPsAKE 1 trial who received RZB 150 mg achieved the primary efficacy endpoint at week 24. The long-term efficacy, safety and tolerability of RZB has been previously reported through 100 weeks of treatment. Here, we report the efficacy and safety results through week 148.

Materials & Methods: KEEPsAKE 1 is an ongoing, global, phase 3, multicenter clinical trial to evaluate the efficacy and safety of RZB versus PBO in patients with active PsA. Eligible patients were at least 18 years old and demonstrated an inadequate response, intolerance or contraindication to ≥1 conventional synthetic disease modifying antirheumatic drug (csDMARD-IR). Following a 24-week double-blind, placebo-controlled, parallel-group treatment period (period 1), the trial is ongoing with an open-label extension treatment period from week 24 through week 316 (period 2). In period 1, patients were randomized 1:1 to receive subcutaneous RZB 150 mg or placebo at weeks 0, 4 and 16. At week 24, patients who were randomized to RZB received blinded PBO and patients who were randomized to PBO received the first dose of blinded RZB. Starting at week 28, all patients continue to receive open-label RZB 150 mg every 12 weeks until week 316. Beginning at week 36, patients who were classified as non-responders (defined as <20% improvement in tender or swollen joint count on two consecutive visits compared with baseline) were discontinued from the study drug. Efficacy and safety analyses were conducted in all randomized patients who received one or more doses of the study drug. Safety assessments were based on monitoring of treatment-emergent adverse events (TEAEs).

Results: Overall efficacy results were maintained at week 148 of the KEEPsAKE 1 trial, as compared to week 52 and 100 (Table 1). At week 148, 41.1% of RZB and 41.5% of PBO/RZB patients achieved ACR50 and 38.1% of RZB and 35.5% of PBO/RZB patients achieved MDA (Figure 1). 69.3% of RZB and 67.1% of PBO/RZB patients achieved PASI90 at week 148. mNAPSI and PGA-F scores improved from baseline by 15.01 and 1.5 points, respectively, for RZB patients and by 13.99 and 1.4 points for PBO/RZB patients. For patients with enthesitis at baseline, resolution was seen in 62.6% of RZB and 62.4% of PBO/RZB patients. For patients with dactylitis at baseline, resolution was seen in 77.5% of RZB and 74.8% of PBO/RZB patients. At week 148, the mean PSA-mTSS score increased by 0.55

from baseline for RZB and by 0.94 for PBO/RZB patients. 88.5% of RZB and 84.4% of PBO/RZB patients showed no radiographic progression (PSA-mTSS ≤0 from baseline). At week 148, HAQ-DI (RZB -0.41, PBO/RZB -0.35), SF-36 PCS (RZB 8.61, PBO/RZB 7.78) and FACIT-Fatigue (RZB 7.4, PBO/RZB 6.4) scores showed consistent increase from baseline. The overall rates of TEAEs, serious TEAEs and AEs leading to discontinuation of study drug have remained stable and comparable to those reported in period 1 (Table 2).

Conclusion: The 148-week results of the ongoing KEEPsAKE 1 trial demonstrate the durable efficacy of RZB 150 mg in treating the clinical manifestations and improving health-related quality of life in csDMARD-IR patients with PsA. RZB was well-tolerated, with no new safety signals.

Table 1. Efficacy Results for KEEPsAKE 1 at Week 52, Week 100 and Week 148

	KEEPsAKE 1					
	Week 52		Week 100		Week 148	
	RZB 150 mg (N=483)	PBO to RZB 150 mg (N=481)	RZB 150 mg (N=483)	PBO to RZB 150 mg (N=481)	RZB 150 mg (N=483)	PBO to RZB 150 mg (N=481)
ACR20, % (n)[a]	70.6	63.7	64.4	60.9	58.3	60.7
ACR50, % (n)[a]	43.6	38.3	42.2	44.1	41.1	41.5
ACR70, % (n)[a]	25.9	20.5	27.1	26.9	27.4	26.1
Change in HAQ-DI[f], mean (95% CI)[b]	-0.41 [N=479] (-0.46, -0.36)	-0.32 [N=476] (-0.37, -0.27)	-0.41 [N=479] (-0.45, -0.36)	-0.36 [N=476] (-0.41, -0.31)	-0.41 [N=479] (-0.46, -0.36)	-0.35 [N=476] (-0.40, -0.29)
PASI 90, % (n/N)[a,c]	68 (186/273)	61.1 (166/272)	72.3 (197/273)	68.6 (187/272)	69.3 (189/273)	67.1 (183/272)
Change in mNAPSI[h], mean (95% CI)[b,d]	-12.61 [N=291] (-13.48, -11.74)	-11.34 [N=311] (-12.18, -10.50)	-14.09 [N=264] (-14.94, -13.25)	-13.52 [N=291] (-14.33, -12.70)	-15.01 [N=253] (-15.81, -14.21)	-13.99 [N=280] (-14.75, -13.22)
Change in PGA-F[i], mean (95% CI)[b,d]	-1.2 [N=292] (-1.3, -1.1)	-1.1 [N=311] (-1.2, -1.0)	-1.4 [N=264] (-1.5, -1.3)	-1.3 [N=291] (-1.4, -1.2)	-1.5 [N=253] (-1.6, -1.4)	-1.4 [N=280] (-1.5, -1.3)
MDA, n (%)[a]	38.3 (185)	28.0 (134)	38.5 (186)	35.1 (169)	38.1 (184)	35.5 (171)
Change in SF-36 PCS score[g], mean (95% CI)[b]	8.42 [N=476] (7.73, 9.12)	7.34 [N=473] (6.64, 8.05)	8.43 [N=476] (7.70, 9.16)	7.47 [N=473] (6.74, 8.21)	8.61 [N=476] (7.83, 9.39)	7.78 [N=473] (7.00, 8.57)
Change in FACIT-Fatigue score[j], mean (95% CI)[b]	8.0 [N=476] (7.2, 8.8)	6.5 [N=473] (5.7, 7.3)	7.7 [N=476] (6.9, 8.6)	6.8 [N=473] (5.9, 7.6)	7.4 [N=476] (6.5, 8.2)	6.4 [N=473] (5.5, 7.2)
Resolution of enthesitis, % (n/N)[a,d]	60.6 (180/297)	60.0 (174/290)	61.6 (183/297)	63.4 (184/290)	62.6 (186/297)	62.4 (181/290)
Resolution of dactylitis, % (n/N)[a,e]	79.2 (117/148)	73.5 (108/147)	76.6 (113/148)	77.3 (114/147)	77.5 (115/148)	74.8 (110/147)
Change from baseline PsA-mTSS,[b,g] mean (95%	0.20 [N=365] (0.05, 0.36)	0.35 [N=367] (0.19, 0.51)	0.41 [N=365] (0.09, 0.74)	0.67 [N=367] (0.34, 1.00)	0.55 [N=365] (0.12, 0.97)	0.94 [N=367] (0.52, 1.37)
PsA-mTSS ≤ 0,[g] % [n/N] (95% CI)	91.7 [333/363] (88.9, 94.6)	89.0 [323/363] (85.8, 92.2)	90.0 [325/361] (86.9, 93.1)	86.3 [315/365] (82.8, 89.8)	88.5 [322/364] (85.2, 91.7)	84.4 [308/365] (80.7, 88.1)
PsA-mTSS ≤ 0.5,[g] % [n/N] (95% CI)	94.2 [342/363] (91.8, 96.6)	91.7 [333/363] (88.9, 94.6)	92.2 [333/361] (89.5, 95.0)	89.0 [325/365] (85.8, 92.2)	91.2 [332/364] (88.3, 94.1)	86.6 [316/365] (83.1, 90.1)

All changes are least square mean changes from baseline.

[a]Results for binary endpoints are based on as-observed (AO) data with missing data imputed as non-responder imputation incorporating multiple imputation (NRI-MI) if there are missing data due to COVID-19 or geo-political conflict in Ukraine and Russia.

[b]Results for continuous endpoints are reported by mixed-effect model repeated measurement (MMRM). Number of unique patients contributing to MMRM model estimates: patients with at least one available change from baseline value and no missing data for the factors and covariates in the model. The MMRM N is not visit-specific and is displayed for model estimates for all visits.

[c]Reported for patients with ≥ 3% of body surface area (BSA) affected by psoriasis at baseline (RZB, n=273; PBO/RZB, n=272).

[d]Reported for patients with nail psoriasis at baseline.

[e]Defined as Leeds Enthesitis Index (LEI)=0 and reported among patients with LEI >0 at baseline (RZB, n=297; PBO/RZB, n=290).

[f]Defined as Leeds Dactylitis Index (LDI)=0 and reported among patients with LDI>0 at baseline (RZB, n=148; PBO/RZB, n=147).

[g]Results for PsA-mTSS were recorded from reading session 4 and reported as observed.

[f]For HAQ-DI, lower scores indicate lower difficulty.

[h]For NAPSI, lower scores indicate lower severity of nail psoriasis.

[i]For PGA-F, lower scores reflect lower severity of finger-nail psoriasis.

[g]For SF-36, higher scores reflect better health-related quality of life.

[j]For FACIT-Fatigue, higher scores reflect lower levels of fatigue.

ACR20/50/70, ≥20/50/70% improvement in American College of Rheumatology score; BSA, body surface area; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy-Fatigue Questionnaire; HAQ-DI, Health Assessment Questionnaire-Disability Index; LDI, Leeds Dactylitis Index; LEI, Leeds Enthesitis Index; LS, least square; MDA, minimal disease activity; PASI 90, ≥90% reduction in Psoriasis Area and Severity Index; PBO, placebo; PGA-F, Physician Global Assessment of Fingernail Psoriasis; PsA-mTSS, psoriatic arthritis modified Total Sharp Score; RZB, risankizumab; SF-36 PCS, 36-Item Short Form Health Survey Physical Component Summary.

Table 2. Safety Summary for KEEPsAKE 1 through Week 148

Parameter, (Events/100PYs)	RZB Week 24[a] N=483 PYs=224.1	PBO Week 24[a] N=481 PYs=223.5	RZB and PBO/RZB Week 148 N=946 PYs = 2412.2
Any TEAE	398 (177.6)	387 (173.2)	3005 (124.6)
Serious TEAE	15 (6.7)	22 (9.8)	185 (7.7)
TEAE leading to discontinuation of study drug	6 (2.7)	4 (1.8)	45 (1.9)
COVID-19 related TEAE	1 (0.4)	2 (0.9)	215 (8.9)
Any MACE	0	0	5 (0.2)
Cardiovascular death - sudden cardiac death	0	0	2 (<0.1)
Non-fatal myocardial infarction	0	0	2 (<0.1)
Non-fatal stroke	0	0	1 (<0.1)
Any serious infection	6 (2.7)	8 (3.6)	47 (1.9)
Any serious hypersensitivity	0	0	1 (<0.1)
Opportunistic infections excluding TB and herpes zoste	0	0	1 (<0.1)
Active TB	0	0	0
Herpes zoster	2 (0.9)	1 (0.4)	6 (0.2)
Malignant tumors	0	2 (0.9)	18 (0.7)
Including NMSC	0	0	3 (0.1)
Excluding NMSC	0	2 (0.9)	15 (0.6)
Any adjudicated anaphylactic reaction	0	0	0
All Deaths	1 (0.4)	0	9 (0.4)[b]

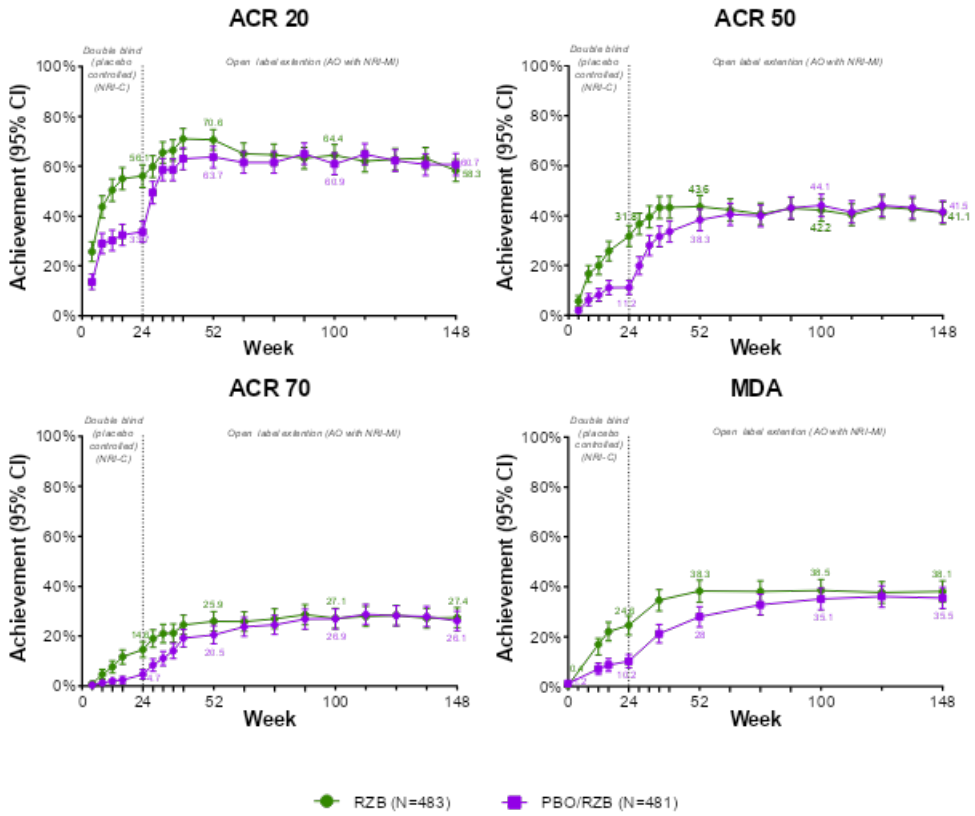
Treatment-emergent adverse events (TEAE) were defined as any AE with an onset date that was on or after the first dose of risankizumab and up to 140 days after the last dose of risankizumab if the patient discontinued the study drug prematurely.

[a]24 week data from KEEPsAKE 1 was previously published in Kristensen, et. al. Ann Rheum Dis. 2022;81(2):225-231.

[b]There were 8 patients reported with fatal TEAEs. 2 deaths were related to COVID 19; 1 was due to complications related to acute leukemia; 1 patient with anemia from diverticulosis died due to multiorgan failure from septicemia as a complication from anastomosis surgery (left hemicolectomy surgery); 1 patient, who was 81 years old with dementia, was hospitalized for pneumonia, developed urosepsis and died from related complications; 1 patient was hospitalized for anxiety and depression, developed septicemia, nausea, vomiting, fever and loss of appetite a week after discharge, and died from unknown causes a week later; 2 patients died of unknown causes (one had a 40 year history of smoking and died after COPD exacerbation). Additionally, 1 patient died on day 363 (166 days after last dose; non treatment emergent) from cardiorespiratory arrest.

MACE, major adverse cardiovascular events; NMSC, non-melanoma skin cancer; PBO, placebo; PYs, patient-years; RZB, risankizumab; TB, tuberculosis; TEAE, treatment-emergent adverse events.

Figure 1. Achievement of ACR 20, 50, 70 and MDA Over 148 Weeks in KEEPsAKE 1



DB, double-blind; NRI-C, non-responder imputation incorporating multiple imputation to handle missing data due to COVID-19; AO with NRI-MI, as-observed (AO) data with missing data imputed as non-responder imputation incorporating multiple imputation (NRI-MI) if there are missing data due to COVID-19; PBO, placebo; RZB, risankizumab.

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Abstract N°: 1755

Screening for hepatic fibrosis in psoriasis patients prescribed methotrexate: Can we make a change?

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Introduction & Objectives:

Patients with psoriasis are at increased risk of developing non-alcoholic fatty liver disease (NAFLD) and subsequent hepatic fibrosis. This risk is further increased with concomitant use of methotrexate. Procollagen III N-terminal peptide (P3NP) levels are routinely monitored by dermatologists as a marker of hepatic fibrosis in this cohort. It is recommended by the British Association of Dermatologists (BAD) to be monitored at least every 3 months. Time-consuming and expensive, in our institution it is outsourced to the U.K., with a delay of 12 weeks for results and a cost of €35 per test. Depending on the value obtained, further serial testing may be required before a test may be construed as positive, and onward referral to hepatology made for formal diagnosis with transient elastography, which is used as the reference standard in our institution. Fibrosis-4 (Fib-4) score is a commonly used screening tool for hepatic fibrosis in NAFLD. It is recommended by the British Society of Gastroenterology for monitoring at 1–3-year intervals, as it is generally accepted that the rate of progression to clinically significant fibrosis is slow and takes years to develop. Indeed, the American Academy of Dermatology now advise a Fib-4 score every 12 months in psoriasis patients prescribed methotrexate. Our main aim was to determine if correlation existed between, (a) the two screening methods and (b) the resultant transient elastography scores, thus potentially changing current monitoring practices for this cohort.

Materials & Methods:

Patients were identified via our institution's laboratory database of P3NP levels between 01/01/2019-30/11/2022. 2019 was used as a cut-off, as aspartate transaminase, required for calculating Fib-4 score, was only added as part of the liver function panel at this time in our institution. The P3NP levels were compared to the corresponding Fib-4 scores and then both to available transient elastography results.

Results:

A total of 137 results for P3NP were identified during the period. Of the 137 P3NP results, 19 (13.87%) abnormal corresponding Fib-4 scores were identified. Eleven (57.89%) of these had a normal corresponding P3NP level, suggesting that elevated P3NP levels did not consistently correlate with an elevated Fib-4 score. In total, 13 patients were referred for hepatologist review and transient elastography, based on elevated P3NP levels. Four cases (30.77%) of abnormal liver stiffness were identified. Three (75%) of these had abnormal Fib-4 scores.

Conclusion:

Based on these results, had Fib-4 score been used as the standard predictor in our institution it would have led to the diagnosis of NAFLD or cirrhosis in 75% of the patients that had this diangosis confirmed based on the use of P3NP. However, the small sample size means correlation of screening methods to our institution's reference standard could not yield statistical power. Further research is required allowing for an expanded data set to accurately determine correlation. Nonetheless, it is hoped that the results of this observational study, along with the validity of alternative screening tools, may act as reassurance for dermatologists, that making changes to less time-consuming and less expensive monitoring methods may be possible. This would move our practices in line with other dermatology organisations as well as our gastroenterology colleagues, thus, potentially improving both

patient and economic outcomes.

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Abstract N°: 1828

Infiltration of Methotrexate in Acrodermatitis Continua of Hallopeau: A Case Report

Matheus Alves Pacheco* , Marcelo Rigatti , Amanda Buratte , Athos Martini

Introduction & Objectives:

Acrodermatitis continua of Hallopeau (ACH) is a rare type of pustular psoriasis that can cause severe nail abnormalities. Treatment options for this condition are limited, and there are no established guidelines. However, the advent of immunobiological therapies and the use of intralesional treatments offer new possibilities. The objective of this case report is to present a successful case of severe ACH treated with intralesional methotrexate, highlighting the therapeutic potential of this approach.

Materials & Methods:

A 36-year-old male patient with a 4-year history of recurrent pustules and inflammation in the right hallux, indicative of ACH, was evaluated. After an unsuccessful trial of local treatment, the patient received two sessions of intralesional methotrexate injections, with a 30-day interval. Clinical and dermatoscopic photos were used for therapeutic monitoring. The response to treatment was evaluated based on the remission of nail lesions and improvement in symptoms.

Results:

Following two sessions of intralesional methotrexate, the patient experienced complete remission of the nail lesion, as evidenced by the resolution of erythema, scaling, pustule formation, and hyperkeratosis. The therapeutic response was maintained for 1 year after the last injection, with no recurrence of symptoms. The patient reported a significant improvement in quality of life and was satisfied with the treatment outcome.

Conclusion:

Intralesional methotrexate appears to be an effective and well-tolerated treatment option for severe ACH involving a limited number of nails. This case report highlights the potential of intralesional therapy as an alternative for patients who are unwilling or unable to undergo systemic immunosuppressive treatments. Further studies are needed to establish the optimal dosage and frequency of intralesional methotrexate injections and to evaluate its long-term efficacy and safety.

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Abstract N°: 1855

Guselkumab improves psoriasis, sexuality, and stigmatization through Week 28 – Results from the real-life G-EPOSS study

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Introduction & Objectives: Patients with psoriasis have a higher risk of stigmatization and sexual dysfunction compared with healthy individuals. Guselkumab is an IL-23 inhibitor with proven efficacy in patients with moderate to severe plaque psoriasis. The G-EPOSS study evaluates the long-term effectiveness of guselkumab and its effect on patient-reported outcomes (PROs), sexual impairment, and stigmatization in clinical routine in patients with moderate to severe psoriasis.

Materials & Methods: G-EPOSS is a prospective, non-interventional, multicenter study of adults with moderate to severe plaque psoriasis in Germany. Patients starting treatment with guselkumab were enrolled from October 2019 until August 2021. The primary endpoint was the achievement of psoriasis area and severity index (PASI) ≤ 3 at Week 28. The effectiveness of guselkumab on quality of life, sexuality, and stigmatization was evaluated at Week 28 using the following questionnaires: Dermatology Life Quality Index (DLQI), anogenital Physician Global Assessment (PGA), Relationship and Sexuality Scale (RSS), and Perceived Stigmatization Questionnaire (PSQ). The Week 28 data of 293 patients are presented here.

Results: At baseline, the mean age was 45.6 ± 14.6 years, the mean duration of psoriasis was 17.6 ± 13.4 years, the mean body mass index (BMI) was 28.9 ± 6.1 kg/m^2, the mean PASI was 15.3 ± 8.7, and the mean DLQI was 11.3 ± 6.6. Overall, 24.6% of patients had concomitant psoriatic arthritis and 25.6% had received prior biologics. At Week 28, 83.0% of patients reached PASI ≤ 3; 35.1% PASI = 0 and 61.1% achieved an anogenital physician global assessment (PGA) of 0. Patient satisfaction, sexuality, and stigmatization improved overall. At Week 28, 61.4% of patients achieved DLQI 0/1 (4.4% at baseline); 4% stated “I’m often / always afraid of sexual intercourse” (12.9% at baseline), 3.8% stated “People feel often / always sorry for me” (30.9% at baseline). No new safety signals were observed.

Conclusion: Previous results regarding the improvement of PASI and DLQI under guselkumab were confirmed. However, this is the first study showing the association between disease control of psoriasis and improvements in sexuality, stigmatization, and patient satisfaction in clinical routine until Week 28.

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Abstract N°: 1874

Significant improvements in signs and symptoms with orismilast in moderate-to-severe psoriasis: Efficacy, safety, and subanalyses from the phase IIb IASOS trial

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Introduction & Objectives:

Orismilast is a potent selective phosphodiesterase 4 (PDE4)-B and -D inhibitor, having shown significant efficacy in a previous Phase 2a psoriasis study.1,2 PDE4-B and PDE4-D isoforms are over-expressed in the skin of patients with psoriasis and atopic dermatitis, compared to healthy individuals.3 When compared with apremilast, orismilast inhibits PDE4-B/D isoforms up to 39 times more potently,1 with consequent suppression of Th1, Th17, and Th2 effector cytokines.1 Here, efficacy and safety of orismilast modified release tablet were evaluated versus placebo in adults with moderate-to-severe psoriasis.

Materials & Methods:

IASOS (NCT05190419) is a 16-week, Phase 2b, double-blinded, placebo-controlled, dose-finding study assessing efficacy and safety of orismilast modified-release (MR) tablets in adults with moderate-to-severe psoriasis. Patients were randomized (1:1:1:1) to orismilast 20, 30, 40 mg or placebo, twice daily. Randomized and dosed patients were included in the Intent-to-Treat Population (used for efficacy and safety). Missing data was handled using Multiple Imputation (MI) for the analysis of primary and secondary efficacy endpoints and Non-responder Imputation (NRI) for sensitivity analyses.

Results:

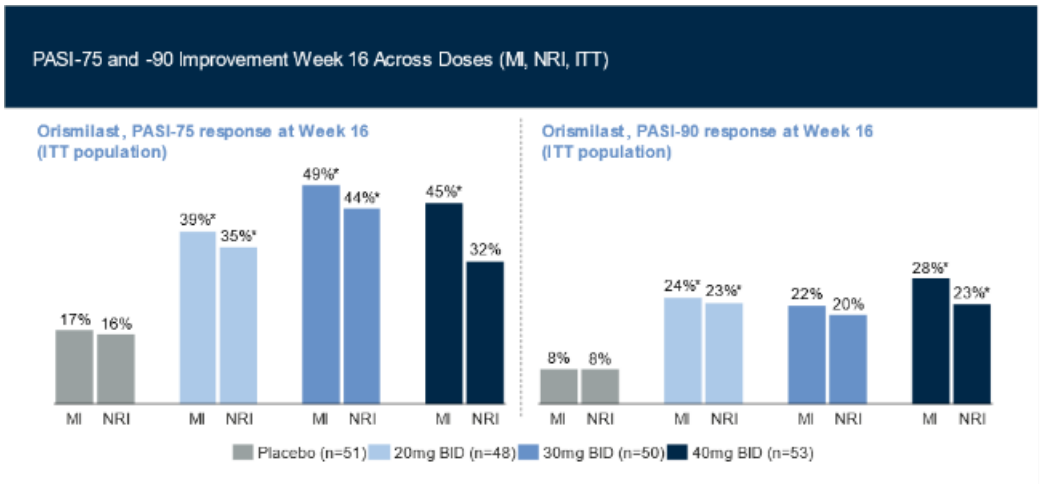
Baseline demographics and disease characteristics were generally balanced across treatment groups for the 202 dosed patients. The primary endpoint, mean percentage change in PASI at week 16, was statistically significant for all orismilast groups compared to placebo. Orismilast 20 (n=48), 30 (n=50), 40 mg (n=53), and placebo (n=51) groups demonstrated mean PASI improvements of 52%, 62%, 64%, and 17%, respectively (p=<0.001 vs. placebo for all orismilast groups, (MI)).

Significantly more patients achieved PASI75 responses at week 16 in orismilast 20, 30, and 40 mg groups compared to placebo (MI: 39%, 49%, 45%, and 17%, all p<0.05 (NRI): 35%, 44%, 32%, and 16%, p<0.05 for 20 and 30 mg). PASI90 responses at week 16 were 24/23%, 22/20%, 28/23%, and 8/8% (MI/NRI, p<0.05 for 20 and 40 mg). In a subgroup analysis (NRI), orismilast was equally efficacious in 20 and 30 mg doses in patients weighing <100 kg (PASI75 36%, 34 %, 32%, 15% for 20, 30, 40 mg, and placebo), whereas patients weighing ≥100 kg saw additional efficacy with 30 mg (PASI75 33%, 67%, 33% 18 % for 20, 30, 40 mg, and placebo).

Through Week 16, percentages of patients experiencing ≥1 Treatment Emergent Adverse Event (TEAE) were as follows: orismilast 20 mg 77%; 30 mg 84%; 40 mg 94%; placebo 45%. Infection and depression rates were similar to placebo, and no malignancies or deaths were reported.** The most common adverse events observed were diarrhea, nausea, and headache, which were dose-dependent, mainly seen within the first month, mostly mild in severity, and the majority did not lead to study discontinuation.

Conclusion:

Orismilast demonstrated significant efficacy vs. placebo at week 16 for the primary endpoint, mean percentage PASI improvement, and as early as the first measured timepoint (Week 4). Significant improvements were also seen in PASI90, a harder to achieve response. The overall safety profile was similar to that previously demonstrated for PDE4 inhibitors. The most frequent TEAEs were gastrointestinal-related and headache. These data confirm high potency PDE4-B/D inhibition with orismilast, and potentially offer a novel oral therapy for the treatment of psoriasis.



1 Silverberg et al. *JEADV* 2022

2 Warren et al. *JEADV* 2022

3 Schafer et al. *Cell Signal* 2016

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Abstract N°: 1897

A curriculum of online education significantly improved dermatologists' knowledge and confidence in managing patients with psoriasis in a complex treatment landscape

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Introduction & Objectives:

In recent years, many new treatments have been developed for psoriasis (PSO), such that clinicians are now faced with increasingly complex treatment choices for individual patients. We assessed whether a curriculum of online educational activities could improve dermatologists' knowledge and confidence in understanding novel therapies and considering them for appropriate patients with PSO.

Materials & Methods:

A curriculum of 6 activities was developed on treatment of PSO in a complex and evolving treatment landscape, including a video lecture, panel discussion, chapterized video activity, enduring version of an EADV symposium, and interactive case-based education. Data were collected between 2020 and 2022 with n numbers for each activity ranging from 60 to 162 completing pre- and post-activity questions. For each activity, educational effect was assessed with a repeated-pairs pre-/post-assessment; 3 multiple-choice, knowledge questions and 1 self-efficacy, 5-point Likert scale confidence question were analyzed. Data were subsequently combined and analyzed by 4 themes to provide a summative overview of the effect of the education across the combined activities. A McNemar's test was conducted to assess statistical significance of changes from pre- to post-assessment.

Results:

- 22,007 MD learners participated in the activities including 5,843 dermatologists, 7,444 pediatricians and 6,524 primary care physicians (PCPs)
- Dermatologists (n=60 to 665) demonstrated a statistically significant improvement in knowledge or competence across all 4 learning themes (clinical data on novel biologics, novel drugs targeting the IL-23/-17 pathway, selecting an appropriate biologic therapy, and using IL-17 inhibitor in clinical practice; all P <0.001)
- For dermatologists, the relative improvements in percentage of correct responses for each learning theme ranged from 20%–88%
- Overall, as a result of completing the activities, 35% of dermatologists reported increased confidence e.g. in differentiating between IL-23 and IL-17 inhibitors to treat psoriais, and in integrating new therapies into clinical practice: for confidence questions aligned with each individual activity, the percentage of dermatologists who gained confidence ranged from 28% to 47%

Conclusion:

These results highlight the benefits of a curriculum of education in helping dermatologists understand novel therapies and their use in clinical practice. As the treatment landscape continues to evolve, dermatologists will likely benefit from further education on translating knowledge of novel treatment strategies into clinical practice in order to optimize outcomes for patients with PSO.

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Abstract N°: 1902

Online case-based education improved dermatologists' knowledge and confidence regarding treatment choice for patients with psoriasis in an evolving treatment landscape

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Introduction & Objectives:

The treatment landscape for psoriasis has expanded at a rapid pace in recent years such that physicians are faced with increasingly complex treatment choices for individual patients. We assessed whether online education could improve dermatologists' knowledge and confidence in selecting appropriate treatments for patients with psoriasis.

Materials & Methods:

Dermatologists participated in an online text-based Test and Teach activity featuring two patient cases with questions that "tested" knowledge and discussion of the main "teaching" points. Educational effect was assessed using a repeated-pair design, pre-/post-assessment. A paired samples t-test was conducted for significance testing on overall average number of correct responses and for confidence rating, and a McNemar's test was conducted at the question level (5% significance level, P <.05). Cohen's d with correction for paired samples estimated the effect size of the education on number of correct responses (<.20 modest, .20-.49 small, .59-.79 moderate, ≥.80 large). Data were collected from 19th January to 31st April 2022.

Results:

- This educational activity significantly improved dermatologists' knowledge in treatment choice for psoriasis management (45% correct answers pre-activity, 86% post-activity; *P* <.001) and had a large educational impact (Cohen's d=1.33)
- Dermatologists (n=49) showed significant knowledge improvements in:
  - treatment choice for a patient with moderate to severe psoriasis, not responding to an anti-TNF, who needed to quickly achieve clear skin and reduce scalp involvement (63% correct answer pre-activity, 86% post-activity; *P* < .01)
  - metabolic comorbidities associated with psoriasis (24% correct answer pre-activity, 86% post-activity; *P* < .001)
  - drug class NOT recommended in the guidelines for a patient with psoriasis and suspected inflammatory bowel disease (47% correct answer pre-activity, 86% post-activity; *P* < .001)
- The percentage of dermatologists answering all 3 questions correctly rose from 4% at baseline to 78% post-activity
- 43% of dermatologists reported a measurable increase in confidence in managing patients with moderate to severe psoriasis using anti-interleukin (IL)-17 therapies, when appropriate, with an average confidence shift (for those who increased confidence) of 63%

Conclusion:

This interactive 'test then teach' activity was highly successful in educating dermatologists about treatment choice

in individual patients with psoriasis. Dermatologists would likely benefit from further education to reinforce and embed their knowledge and to support confidence in treatment choices for psoriasis management and improved patient outcomes.

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Abstract N°: 1906

Evaluation of the efficacy of a celastrol-containing balm as a relay for drug treatments in psoriasis: study co-created with patients

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Introduction & Objectives

Psoriasis is a common chronic disease that has major impact on quality of life with the burden that goes beyond suffering caused by the lesions.

Emollients application on the whole body is internationally acknowledged in the standard care of psoriasis.

To assess the efficacy of a celastrol-containing balm, we engaged patients suffering from psoriasis in each step of our clinical development to understand their needs and expectations and we co-created a clinical study with them.

Materials & Methods

We listened patient's needs during a 1-week online community and built the study design with patients during a focus group. The patient-approved clinical study enrolled adults suffering from plaque psoriasis with severity assessed by PASI (Psoriasis Area Severity Index) < 10 and flare frequency ≥ 3/year in a monocentric, randomized, open-labelled study comparative vs. Untreated Control Group. In case of psoriasis flare-up during the study, investigators prescribed local treatment as dermocorticoid alone, vitamin D alone or combination of both and patients in Product Group continued to apply the study product.

Patients randomized in Product Group applied the product once a day on whole body for 6 months. Five visits were organised: after 1, 2, 4 and 6 months. At each visit, investigators assessed severity of psoriasis using PASI and pruritus using a NRS (Numeric Rating Scale). Psoriasis flare-ups were also assessed. At each visit, patients assessed their skin suppleness and softness using a NRS. A psychologist performed patient's interviews at inclusion and after 6 months.

Results

98 patients aged 19 to 85 years suffering from plaque psoriasis were included in the study: 49 patients in each group. A significant decrease of PASI was shown in Product Group after 6 months vs. baseline (p=0.0153) with significantly greater improvement vs. Control Group (p=0.0316). A significantly higher number of subjects without psoriasis flare-up were observed in Product Group vs. Control Group (p=0.0433).

Significant decrease of pruritus severity was shown after first application of study product ($p<0.0001$).

Patients observed a significant improvement of their skin suppleness after 2 ($p=0.0057$) and 4 months ($p=0.0135$) of product application vs. baseline. This improvement was significantly greater in the Product Group vs. Control Group ($p=0.0396$ and $p=0.0487$ respectively). They also noticed an improvement of skin softness after 2 ($p=0.0018$) and 4 months ($p=0.0075$) of application vs. baseline while in Control Group, this improvement was noticed after 2 months only ($p=0.0412$).

Psychological analysis showed that psoriasis seniority caused resignation from patients who expressed a resistance to change. At the end of the study, the psychologist did not observe any change in the habits and beliefs of these patients who have been living with their psoriasis for many years. In a younger patient whose diagnosis was more recent, the psychologist observed a greater ability to change. After changing her habits during the study, this patient noticed an improvement in her symptoms.

Conclusion

This study, co-created with patients suffering from psoriasis, shows the efficacy of a celastrol-containing balm to improve physical signs of psoriasis, skin suppleness and softness.

The psychological approach highlights resignation of patients who live with their disease for many years and draw our attention to the importance of accompanying patients from the diagnosis of their dermatosis.

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BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 1924

Trial-in-Progress - Deucravacitinib in Routine Clinical Practice: A 5-year, Multicenter, Prospective, Non-Interventional Cohort Study to Evaluate Effectiveness and Quality of Life in Patients with Moderate-to-Severe Plaque Psoriasis in Germany (DELPHIN)

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Introduction & Objectives:

Deucravacitinib (DEUC) is a novel, oral, selective tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy. This small molecule has a unique mechanism of action by binding to the regulatory pseudokinase domain of TYK2, resulting in a ≥ 100-fold greater selectivity for TYK2 vs Janus kinase (JAK) 1/3 and ≥ 2000-fold greater selectivity for TYK2 vs JAK2. The efficacy and safety of DEUC have been demonstrated in the 52-week, global, multicenter, randomized, double-blind phase 3 clinical studies POETYK PSO-1 (n=666, NCT03624127) and POETYK PSO-2 (n=1020, NCT03611751), as well as the ongoing POETYK long-term extension (LTE) study (n=1452, NCT04036435), in which patients completing the PSO-1 or PSO-2 trial could enroll. On March 24, 2023, DEUC was approved in Germany for the treatment of moderate-to-severe plaque psoriasis patients who are candidates for systematic therapy. The objective of the current study is to investigate the effectiveness of DEUC and quality of life in those patients in a real-world setting in Germany.

Materials & Methods:

The non-interventional study DELPHIN is a prospective, multi-regional, multicenter, post-authorization observational cohort study enrolling adults with moderate-to-severe plaque psoriasis who previously initiated treatment with commercially available DEUC 6 mg once daily according to the summary of product characteristics in Germany over a 5-year period. Thus, long-term data on the effectiveness and quality of life in DEUC patients under real-world conditions in routine care gathered by primary data collection methods will be generated. Approximately 450 adults with moderate-to-severe plaque psoriasis will be enrolled in up to 70 study sites including office-based dermatologists and clinics across Germany. The planned enrollment period is 24 months. The primary study objective is assessment of the proportion of patients achieving an absolute Psoriasis Area Severity Index (PASI) score ≤ 3 at week 24. Secondary study objectives include evaluation of effectiveness during the study, as well as evaluation of treatment modalities, patient satisfaction, and patient's quality of life.

Results:

Enrollment began in April 2023. The first interim analysis report on baseline characteristics is planned as soon as >25% enrollment is achieved. Long-term results are anticipated later.

Conclusion:

This study aims to address the data gap by evaluating DEUC in a real-world population and with additional real-world treatment outcome measures in plaque psoriasis patients in Germany who have begun a systemic DEUC therapy. The data will supplement the phase 3 clinical study results by contributing knowledge on effectiveness. It

will also yield important findings on the quality of life in patients and on the use of DEUC under everyday conditions.

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Abstract N°: 1941

Cognition and behaviors of skin barrier repair in Chinese psoriasis patients

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Introduction & Objectives:

Psoriasis is a chronic immune-mediated skin disease with complex pathogenesis. Guidelines and consensus on psoriasis have recommended the use of emollients as the basic treatment method to repair the skin barrier damage caused by psoriasis. However, studies on the status and feedback of emollient use in Chinese psoriasis patients are limited. The objective of this study is to evaluate the current situation of the cognition and behaviors of skin barrier repair in Chinese psoriasis patients.

Materials & Methods:

Online questionnaires were distributed to six core hospitals in China from March to May 2022. Finally, 2095 questionnaires were collected, of which 2043 were validated. All participants provided written informed consent and were recruited according to the protocols approved by the Institutional Ethics Committee of a Hospital. Statistical analyses were performed using SPSS 23.0 software. Descriptive statistics were calculated for each variable using frequencies and percentages for categorical variables and means and standard deviations for continuous variables. OR [95% confidence interval (95% CI)] was also calculated.

Results:

Emollients were the most commonly used method for improving dry skin in psoriasis patients (67.4%). Overall, 1693 (82.9%) of the respondents had a habit of using emollients, of which 61.4% had received health education (61.4%) on their use by professional doctors. **(Table 1).** We analyzed the respondents' preferences regarding the use of emollients for improving scales **(Table 2)**, dryness **(Table S1)**, and pruritus (**Table S2**). We found that patients with drier, more sensitive, and itchier lesions preferred using emollients. We also analyzed the survey respondents' preference for using emollients, including their frequency, type, time, quantity, seasons, body parts, and sequence, in three dimensions: scale, dryness, and pruritus improvement rate. Interestingly, patients who used emollients twice a day or more had better improvement of scales **(OR 2.857, 95% CI 1.962–4.161, P<0.001)** and pruritus **(OR 2.282, 95% CI 1.657–3.145, P<0.001)** in the lesion area than those who used emollients once a day or occasionally. Patients who applied the emollient to and around the lesion or the whole body showed a better rate of improvement in dryness than those who applied the emollient only to the lesion **(OR=1.593, 95% CI 1.119–2.266, P=0.01**).

Conclusion:

The results revealed that emollients may reduce scale, dryness, and pruritus to some extent and that the proportion of respondents who were able to apply emollients correctly was not ideal, suggesting that psoriasis patients need to be further educated in this area. This study provides important insights into caring for psoriasis patients.

Table 1 Characteristics of psoriasis patients

Characteristics		Participants (N=2043), No. (%)
Sex		
	Male	1320 (64.6)
	Female	723 (35.4)
Age, year (mean ± SD)		41.35 ±14.71
Diagnosis Age	<10	135 (6.6)
	10~20	413 (20.2)
	20~30	623 (30.5)
	30~40	372 (18.2)
	40~50	264 (12.9)
	50~60	148 (7.2)
	>60	88 (4.3)
Duration	<1 year	102 (5.0)
	1~3 years	299 (14.6)
	3~5 years	261 (12.8)
	5~10 years	463 (22.7)
	>10 years	918 (44.9)
Type	Psoriasis vulgaris	1551 (75.9)
	Psoriatic arthritis （PsA）	131 (6.4)
	Pustular psoriasis	55 (2.7)
	Erythrodermic psoriasis	88 (4.3)
	Unclear	218 (10.7)
Main skin lesions	Scalp	1500 (73.4)
	Upper extremities	1262 (61.8)
	Lower extremities	1503 (73.6)
	Back	1293 (63.3)
BSA	<3%	1020 (49.9)
	3%-10%	549 (26.9)
	＞10%	474 (23.2)
Comorbidities	Hypertension	297 (14.5)
	Diabetes	135 (6.6)
	Obesity	356 (17.4)
	hyperlipidemia	208 (10.2)
Current treatment	Topical	893 (43.7)
	Oral medication	280 (13.7)
	Phototherapy	207 (10.1)
	Biologic drugs	
	Adalimumab	254 (22)
	Secukinumab	682 (58.9)
	Ixekizumab	164 (14.2)
	Guselkumab	33 (2.9)
	Ustekinumab	77 (6.7)
Sensory of skin lesions	Dryness	1799 (88.1)
	Pruritus	1730 (84.7)
	Sensitive	1604 (78.5)
	Tightness	1521 (74.4)
Emollient use	Yes	1377 (67.4)
	No	666 (32.6)
Emollient types	Lotions	916 (54.1)
	Creams	784 (46.3)
	Gels	88 (5.2)
	Ointments	434 (25.6)
	Unclear	59 (3.5)
Emollient dosage	＜20g	999 (59)
	20-50g	559 (33)
	＞50g	135 (8)
Emollient frequency	≥2 times/day	388 (22.9)
	1 time/day or occasionally	1305 (77.1)

Table 2: Scale improvement rate due to different usage preferences for emollients (N=1693)

Emollients usage Preferences	Options, N (%) Positive	Negative	OR (95% CI)	*P*
Texture				
Lotion	766 (83.6)	612 (78.8)	1.377 (1.077–1.760)	0.011
Cream	661 (84.3)	717 (78.9)	1.439 (1.121–1.847)	0.004
Dosage				
≥20 g/per time	583 (84.0)	-	1.348 (1.045–1.739)	0.022
<20 g/per time	795 (79.6)	-		
Frequency				
≥2 times/day	354 (91.2)	-	2.857 (1.962–4.161)	<0.001
1 time/day or occasionally	1024 (78.5)	-		
Usage scenarios				
Post-bath	763 (82.0)	-	-	0.449
Non	615 (80.6)	-		
Time				
Both morning and evening	406 (85.5)	972 (79.8)	1.489 (1.113–1.992)	0.008
Before or immediately after disease onset	470 (84.7)	-	1.401 (1.066–1.840)	0.015
Any time after disease onset	908 (79.8)	-		
Seasons				
Spring	844 (85.4)	534 (75.7)	1.877 (1.466–2.402)	<0.001
Summer	591 (84.8)	787 (79.0)	1.481 (1.145–1.914)	0.003
Autumn	938 (85.7)	440 (73.6)	2.145 (1.674–2.750)	<0.001
Winter	1249 (82.3)	129 (73.3)	1.698 (1.186–2.431)	0.004
Change emollients base on seasons	556 (89.8)	822 (76.5)	2.706 (2.012–3.639)	<0.001
Order				
Drugs first	544 (92.8)	-	-	0.077
Emollients first & non-drug	863 (89.5)	-		
Site				
Lesion areas only	426 (79.8)	-	-	0.486
Exceeded lesion areas	508 (82.5)	-		
Method of application				
Follow the direction of the hair	250 (92.3)	-	3.103 (1.952–4.932)	<0.001
Reverse the direction of the hair, or back and forth	1128 (79.3)	-		

Table S1: Dryness improvement rate due to different usage preferences for emollients (N=1550)

Emollients usage Preferences	Options, N (%) Positive	Negative	OR (95% CI)	*P*
Texture				

Table S2: Pruritus improvement rate due to different usage preferences for emollients (N=1529)

Emollients usage Preferences	Options, N (%)		OR (95% CI)	*P*
	Positive	Negative		
Texture				
Lotion	639 (76.8)	521 (74.7)	-	0.477
Cream	562 (78.1)	598 (73.9)	-	0.059
Dosage				
≥20 g/per time	493 (77.4)	-	-	0.238
<20 g/per time	667 (74.8)	-		
Frequency				
≥2 times/day	316（85.9）	-	2.282 (1.657–3.145)	<0.001
1 time/day or occasionally	844 (72.7)	-		
Usage scenarios				
Post-bath	639 (76.4)	-	-	0.568
None	521 (75.2)	-		
Time				
Both morning and evening	373 (82.3)	787 (73.1)	1.712 (1.298–2.258)	<0.001
Before or immediately after disease onset	408 (79.1)	-	1.311 (1.016–1.691)	0.037
Any time after disease onset	752 (74.2)	-		
Seasons				
Spring	720 (79.4)	440 (70.7)	1.593 (1.258–2.017)	<0.001
Summer	493 (78.0)	667 (74.4)	-	0.101
Autumn	789 (79.0)	371 (70.0)	1.610 (1.266–2.047)	<0.001
Winter	1052 (76.7)	108 (68.8)	1.492 (1.041–2.138)	0.03
Changed emollients based on seasons	486 (85.0)	674 (70.4)	2.373 (1.815–3.102)	<0.001
Order				
Drugs first	461 (79.6)	-	1.403 (1.094–1.798)	0.008
Emollients first and non-drugs	699 (73.6)	-		
Site				
Lesion areas only	367 (77.3)	-	-	0.392
Exceeded lesion areas	793 (75.2)	-		
Method of application				
Follow the direction of the hair	229 (88.4)	-	2.779 (1.862–4.148)	<0.001
Reverse the direction of the hair or back and forth	931 (73.3)	-		

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 1954

Validation of a Dermatology-Specific Treatment Satisfaction Instrument: A Multicenter Study Evaluating the Construct and Known-Groups Validity of the Dermatology Treatment Satisfaction Instrument in Psoriasis Patients

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Introduction & Objectives:

The Dermatology Treatment Satisfaction Instrument (DermSat) is a patient-reported treatment satisfaction instrument specific to dermatological therapies. It measures treatment satisfaction in the categories of effectiveness, convenience, and overall satisfaction.

Materials & Methods:

A multicenter study was conducted to evaluate the construct and known-groups validity of the 7-item DermSat instrument (DermSat-7). A total of 142 psoriasis patients were enrolled across the University of Southern California, Brigham and Women's Hospital, and Mount Sinai Health System. Eligible patients were ≥ 18 years old, English-speaking, and receiving ongoing treatment for psoriasis. Participants completed an online survey consisting of demographic information in addition to the 9-item Treatment Satisfaction Questionnaire for Medication (TSQM-9), the Dermatology Life Quality Index (DLQI), a patient self-reported physician global assessment (PGA), and the DermSat-7. Investigators reported the patient's PGA, Body Surface area (BSA), and Psoriasis Area and Severity Index (PASI) scores.

Results:

DermSat-7 Effectiveness and Overall Satisfaction subscores were found to be very strongly correlated with their respective TSQM-9 subscores (Spearman's correlation r -value between DermSat Effectiveness and TSQM-9 Effectiveness ≥ 0.7, $p<0.001$; Spearman's correlation r -value between DermSat Overall Satisfaction and TSQM-9 Overall Satisfaction ≥ 0.7, $p<0.001$). The DermSat-7 Convenience subscore was strongly correlated with the TSQM-9-Convenience score (Spearman's correlation r -value= 0.68, $p<0.001$). The DermSat-7 Effectiveness and Overall Satisfaction subscores were also found to be correlated with PASI, Investigator-reported PGA, and DLQI scores (all Spearman's correlation r's ≥ 0.4, $p<0.001$). One-Way Analysis of Variance testing demonstrated a statistically significant association with the Investigator-reported Physician's Global Assessment (PGA) and all three DermSat-7 subscores ($p<0.001$ for DermSat-7 Effectiveness, Convenience, and Overall Satisfaction scores). A statistically significant association between the Psoriasis Area and Severity Index (PASI) and DermSat scores was also observed ($p<0.05$ for DermSat-7 Effectiveness, Convenience, and Overall Satisfaction scores).

Conclusion:

Our results show that the DermSat-7 instrument demonstrates strong construct and known-groups validity and validly measures patient treatment satisfaction in psoriasis patients. The instrument may be considered to evaluate patient satisfaction in other dermatologic conditions.

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Abstract N°: 1968

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Japanese patients with moderate to severe plaque psoriasis: safety findings from the phase 3 POETYK PSO-4 trial

Akimichi Morita[1], Yukari Okubo[2], Yayoi Tada[3], Mamitaro Ohtsuki[4], Yanqiu Shao[5], Elizabeth Colston[5], Andrew Napoli[5], Subhashis Banerjee[5], Shinichi Imafuku[6]

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis (PP) who are candidates for systemic therapy. Deucravacitinib has a unique mechanism of action. In two multinational phase 3 trials, POETYK PSO-1 and PSO-2, deucravacitinib was not associated with an increased risk of infection, cardiovascular events, or malignancies in patients with moderate to severe PP. This study reports safety results from the open-label, single-arm, phase 3 POETYK PSO-4 trial of deucravacitinib in Japanese patients with psoriasis.

Materials & Methods: In POETYK PSO-4 (NCT03924427), adult patients with moderate to severe PP, generalized pustular psoriasis (GPP), or erythrodermic psoriasis (EP) were treated with deucravacitinib 6 mg once daily. Safety outcomes were assessed through Week 52. Adverse events (AEs) of interest included infections (influenza, opportunistic, tuberculosis, herpes zoster), major adverse cardiovascular events (MACE; eg, cardiovascular death, nonfatal stroke, nonfatal myocardial infarction), venous thromboembolism, and malignancies.

Results: A total of 74 patients were included in the trial (PP, n=63; GPP, n=3; EP, n=8). The total exposure (person-years) was 60.6 (PP), 3.0 (GPP), and 6.8 (EP). Over 52 weeks, the exposure-adjusted incidence rates (EAIRs) per 100 person-years for AEs, serious AEs, discontinuations, and deaths in groups with >5 patients (excluding GPP) were 172.6, 6.7, 3.3, and 0 (PP) and 279.7, 14.6, 29.8, and 0 (EP), respectively. Four patients (PP, n=2; EP, n=2) discontinued treatment due to AEs (PP, psoriasis aggravation and decreased neutrophil count; EP, photosensitivity and Hodgkin's disease). Two serious infections (pneumonia, COVID-19) were reported in patients with PP. There were no deaths. Hodgkin's disease (T-cell type) was the only malignancy reported (EP patient) and was considered unrelated to treatment. No influenza, opportunistic infection, tuberculosis, or MACE/thromboembolic events were reported. Herpes zoster occurred in 1 patient with PP but was not considered related to treatment.

Conclusion: Deucravacitinib was generally safe and well tolerated over 52 weeks in Japanese patients with PP, GPP, or EP.

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Abstract N°: 1970

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Japanese patients with moderate to severe plaque psoriasis: laboratory parameters in the phase 3 POETYK PSO-4 trial

Shinichi Imafuku[1], Yukari Okubo[2], Yayoi Tada[3], Mamitaro Ohtsuki[4], Yanqiu Shao[5], Elizabeth Colstson[5], Andrew Napoli[5], Subhashis Banerjee[5], Akimichi Morita[6]

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis (PP) who are candidates for systemic therapy. Deucravacitinib uniquely binds to the regulatory domain. In two phase 3 trials, POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751), deucravacitinib was significantly more efficacious than placebo or apremilast and was well tolerated in patients with moderate to severe PP. This study evaluated the effects of deucravacitinib on multiple laboratory parameters in Japanese patients with stable moderate to severe psoriasis.

Materials & Methods: Patients ≥20 years of age with moderate to severe PP, generalized pustular psoriasis (GPP), or erythrodermic psoriasis (EP) (baseline Psoriasis Area and Severity Index ≥12, static Physician's Global Assessment ≥3, body surface area involvement ≥10%) received deucravacitinib 6 mg once daily in the 52-week, open-label, single-arm, phase 3 POETYK PSO-4 trial (NCT03924427). Changes from baseline levels of standard hematologic (lymphocytes, neutrophils, platelets, hemoglobin) and chemistry parameters, including lipids (total cholesterol, high- and low-density lipoprotein cholesterol, triglycerides) and creatine phosphokinase in the blood, were evaluated. Shifts in Common Terminology Criteria for Adverse Events (CTCAE; version 5.0) severity grade of laboratory parameter abnormalities between baseline and Week 52 were assessed

Results: A total of 74 patients were enrolled (PP, n=63; GPP, n=3; EP, n=8). No clinically meaningful changes or trends from baseline levels were observed in any laboratory parameter up to Week 52. The majority of patients remained within the normal range throughout the trial, and shifts of ≥2 CTCAE grades from baseline were infrequent across all psoriasis groups. One patient with PP discontinued treatment due to grade 3 neutropenia.

Conclusion: Deucravacitinib treatment did not result in clinically significant laboratory parameter abnormalities in adult Japanese patients with psoriasis.

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Abstract N°: 2002

Demographics and baseline characteristics of Canadian patients with pediatric-onset psoriasis: Real-world data from the Psoriasis Longitudinal Assessment and Registry (PSOLAR)

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Introduction & Objectives:

The PSOriasis Longitudinal Assessment and Registry (PSOLAR) was initiated in 2007 to assess long-term safety and improve understanding of real-world biologic use. This analysis describes the demographics and baseline [BL] characteristics of Canadian patients with pediatric-onset psoriasis [PsO] relative to patients with adult-onset PsO enrolled in PSOLAR.

Materials & Methods:

PSOLAR is an international, prospective, longitudinal, disease-based registry that collects data on patients ≥18 years of age with a confirmed diagnosis of PsO, who are receiving, or are eligible to receive, systemic non-biologic or biologic therapies for PsO (ClinicalTrials.gov NCT00508547). Demographics and BL characteristics collected at the time of enrollment are described for Canadian patients enrolled in PSOLAR from June 2007 to June 2013, then followed for up to 8 years. Patients were grouped by age of PsO onset: <18 years, 18-25 years, or >25 years.

Results:

Approximately 12,000 PsO patients were enrolled in PSOLAR globally; of these, 1891 patients were Canadian, including 552 (29.2%) with age of onset <18 years, 428 (22.6%) with 18-25 years age of onset, and 911 (48.2%) with age of onset >25 years.

Most patients were male, white, and either overweight or obese (Table 1). Patients <18 years of age at PsO onset were more likely to be female compared to patients with older age of PsO onset (47% vs 35.5% vs 35%, respectively). Fewer patients aged ≥55 at enrollment were 25 years of age or younger at PsO onset. The distribution by race and Fitzpatrick skin type [FST] were similar across age of onset groupings. All three groups had similar mean body weight (91.7 kg vs 91.5 kg vs 91.2 kg), mean body mass index [BMI] (31.5 kg/m2 vs 31.1 kg/m2 vs 31.2 kg/m2), and obesity class distribution at BL.

Most patients had moderate-to-severe plaque PsO (mean BL body surface area [BSA]: 8.7% vs 7.0% vs 6.8%; mean peak activity BSA: 27.1% vs 22.8% vs 20.4%). The self-reported prevalence of psoriatic arthritis [PsA] and Dermatology Life Quality Index [DLQI] scores were similar among the three categories (32.8% vs 34.8% vs 32.8% and 5.4 vs 5.0 vs 5.3). A greater proportion of patients <18 years of age at onset reported prior treatment with phototherapy (81.7% vs 76.2% vs 66.1%), systemic corticosteroids (11.8% vs 7.5% vs 9.7%), and systemic immunomodulators (61.2% vs 59.3% vs 50.9%). Prior biologic use was similar (87.7% vs 86.9% vs 84.6%) across groups.

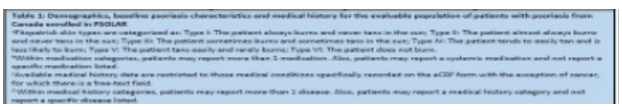
A history of cardiovascular disease (i.e., hypertension, hyperlipidemia, atherosclerosis) was more prevalent among patients with older age of PsO onset. A history of pulmonary or psychiatric illnesses were balanced across groups, but higher proportions of patients with onset of PsO >25 years of age had a history of skin cancer, other types of cancer, and diabetes mellitus type II compared to patients with younger age of PsO onset.

Conclusion:

In this real-world cohort of Canadian patients, race and FST distribution, BL body weight, BMI, prevalence of PSA, and DLQI scores were generally balanced across the three groups designated by age of PsO onset. Patients with PsO onset <18 years of age reported a higher mean BL and peak activity BSA with greater use of phototherapy and systemic non-biologic therapy. Generally, higher proportions of patients with PsO onset >25 years of age had a history of comorbidities. This descriptive analysis should provide meaningful insights into patients with pediatric-onset PsO and improve patient management.

Demographics	<18 years age of onset (n=552)	18-25 years age of onset (n=428)	>25 years age of onset (n=911)
Age [years], n	552	428	911
Mean age (SD) [years]	41.8 (12.6)	45.0 (11.7)	54.7 (10.0)
Age category [years], n (%)	552	428	911
18-24	51 (9.2%)	14 (3.3%)	0
25-34	120 (21.7%)	66 (15.4%)	18 (2.0%)
35-44	148 (26.8%)	115 (26.9%)	135 (14.9%)
45-54	138 (25.0%)	133 (31.1%)	268 (29.4%)
55-64	75 (13.6%)	75 (17.5%)	344 (37.8%)
265	20 (3.6%)	25 (5.8%)	145 (15.9%)
Gender, n	552	428	911
Male, n (%)	291 (52.7%)	276 (64.5%)	593 (65.1%)
Race, n (%)			
White	519 (94.0%)	399 (93.2%)	816 (89.6%)
Black or African American	2 (0.4%)	2 (0.5%)	7 (0.8%)
Hispanic or Latino	0	2 (0.5%)	5 (0.5%)
Asian	16 (2.9%)	13 (3.0%)	44 (4.8%)
Chinese	11 (2.0%)	9 (2.1%)	20 (2.2%)
Japanese	0	0	0
Korean	0	1 (0.2%)	1 (0.1%)
North Indian	1 (0.2%)	1 (0.2%)	5 (0.5%)
South Indian	4 (0.7%)	0	11 (1.2%)
Other, not specify	0	2 (0.5%)	7 (0.8%)
Other	15 (2.7%)	12 (2.8%)	39 (4.3%)
Native American	0	0	0
Indigenous of the America	2 (0.4%)	1 (0.2%)	11 (1.2%)
Other, not specify	13 (2.4%)	11 (2.6%)	28 (3.1%)
Fitzpatrick skin type[a], n (%)	552	426	910
Type I	32 (5.8%)	23 (5.4%)	48 (5.3%)
Type II	100 (18.1%)	74 (17.4%)	153 (16.8%)
Type III	216 (39.1%)	161 (37.8%)	310 (34.1%)
Type IV	141 (25.5%)	125 (29.3%)	271 (29.8%)
Type V	53 (9.6%)	38 (8.9%)	112 (12.3%)
Type VI	10 (1.8%)	5 (1.2%)	16 (1.8%)
Body weight [kg], n	551	425	906
Mean weight (SD) [kg]	91.7 (22.5)	91.5 (21.7)	91.2 (20.6)
Body mass index [kg/m²], n	551	424	900
Mean BMI (SD) [kg/m²]	31.5 (7.2)	31.1 (7.1)	31.2 (6.4)
Obesity class, n (%)	551	424	906
Underweight (BMI < 18.5 kg/m²)	3 (0.5%)	1 (0.2%)	2 (0.2%)
Normal (18.5-24.9 kg/m²)	94 (17.1%)	68 (16.0%)	117 (12.9%)
Overweight (25.0-29.9 kg/m²)	161 (29.2%)	145 (34.2%)	331 (36.5%)
Obesity Class I (30.0-34.9 kg/m²)	140 (25.4%)	107 (25.2%)	240 (26.5%)
Obesity Class II (35.0-39.9 kg/m²)	83 (15.1%)	57 (13.4%)	129 (14.2%)
Obesity Class III (≥40.0 kg/m²)	70 (12.7%)	46 (10.8%)	87 (9.6%)

Baseline psoriasis characteristics			
Psoriasis type, n (%)	552	428	911
Plaque	549 (99.5%)	426 (99.5%)	902 (99.0%)
Other	14 (2.5%)	8 (1.9%)	25 (2.7%)
BSA at baseline [%], n	552	428	911
Mean BSA (SD)	8.7 (13.4)	7.0 (11.6)	6.8 (11.0)
PGA score at baseline, n	551	426	911
Mean PGA score (SD)	1.9 (1.2)	1.9 (1.2)	2.0 (1.2)
PGA score distribution, n (%)	551	426	911
0 - clear	83 (15.1%)	66 (15.5%)	142 (15.6%)
1 - minimal	117 (21.2%)	85 (20.0%)	169 (18.6%)
2 - mild	177 (32.1%)	119 (27.9%)	249 (27.3%)
3 - moderate	127 (23.0%)	125 (29.3%)	267 (29.3%)
4 - marked	44 (8.0%)	28 (6.6%)	79 (8.7%)
5 - severe	3 (0.5%)	3 (0.7%)	5 (0.5%)
BSA at peak activity [%], n	285	199	484
Mean BSA at peak activity (SD)	27.1 (20.2)	22.8 (17.5)	20.4 (16.0)
PGA score at peak activity, n	290	200	487
Mean PGA score at peak activity (SD)	3.4 (0.7)	3.4 (0.6)	3.4 (0.7)
PGA score at peak activity, n (%)	290	200	487
0 - clear	0	0	1 (0.2%)
1 - minimal	1 (0.3%)	1 (0.5%)	2 (0.4%)
2 - mild	13 (4.5%)	7 (3.5%)	21 (4.3%)
3 - moderate	161 (55.5%)	117 (58.5%)	275 (56.5%)
4 - marked	103 (35.5%)	68 (34.0%)	166 (34.1%)
5 - severe	12 (4.1%)	7 (3.5%)	22 (4.5%)
DLQI score (0-30), n	525	418	871
Mean score (SD)	5.4 (6.6)	5.0 (6.1)	5.3 (6.2)
Age at onset of psoriasis [years], n	552	428	911
Mean age (SD) [years]	11.9 (4.5)	21.2 (2.1)	39.4 (11.01)
Time since psoriasis diagnosed [years], n	552	428	911
Mean years (SD)	30.4 (12.7)	25.3 (11.7)	15.9 (9.8)
Medical history[c,d]			
Psoriatic arthritis, n (%)	181 (32.8%)	149 (34.8%)	299 (32.8%)
Cardiovascular, n (%)	179 (32.4%)	174 (40.7%)	486 (53.3%)
Hypertension	138 (25.0%)	138 (32.2%)	390 (42.8%)
Hyperlipidemia	95 (17.2%)	95 (22.2%)	280 (30.7%)
Atherosclerotic disease	12 (2.2%)	9 (2.1%)	58 (6.4%)
Diabetes mellitus type II, n (%)	44 (8.0%)	57 (13.3%)	154 (16.9%)
Pulmonary, n (%)	70 (12.7%)	42 (9.8%)	106 (11.6%)
Psychiatric illness, n (%)	147 (26.6%)	91 (21.3%)	229 (25.1%)
Skin cancer, n (%)	15 (2.7%)	10 (2.3%)	36 (4.0%)
Other types of cancer, n (%)	12 (2.2%)	6 (1.4%)	40 (4.4%)



EA DV CONGRESS
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 2029

Effectiveness and safety of guselkumab in patients with facial and/or genital psoriasis: interim results up to week 28 from the GULLIVER Study

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Introduction & Objectives:

Psoriasis is a chronic immune mediated systemic inflammatory disease that mainly affects the skin and joints, and that has a strong negative influence on the patient's quality of life (QoL). Hard-to-treat facial (FP) and genital (GP) psoriasis significantly contributes to the burden of the disease and has a detrimental impact on patient's life when compared to psoriasis localized in other parts of the body. Guselkumab is an interleukin-23 pathway inhibitors with proven efficacy in patients with moderate to severe plaque psoriasis. The ongoing GULLIVER study is aimed to investigate the effects of guselkumab in patients with FP and/or GP psoriasis in a real-life setting.

Materials & Methods:

The study includes adult patients with psoriasis requiring a systemic treatment with a significant involvement (defined as a static physician global assessment (sPGA) score ≥ 3) of the genitals and/or facial area and having started a treatment with guselkumab according to the approved indications in Italy. Treatment effectiveness is assessed using the sPGA score. An interim analysis has been conducted to evaluate the baseline characteristics (n=351) and the results (separately in the two predominant areas) at week 12 (n=348) and week 28 (n=331) in patients who reached 28 weeks of treatment as of 31 Dec 2022.

Results:

Overall, 147 patients (56.5% men, mean age 41.9 years) had predominantly FP and 204 (59.3% men, mean age 47.4 years) had predominantly GP. Mean BMI at baseline was 27.5 and 26.8 kg/m2, respectively in the two subgroups. 10.9% and 10.8% of FP and GP patients respectively, had a diagnosis of psoriasis < 3 years. Moreover, the percentage of patients naïve to biologic agents was 60.7%. The mean (±SD) time from diagnosis to first dose of guselkumab was 17.0±13.0 years in FP patients and 15.0±11.7 years in GP patients. The percentage of FP and GP patients who achieved sPGA score 0/1 and ≥2 grade improvement at week 12 was 83.3% and 76.5%,

respectively (79.4% total patients); rates at week 28 were 90.2% and 93.1%, respectively (91, 8 % total patients). Improvements from baseline up week 28 in thickness, scaling and erythema were observed in both subgroups: 88.2%, 92.3% and 83.5% of patients with FP, and 82.1%, 84.6% and 78.0% of patients with GP, having a moderate to severe score at baseline achieved a score of 0/1 (clear/almost clear) for thickness, scaling and erythema at week 12, respectively. The corresponding rates at week 28 were 91.0%, 93.5% and 91.4% in patients with FP, and 94.0%, 96.7% and 93.7% in patients with GP, respectively for thickness, scaling and erythema.

Conclusion:

The results of this interim analysis have shown that treatment with guselkumab is effective, and it is associated with an improvement of the sPGA score both for hard-to-treat facial and genital psoriasis. Particularly, the effectiveness of guselkumab was evident at week 12 and was sustained and enhanced up to week 28. Final data at one year will evaluate if benefits are sustained over time and will assess the long-term impact of treatment on quality of life and on living with facial and/or genital psoriasis.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 2041

A curriculum of online education significantly improved dermatologists' knowledge, competence and confidence in managing patients with generalized pustular psoriasis (GPP)

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Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare, chronic autoinflammatory skin condition that causes widespread skin lesions and fever, and which can have a serious impact on patients' quality of life. Some cases may result in organ failure and severe infections that require emergency care. We assessed whether an online curriculum of activities could improve dermatologists' understanding of GPP, and their competence and confidence in GPP management.

Materials & Methods:

A curriculum of 5 activities was developed on GPP, including video activities featuring discussion between 2 expert faculty, and an interactive video case-based activity. Data were collected from 2021 to 2022 for learners completing pre- and post-activity questions. For each activity, educational effect was assessed with a repeated-pairs pre-/post-assessment; 3 multiple-choice, knowledge questions and 1 self-efficacy, 5-point Likert scale confidence question were analyzed. A McNemar's test was conducted to assess statistical significance of changes from pre- to post-assessment. Data were subsequently combined and analyzed by 5 key themes to provide a summative overview of the effect of the education across the combined activities, with n numbers ranging from 52 to 443 by theme.

Results:

- 12,520 dermatologist learners participated in this activity; of these, 3,569 were from Asia, 3,772 from Europe and 2,347 from the Middle East and North Africa
- Dermatologists (n ranged from 52 to 443 for each theme) demonstrated a statistically significant improvement in knowledge or competence across 4 of the 5 learning themes (3 knowledge themes: new & emerging treatment options, diagnosing GPP, burden of GPP; and for the competence theme, optimizing management of GPP, all $P < 0.001$)
- There was a numerical improvement in knowledge, from a high baseline, regarding GPP as a neutrophilic disease
- The relative improvements in % of correct responses for 4 of the 5 learning themes ranged from 10%–109%
- 46% dermatologists reported increased confidence in managing people with GPP

Conclusion:

The success of this educational curriculum highlights the benefits of delivering education in this way, with dermatologists demonstrating significant gains in knowledge, competence and confidence. Given the challenges in treating patients with GPP, dermatologists would benefit from further education to enhance their knowledge of novel treatment strategies and translate this knowledge into improved outcomes for patients.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 2042

Treatment-free period of more than 1 year in guselkumab super responders with short disease duration of psoriasis: withdrawal data from the GUIDE trial

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Introduction & Objectives:

GUIDE is an ongoing Phase 3b, randomized, double-blind trial for guselkumab (GUS) in patients (pts) with moderate-to-severe psoriasis. Previously, we demonstrated the benefit of early intervention with GUS for achieving super responder (SRe; defined as PASI=0 at Week [W] 20+28) status, and showed non-inferiority of GUS every 16-week (q16w) vs q8w dosing in SRes for maintenance of disease control (PASI <3) at W68, meeting the primary endpoint. Here, we report data from part 3 of GUIDE, assessing maintenance of response in SRes after withdrawal from GUS at W60 (q8w) or W52 (q16w) through W116, to evaluate the impact of early intervention on the treatment-free period.

Materials & Methods:

In part 1 of GUIDE (W0–28), pts received GUS 100 mg at W0, 4, 12, and 20. In part 2 (W28–68), SRes were randomized to GUS 100 mg q8w or q16w, stratified by short disease duration (SDD; ≤2 years) or long disease duration (LDD; >2 years). In part 3 (W68–220), SRes with PASI <3 at W68 were withdrawn from GUS. Loss of maintenance of response was defined as PASI >5, which made pts eligible for re-treatment. We report outcomes for the ITT set; *P* values are nominal.

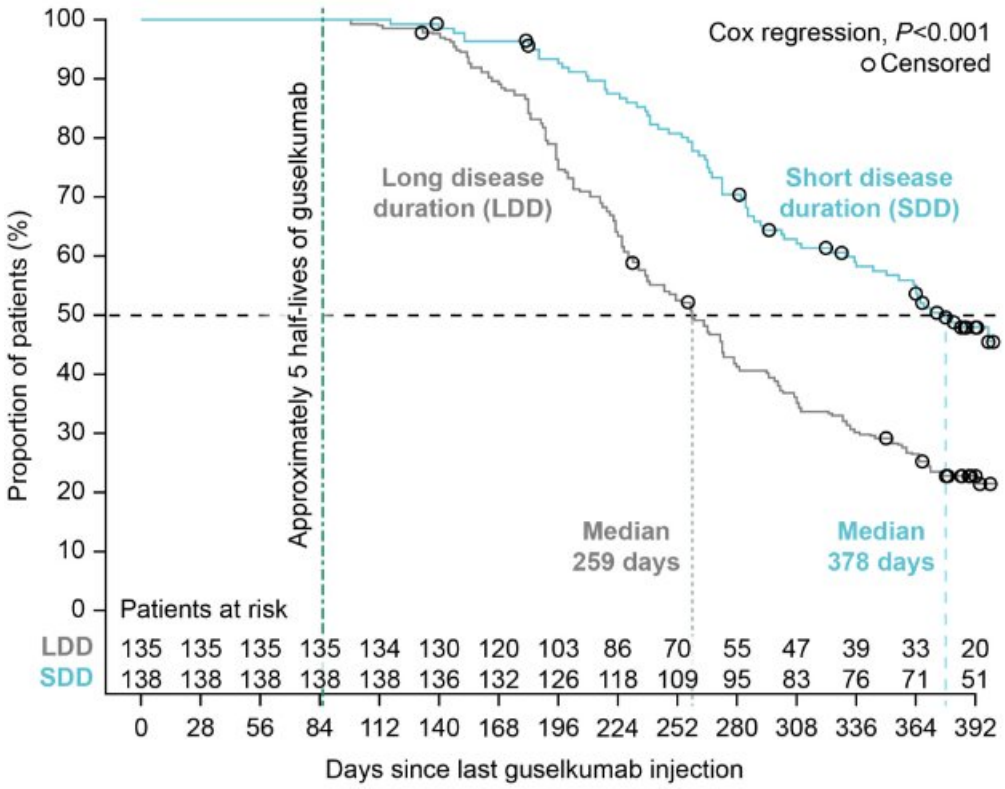
Results:

A total of 273 SRes entered study part 3, including 138 (50.5%) and 135 (49.5%) pts with SDD and LDD, respectively, and 136 (group 3a) and 137 (group 3b) pts who received GUS q8w and q16w, respectively, in part 2. In total, 68.5% of pts in part 3 were male, and median baseline values were 38.0 years for age, 2.1 years for disease duration, 26.2 kg/m² for BMI, and 16.5 for PASI, and 7.7**%** of pts had received prior biologics.

Overall, the median treatment-free time was 302 days, and it was substantially longer in SDD vs LDD pts (378 vs 259 days; *P*<0.001; **Fig 1**). Of all pts who entered the withdrawal phase, at W116, 20.9% had PASI <3, 13.2% PASI ≤1 and 8.4% PASI=0 (NRI). Importantly, SDD pts showed greater responses than LDD pts at W116 (PASI <3: 30.4% vs 11.1%, *P*<0.001; PASI ≤1: 21.7% vs 4.4%, *P*<0.001; PASI=0: 13.8% vs 3.0%, *P*=0.001, respectively; **Fig 2**). Of pts who remained re-treatment-free until W116 (n=74), 79.7% had PASI <3, 48.6% PASI ≤1 and 31.1% PASI=0. Again, SDD pts (n=49) better maintained responses than LDD pts (n=25) at W116 (PASI <3: 87.8% vs 64.0%; PASI ≤1: 61.2% vs 24.0%; PASI=0: 38.8% vs 16.0%, respectively). Of pts with PASI=0 at W116, most (14/23; 60.9%) had a disease duration ≤15 months at baseline.

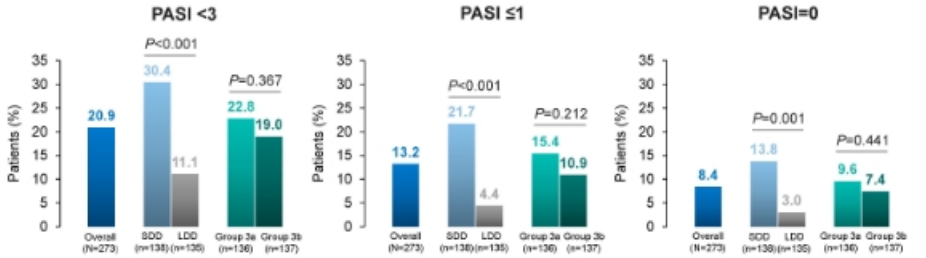
No significant differences were observed between groups 3a (prior GUS q8w) and 3b (prior GUS q16w). Median treatment-free time was 301 vs 310 days, and PASI response rates at W116 were similar (NRI, PASI <3: 22.8% vs 19.0%; PASI ≤1: 15.4% vs 10.9%; PASI=0: 9.6% vs 7.3%; **Fig 2**; observed cases, PASI <3: 76.7% vs 83.9%; PASI ≤1: 48.8% vs 48.4%; PASI=0: 30.2% vs 32.3%) in groups 3a vs 3b, respectively.

Figure 1. Proportion of patients who remain treatment-free by short (≤2 years) or long (>2 years) disease duration



P value is considered nominal. Loss of maintenance of response was defined as PASI >5, at which point treatment was re-initiated. The treatment-free observation period is ongoing.
PASI, Psoriasis Area and Severity Index.

Figure 2. Absolute PASI <3, PASI ≤1 and PASI=0 response rates at W116, overall, by disease duration, and by dosing interval received in study part 2, among all patients withdrawn from guselkumab (NRI)



P values are considered nominal. Patients in group 3a and 3b previously received guselkumab q8w and q16w, respectively, in part 2 of the study.
The last injection for those who received guselkumab q8w and q16w was at W60 and W52, respectively.
Patients with PASI >5 (loss of maintenance of response) at any visit in part 3 of the study were re-treated with guselkumab.
PASI, Psoriasis Area and Severity Index; NRI, non-responder imputation; LDD, long disease duration; SDD, short disease duration; W, Week.

Conclusion:

In the withdrawal phase of GUIDE, overall maintenance of response remained high in SRes to W116. Furthermore, SRes with SDD had a greater median treatment-free time (378 days; 119 days [46%] longer), and substantially higher PASI response rates at W116 than those with LDD. These data suggest that the benefits derived by SRes go beyond greater PASI responses and may also allow for tailored treatment strategies to address individual patient needs. Combined with earlier findings demonstrating that SDD increases the likelihood of achieving SRe status, our data emphasize the relevance of early intervention with GUS and its potential for modifying the disease course. Ongoing clinical and biomarker analyses will further examine this concept.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 2048

Overexpression and Potential Roles of Midkine via Regulation of Vascular Endothelial Growth Factor A in Psoriasis

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease that affects approximately 2-3% of the world population. The pathogenesis of psoriasis is complex and involves genetic, environmental, and immune factors. Angiogenesis, the formation of new blood vessels, is a critical process in psoriasis pathogenesis. Vascular endothelial growth factor (VEGF) is a key angiogenic factor that is overexpressed in psoriatic skin lesions. Midkine is a heparin-binding growth factor that has been shown to play a critical role in angiogenesis by regulating the VEGF signaling pathway. Despite the growing evidence of the involvement of midkine in angiogenesis, its role in psoriasis pathogenesis remains unclear. Therefore, this study aimed to investigate the potential role of midkine in psoriasis pathogenesis. The objective of this study was to measure midkine expression in psoriasis and investigate its potential role in the disease. The study aimed to assess the effect of midkine on HaCaT cell proliferation, VEGF-A production, and signaling pathways. In addition, the study aimed to evaluate the effect of midkine on the migration and tube formation of human dermal microvascular endothelial cells. Furthermore, the study aimed to investigate the effect of midkine on murine psoriasiform models.

Materials & Methods:

The study included patients diagnosed with psoriasis, and midkine expression was measured using immunohistochemistry and ELISA. HaCaT cell proliferation, VEGF-A production, and signaling pathways were assessed using CCK8, RT-PCR, and WB. Scratch and in vitro tube formation tests were used to evaluate the effect of HaCaT-cell-activated midkine on the migration and tube formation of human dermal microvascular endothelial cells. Murine psoriasiform models were injected with midkine recombinant protein and midkine monoclonal antibody to investigate skin lesions, tissue sections, and dermal microvessel density.

Results:

The results showed that levels of midkine significantly increased in both lesions and serum of patients with psoriasis. Serum expression of midkine decreased after treatment, and a positive correlation was found between midkine and disease severity. Midkine promoted HaCaT cell proliferation and VEGF-A production. The Notch2/HES1/JAK2-STAT5A pathway expression increased after midkine treatment of HaCaT cells. The supernatant of HaCaT cells treated with midkine promoted HMEC-1 migration and angiogenesis in vitro. Recombinant midkine protein exacerbated psoriasiform lesions with increased expressions of VEGF-A and microvessel density, while midkine monoclonal antibody alleviated psoriasis lesions.

Conclusion:

In conclusion, midkine may have a significant impact on psoriasis angiogenesis by regulating VEGF-A expression through the Notch2/HES1/JAK2-STAT5A pathway. The study findings suggest that midkine could be a potential therapeutic target for psoriasis treatment. Further studies are needed to explore the potential of midkine as a therapeutic target for psoriasis and to evaluate the safety and efficacy of midkine-based therapies.

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BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 2049

The Efficacy of Turmeric-Based Therapies in Treating Psoriasis: a Systematic Review of Clinical Evidence

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Introduction & Objectives: Psoriasis is a chronic, inflammatory, and papulosquamous skin disease that affects approximately 2% of the population. Different biologic agents which target different components of the pathophysiology of psoriasis are considered among the first-line treatment agents. Curcumin is a natural ingredient which has been proven to be effective in various chronic diseases. Curcumin interacts and inhibits different components implicated in the pathophysiology of psoriasis such as Tumor Necrosis Factor Alpha (TNF-a). Curcumin's efficacy in treating psoriasis has been put to test in several clinical trials. The aim of this study is to conduct a systematic review of the clinical evidence of curcumin's efficacy in treating psoriasis.

Materials & Methods: A search strategy was written and run for six different databases, which yielded many articles that were exported to EndNote®, combined, and deduplicated. Article screening was conducted on Rayan, an intelligent systematic review web tool, where inclusion and exclusion criteria were applied. All articles that met the inclusion criteria were selected. Data was then extracted from the remaining articles and risk of bias assessment was conducted.

Results: Six studies were included out of 24204 screened by the two reviewers. Three of the six articles assessed the use of topical curcumin formulations, and three assessed the use of oral curcumin formulations. Of the topical treatments, one used a turmeric tonic, one used a starch fortified turmeric bath, and one used a turmeric microemulgel. Of the oral treatments, one used Meriva (lecithin based delivery system of curcumin) and topical corticosteroids, one used oral curcumin and a retinoid (acitretin), and one used oral curcumin alone. In the control groups, two were placebo controlled, one used retinoids alone, one used corticosteroids alone, one used naturopathy alone, and one study was not controlled. All three of the topical curcumin studies found a significant improvement in PASI scores between treatment and control groups, two of the studies assessed the DLQI and found a significant increase in the score and hence an improvement in the quality of life in the treatment group compared to the control. Of the three oral studies, three assessed the PASI score and two of them found a significant improvement in PASI score in the treatment group compared to control. One study reported a significant improvement in PASI score in patients who completed the treatment but not when intention to treat analysis was considered. In addition, one study found a decrease in Interleukin 22 (IL-22) levels upon oral curcumin administration. One study found no difference in serum lipid levels in both groups. Adverse effects were rare and are presented in Table 1. Risk of bias assessment is presented in table 2.

Conclusion: All in all,** curcumin was efficacious in treating psoriasis in a variety of topical and oral administration methods. More studies that are of better design and on a larger scale are needed to further solidify the current evidence. To add, more studies are needed to assess how curcumin-based therapies can be incorporated into treatment regimens to further decrease the burden of disease and improve quality of life.

Table 1: Data extracted from the articles

Author, Year	Country	Type of Study	Control	Treatment Group	Administration Route	Dosage and Formulation	Duration of Treatment	Concurrent Treatment	Extent of Disease	PASI Score	DLQI	Other Measure 1	Other Measure 2	Adverse Events
Bahraini 2018	Iran	Randomized Controlled Trial	Placebo	Turmeric tonic	Topical	Twice a day for 9 weeks	9 weeks	None (2-week washout period and/or 1- month washout systemic treatment)	Mild to moderate	Turmeric tonic significantly decreased the PASI score at the end of the study (p<0.05)	Turmeric tonic significantly increased patients quality of life at the end of the treatment (p<0.05)	None	None	None
Antiga, 2015	Italy	Randomized Controlled Trial	Topical methylprednisolone aceponate 0.1% ointment and placebo	Meriva, a commercially available lecithin based delivery system of curcumin (plus Topical methylprednisolone aceponate 0.1% ointment)	Oral	2g/day (2 tablets 2 times a day, each tablet containing 500 mg Meriva)	12 weeks	topical methylprednisolone aceponate 0.1% ointment	Mild to moderate	At T12, both groups achieved a significant reduction in PASI scores, (treatment group PASI at T12=1.3, control PASI at T12=2.4), but reduction was higher in treatment group compared to control, p<0.05	not assessed	IL-17 and IL-22 mean values at T12, no significant changes in IL-17 levels but decreased IL-22 in treatment group only p<0.001	None	n=1, diarrhea
Anna [illegible], 2018	Italy	Randomized Controlled Trial	acitretin 0.4 mg/kg per day plus placebo	oral curcumin (plus acitretin 0.4 mg/kg per day)	Oral (nanoparticles filled into hard capsules)	3g/day	12 weeks	acitretin 0.4 mg/kg per day	moderate-to-severe	At T12, both groups achieved a significant reduction in PASI values (treatment group: PASI at T12 = 3.4; control: PASI at T12 = 6.8), but much higher in arm 1 (P < 0.0001)	not assessed	Serum lipid profile (HDL, LDL, triglycerides and total cholesterol) remained unchanged across both groups during the study	Curcumin permeability was significantly enhanced through nanoparticles when compared to aqueous saturated solutions of curcumin	nausea and vomiting, n=1
Sarafian, 2015	Iran	Randomized Controlled Trial, prospective intra-individual, right–left comparative	placebo	turmeric microemulgel	Topical	Apply twice daily	9 weeks	None	mild to moderate	the side treated with drug improved in PASI score and that level of improvement was steady all the way in the trial (P<0.05).	significant improvement in quality of life was noted in the treatment group compared to the control (p<0.05)	None	None	dryness (6%), burning sensation (6%), irritation (3%)
Shathirapathiy, 2010	India	Randomized Controlled Trial	naturopathy interventions only (e.g. massage, yoga, hydro, diet therapy)	starch fortified turmeric baths (along with naturopathy interventions)	Topical bath	2:1 ratio of uncooked rice to turmeric powder, applied to the body and retained for 40 min	10 days	naturopathy interventions	not mentioned	At day 10, both groups achieved a significant reduction in PASI values (treatment group: PASI = 9.273 (initially 23.20); control: PASI =22.83 (initially 22.983) . The difference between the two groups at day 10 is significant (p<0.05)	not assessed	none	none	none mentioned
Kurd, 2008	USA	Prospective Clinical Trial	non-controlled	Curcuminoid C3 complex capsules	Oral	3x (500-mg capsules) 3 times a day	12 weeks	None	moderate-to-severe	The change in PASI score at week 12 for the patients who completed the trial is 5.4 (p=0.04), while intention to treat analysis showed a decrease of 0.65 (p=0.26)	not assessed	PASI 75, only 2 responders reached PASI 75	none	gastrointestinal upset or heat intolerance/hot flashes

Table 2: Risk of Bias Assessment of Articles

Study	Random Sequence Generation (selection bias)	Allocation concealemnt (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bahraini et al., 2008	Low	Unclear	Low	Low	High	Low	low
Antiga et al., 2015	Low	Unclear	Low	Low	High	Low	low
Anna Rita Bilia et al., 2018	Low	Low	Low	Low	Low	Low	low
Sarafian et al., 2015	Low	Unclear	Low	Low	High	Low	low
Shathirapathiy et al., 2015	Low	Low	High	High	Low	Low	low
Kurd et al., 2008	Not applicable	Not applicable	High	Unclear	High	Low	low

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Abstract N°: 2080

Gender-differences in psoriasis severity and other clinical characteristics in psoriatic arthritis patients. Data from clinical practice

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Introduction & Objectives:

The prevalence of psoriatic arthritis (PsA) is similar in men and women, gener-related differeces hadn't been sufficiently studied. To analyze, in clinical practice, gender influences on psoriasis and other characteristics of PsA.

Materials & Methods:

956 patients (M/F=411 (43%)/545 (57%) with PsA according to CASPAR criteria were included in this observational cohort. Mean age M/F 48.4±12.6/ 53,3±12.7 years ($p<0.001$). All patients underwent standard clinical examination. Skin lesion severity was evaluated in terms of body surface area (BSA) affected.

BSA (%), obesity (BMI), Pain (VAS, mm), Health Assessment Questionnaire-Disability Index (HAQ-DI) were compared between male and female patients at baseline.

M±SD, %, t-test, Pearson-$\chi 2$ were calculated. All $p<0.05$ were considered to indicate statistical significance.

Results:

The following differences were found between males and females with PsA: severe psoriasis (BSA>10%) was found in 54 (13%) versus 102 (18.7%) ($p=0.021$), obesity (BMI>30 kg /m2) was detected in 87 (21.2%) versus 205 (37.6%) ($p<0.001$), Pain was 48.5±22.6 mm VAS versus 51.5±22.8 mm ($p=0.043$), moderate functional impairment (HAQ-DI scores from 1.1 to 2.0) – in 112 (28.5%) versus 202 (38.5%) ($p=0.002$), severe functional impairment (HAQ-DI scores from 2.1 to 3.0) – in 8 (2.0%) versus 36 (6.9%) ($p<0.001$), respectively.

Conclusion:

The comparative analysis of** gender differences in PsA patients showed that females were older and had significantly worse disease status as measured by psoriasis severity, more often obesity, higher pain intensity and reduction of pts' functional capacity.

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Abstract N°: 2085

Diagnostic and therapeutic approach of Crohn's-like ileitis in a patient with chronic plaque psoriasis

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Introduction & Objectives:

Psoriasis is a chronic, inflammatory, multisystemic disease whose onset is triggered by genetic and environmental factors. Psoriasis is associated with comorbid inflammatory conditions, which may influence the decision-making process regarding the most suitable therapeutic option in controlling psoriasis and the potentially concomitant diseases. Because psoriasis patients are predisposed to concurrent inflammatory diseases, our aim was to shed light on the importance of careful monitoring and multidisciplinary approach for a complete, unitary management for each case.

Materials & Methods:

We documented the case of a 33-years-old Male patient with a long-standing history of psoriasis who was treated with Methotrexate for six years. During therapy with Methotrexate, the patient acknowledged mild, unspecified gastrointestinal symptoms, consisting mainly in an accelerated intestinal transit. Eventually, treatment with Methotrexate became inefficient leading, also, to altered hepatic laboratory tests. Consequently, a change in the therapeutic approach was required. The patient did not have a personal or family history of inflammatory bowel disease, therefore, he was initiated on biologic therapy with an IL-17 inhibitor. During biologic therapy for psoriasis, the patient pointed out that he still presented those mild gastrointestinal symptoms, which he correlated with poor dietary habits. A multidisciplinary approach between the Dermatology and Gastroenterology Departments was made for further investigations. Among the laboratory tests performed there was fecal calprotectin, which, initially, had slightly increased values. At the following evaluation, in the context of a significant increase in the calprotectin levels, it was decided to perform a colonoscopy with endoscopic biopsies.

Results:

The colonoscopy and the histopathology report of the endoscopic biopsies from the terminal ileum yielded the diagnosis of Crohn's-like ileitis. The gastroenterology report stated that taking into consideration the patient's personal history of long-standing psoriasis, as well as the results from the laboratory, endoscopic and histopathologic examinations, the final diagnosis was Crohn's-like ileitis possibly in the context of biologic therapy.

The therapeutic approach consisted in corticosteroid therapy tapered over a three-months course which successfully led to the remission of the intestinal symptoms without causing a flare-up of the cutaneous disease. The patient was switched to an IL-23 inhibitor, namely Risankizumab, which has proven to be efficacious in inducing and maintaining clinical remission of inflammatory bowel diseases, while being an excellent therapeutic option for psoriasis, with an optimal administration – subcutaneously, every twelve weeks.

Conclusion:

It is well-known that psoriasis predisposes to a variety of concomitant disorders, inflammatory bowel diseases

included. Our case report aids in increasing awareness on the importance of closely monitoring psoriasis patients for the appearance of additional symptoms, as well as on the necessity of a multidisciplinary approach, thus ensuring a personalized medical care for each case.

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Abstract N°: 2094

Impact of Treatment With Guselkumab on Skin-related Quality of Life in Male and Female Patients with Moderate-to-severe Psoriasis: Results from the VOYAGE 1 and 2 Trials

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Introduction & Objectives: The team evaluated the impact of treatment with guselkumab (GUS) on health-related quality of life due to psoriasis (PsO-HRQoL) in males and females with moderate-to-severe disease in the pooled VOYAGE 1 and VOYAGE 2 trials.

Materials & Methods: In total, 1810 males (n=1289) and females (n=521) receiving GUS (Week [W]0, W4, then every 8W); placebo (PBO: W16àGUS); or adalimumab (ADA) had baseline and W16 Dermatology Life Quality Index (DLQI). The DLQI evaluated PsO-HRQoL (score range 0–30, where ≤1 represented no impact and ≥5-point reduction defined clinically meaningful improvement). The Psoriasis Area and Severity Index (PASI) evaluated disease severity (range 0–72, 3 baseline severity groups: ≥12–<20/≥20–<30/≥30). Descriptive post-hoc analyses were performed for male and female subgroups.

Results: At baseline, a very large effect of psoriasis on PsO-HRQoL was found in males and females, (mean DLQI 13.90 and 15.85, respectively). Both groups reported increasing PsO-HRQoL impact with increasing PASI severity (males/baseline:12.3/14.7/17.5; females/baseline:14.5/17.7/17.8); greater impact was shown in females vs males with PASI≥12 through PASI<30. At W16, GUS-treated patients achieved greater improvements from baseline vs PBO (males/GUS:13.8à2.8, PBO:14.2à12.2; females/GUS:16.0à3.2, PBO:14.7à13.1). Percent patients achieving DLQI ≤1 at W16 who had DLQI >1 at baseline was greater for GUS vs PBO patients: males/W16:55.3% vs 3.3%; females/W16:55.5% vs 5.0%. A minimal 5-point meaningful improvement was reported at W16 for GUS vs PBO males (90.7% vs 33.5%) and females (92.9% vs 30.8%).

Conclusion: In the VOYAGE trials, females reported a higher impact in PsO-HRQoL at baseline. After treatment with GUS, meaningful improvements in PsO-HRQoL were seen in both groups despite baseline differences between sexes.

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Abstract N°: 2146

Palmoplantar pustulosis and Acrodermatitis continua of Hallopeau successfully treated with Risankizumab: a case series

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Introduction & Objectives: Palmoplantar pustulosis (PPP) is a variant of pustular psoriasis, distinguished in two clinical subtypes: localized disease with palmoplantar involvement, and acrodermatitis continua of Hallopeau (ACH), a peculiar subset involving the nail apparatus. These conditions can be painful and disabling, with a strongly negative impact on patients' quality of life. Moreover, treatment of PPP is challenging since the disease is often refractory to conventional therapies. Although it is well established that IL-36 plays a pivotal role in the development of pustular psoriasis, IL-36 and IL-23 pathways closely interact and extensively crosstalk, so dysregulation of either pathway can sustain inflammatory cycle and pustular manifestations. Risankizumab is a humanized IgG monoclonal antibody that targets the p19 subunit of IL-23, but literature data on its use in PPP and ACH are extremely scarce. We report 2 cases of PPP and 1 case of ACH successfully treated with Risankizumab.

Materials & Methods: The assessment tools used were PPPASI (Palmoplantar Pustular Psoriasis Area and Severity Index); sPGA (static Physician's Global Assessment) and DLQI (Daily Life Quality Index).

Results: Case 1: 44-year-old woman with moderate-to-severe plaque psoriasis resistant to treatment with cyclosporine and methotrexate (MTX) started therapy with Ixekizumab, showing complete remission of plaque psoriasis but developing PPP manifestations as a paradoxical reaction at week 16. We decided a switch to Risankizumab. The patient reached complete remission of PPP at week 56 of treatment, maintained at week 156. Case 2: A 65-year-old woman with a history of PPP for 7 years, resistant to cyclosporine, and psoriatic arthropathy for 5 years, unsuccessfully treated with Adalimumab, started therapy with ixekizumab + MTX 10 mg weekly. She persisted on therapy for more than two years, with partial remission of PPP and sufficient benefit on the joint component, until the development of Herpes Zoster Virus reactivation that led to discontinuation of both treatments. The 3-month discontinuation of treatment resulted in reactivation of the palmoplantar manifestations. Therapy with ixekizumab + MTX was resumed, this time without efficacy and with progressive worsening of PPP manifestations. We decided to switch to risankizumab, maintaining MTX 10 mg weekly, observing a complete palmoplantar resolution at week 24, maintained at week 52, and good control of joint symptoms. Case 3: A 33-year-old male with ACH of the toes and plantar pustulosis, resistant to treatment with cyclosporine and acitretin, started Risankizumab therapy with improvement of the pustular component since week 20; by week 64, plantar remission was complete, with only nail involvement persisting, until complete plantar and nail remission was achieved at week 92 and maintained at week 128.

Conclusion: PPP and ACH often represent a therapeutic challenge; Risankizumab in our experience demonstrated to be an effective and safe option in the short and long-term management.**

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Abstract N°: 2164

Bimekizumab in severe refractory psoriasis in special locations and psoriatic arthritis.

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Introduction & Objectives:

Materials & Methods:

Results:

Case 1: 61-year-old woman with severe plaque psoriasis with nails, folds and scalp involvement, peripheral psoriatic arthritis, and several episodes of erythroderma. She has been treated with phototeraphy PUVA and UVBBE; methotrexate (chronic hepatotoxicity); cyclosporine (acute nephrotoxicity), acitretin, etanercept, adalimumab, infliximab, ustekinumab, ixekizumab, secukinumab, brodalumab, risankizumab and guselkumab. All discontinued due to primary or secondary therapeutic failure. She started bimekizumab with PASI (Psoriasis Area and Severity Index) 19.8, BSA (Body Surface Area) 23 and DLQI (Dermatology Life Quality Index) 2. After 4 weeks she had almost complete clearance of all lesions with adequate control of the arthritis. At 16 weeks she continued with PASI 1, BSA 1 and DLQI 0, without adverse effects.

Case 2: 33-year-old woman with obesity, chronic hepatitis B virus infection under treatment with tenofovir. She had severe plaque psoriasis with nail, fold, palmoplantar and scalp involvement and peripheral psoriatic arthritis. She has been treated with adalimumab, secukinumab, ixekizumab and guselkumab, with poor primary response. Bimekizumab was started with PASI 26 and BSA 29. After 6 weeks she presented complete response, remaining stable and without adverse effects at 16 weeks.

Case 3: 59-year-old male with a personal history of overweight, arterial hypertension, dyslipidemia and severe plaque psoriasis predominantly on elbows, arms, legs and nails since he was 25 years old, without arthritis. He has been treated with phototeraphy; cyclosporine (discontinued due to elevated blood pressure) and adalimumab (secondary failure). Bimekizumab was started with PASI 16, BSA 33 and DLQI 2. He had complete clearance of all lesions after 3 weeks and he continued with complete response without adverse effects after 16 weeks.

Bimekizumab is a biologic agent recently approved for moderate-severe plaque psoriasis. It has a novel mechanism of action with dual inhibition of IL-17A and IL-17F. It is postulated that IL-17F is involved in the pathogenesis of psoriasis, being found at high levels in plaques. Most of the available data on bimekizumab are from clinical trials, where superior efficacy has been observed with a similar safety profile compared to other biologics like ustekinumab, adalimumab and secukinumab (BE VIVID, BE SURE, BE RADIANT). However, the clinical trials do not reflect patients in daily practice as the inclusion and exclusion criteria are more restrictive.

Conclusion:

We present our experience with bimekizumab in 3 patients with different comorbidities, involvement of special locations such as folds, palms, soles, scalp and nails and psoriatic arthritis. In addition, two of these patients had presented failure to different classes of biologics. In all of them there was an excellent response with bimekizumab, maintained at 16 weeks, as well as a rapid onset of action that begins in the first 3-4 weeks.

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Abstract N°: 2213

Ixekizumab and brodalumab indirect comparison for the treatment of moderate-to-severe psoriasis: a single-center real-life retrospective study

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Introduction & Objectives: Eleven different biologic drugs are currently approved for psoriasis management. Even if several data have been reported in clinical trials, real-life studies are required to guide clinicians in choosing a tailored-tail therapy in order to reach the goal of the right treatment for the right patient at the right moment. The aim of our retrospective real-life study is to indirectly compare the effectiveness and safety of ixekizumab and brodalumab in patients affected by moderate-to-severe psoriasis.

Materials & Methods: A retrospective study was carried out enrolling moderate-to-severe psoriatic patients receiving biologic treatment with brodalumab or ixekizumab. For each patient, clinical and demographic data were collected, and the efficacy and safety of the investigated drugs were evaluated at weeks 4, 12, and 24. Psoriasis Area Severity Index (PASI) and Body Surface Area (BSA) were used to assess psoriasis severity.

Results: Globally, 139 patients were enrolled in the study. Among these, 98 (70.5%) and 41 (29.5%) patients received ixekizumab and brodalumab, respectively. Mean PASI and BSA significantly reduced at each follow up for both groups. Ixekizumab reached higher rates of PASI90 and PASI100 than brodalumab (PASI90: 43.8% vs. 39.0% PASI100: 20.4% vs. 17.1% at week4 and PASI90: 83.6% vs. 75.6% PASI100: 71.5% vs. 60.9% at week24), without statistically significance. Adverse events, mainly mild, were registered in 25.5% of ixekizumab and 26.8% of brodalumab group, respectively. Discontinuation rate was higher for brodalumab (17.1% vs. 9.1%), without statistical significance.

Conclusion: Our study showed a comparable profile in terms of effectiveness and safety for ixekizumab and brodalumab.

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Abstract N°: 2233

UBE2L3 reduces interleukin-1β secretion in epidermal keratinocytes and deficiency of UBE2L3 results in spontaneous psoriasis-like dermatitis

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Introduction & Objectives:

Psoriasis is a chronic, complex immune-mediated inflammatory disorder with cutaneous and systemic manifestations in which keratinocytes, dendritic cells and T cells have central roles.** Proinflammatory cytokines, such as interleukin-1 beta (IL-1β), are important mediators of psoriasis. Ubiquitin conjugating enzyme E2 L3 (UBE2L3), an E2 enzyme, is thought to be an indirect target of IL-1β secretion by binding to ubiquitin ligases (E3s) such as tripartite motif-containing protein 21 (TRIM21). However, its role in the psoriasis remains unknown.

Materials & Methods:

Multi-color flow cytometry, immunochemistry, immunofluorescence, western blot, Elisa and si-RNA was used to analyze the relationship between UBE2L3 and IL-1β in the epidermis of psoriasis. *Ube2l3* conditional knockout mouse models were established to found the role of Ube2l3 in epidermis of psoriasis.

Results:

In this study, we found that UBE2L3 expression was decreased in psoriatic epidermis, while cysteine-aspartic acid protease 1 (Casp1) and IL-1β signaling were strongly activated. When normal human epidermal keratinocytes (NHEKs) were stimulated with nigericin, adenosine triphosphate (ATP) and poly(dA:dT), downregulation of UBE2L3 and increased secretion of IL-1β were observed. Treatment with a Casp1 inhibitor reversed the decrease in the level of UBE2L3. In addition, UBE2L3 overexpression reduced its binding with TRIM21, decreased STAT3 pathway activity and reduced the level of the IL-1β precursor (pro-IL-1β). Consistently, silencing UBE2L3 enhanced TRIM21 expression, STAT3 activation and pro-IL-1β production. Finally, in an imiquimod-induced mouse model, UBE2L3 reduction and Casp1 activation were localized in the epidermis, while overexpression of UBE2L3 ameliorated psoriasis-like lesions, reduced pro-IL-1β and mature IL-1β levels in the epidermis. Mice with epidermal deficiency of Ube2l3 results in spontaneous psoriasis-like skin disease.

Conclusion:

Thus, UBE2L3 may be a protective biomarker that regulates IL-1β and inhibits TRIM21 in the epidermis of psoriasis.

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Abstract N°: 2254

Characteristic of clinical and dermoscopic features in nail psoriasis patients

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Introduction: Nail psoriasis is one of the clinical manifestations of psoriasis besides the skin. Skin manifestations are the most characteristic findings of psoriasis. However, nail involvement is an often-overlooked clinical symptom of the diseases. While the prevalence of nail psoriasis is high, data on the basic epidemiology and clinical characteristics of nail psoriasis are scarce. Nail involvement includes that nail bed and nail matrix changes. Nail bed changes include oil drops (salmon patch), onycholysis, subungual hyperkeratosis, and splinter hemorrhage. Nail matrix changes are pitting, leukonychia, red spots in the lunula, and crumbling. Recently, dermoscopy has been recognized as an effective tool in the diagnosis and a helpful tool for better visualization of nail diseases. In this study, we investigated detailed nail features and dermoscopic features among patients with nail psoriasis.

Materials & Methods: This was a descriptive study with a cross-sectional approach that involved 207 nail psoriasis subjects. This study was conducted in the Polyclinic of Dermatology and Venereology Department of Haji Adam Malik General Hospital and Universitas Sumatera Utara Hospital Medan. It included a consecutive sampling method involving psoriasis patients who have nail disorders. Only the clinically visible psoriatic fingernails were selected, and toenails were excluded because of anticipated gross nail dystrophies due to trauma and other causes that could interpret with clinical and dermoscopic evaluation. All the participants gave written informed consent. Psoriasis patients who had nail disorders caused by dermatological diseases and systemic diseases were excluded from the study. Demographic variables (age and sex) were recorded. All samples were obtained by examining subjects, which included assessing clinical features of nail psoriasis and dermoscopic features of nail psoriasis. The collected data were tabulated descriptively to see the frequency distribution of the characteristics based on the manifestations of nail psoriasis by clinical features and dermoscopic features.

Results: There was a total of 207 nail psoriasis, including 156 (75.4%) male and 51 (24.6%) female. The mean age of subjects was 43.87±13.98 years, ranged from 19 to 76 years. The most common nail change in our study was nail pitting (69.1%), followed by onycholysis (60.9%), splinter hemorrhage (17.9%), leukonychia (15.5%), crumbling (11.1%), and oil drops (salmon patch) (7.2%). The least nail changes included a red spot in the lunula and subungual hyperkeratosis (1.4%). The most common dermoscopic findings of nail psoriasis in our study included onycholysis (78.3%), pitting (77.8%), splinter hemorrhage (27.5%), leukonychia (16.4%), crumbling (13.5%), oil drops (salmon patch) (13.5%), red spot in the lunula (2.4%), and subungual hyperkeratosis (1.9%).

Conclusion: We observed psoriasis patients who have nail disorders.** Nail pitting, onycholysis, and splinter hemorrhage occupied the top three common nail changes in psoriatic patients in our study. The most common dermoscopic findings included onycholysis, pitting, and splinter hemorrhage. Dermoscopy in nail psoriasis can be a helpful guide to assess nail abnormalities, there are several clinical nail psoriasis that can visualize the subtle changes in the nail plate such as onycholysis. This study presents preliminary evidence for the use of dermoscopy as a first step in the diagnosis of nail psoriasis.

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Abstract N°: 2294

HB0034, a novel anti-IL-36R inhibitor, showed a promising efficacy in controlling acute GPP flare

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Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a potentially life-threatening rare skin disease with significant unmet clinical needs. With an understanding of its pathogenesis, abnormal IL-36/neutrophil axis has been identified as a central driver of GPP. Our novel anti-IL-36R antibody, also known as HB0034, was being developed to treat GPP and showed a favorable safety and promising efficacy in early clinical studies.

Materials & Methods:

HB0034 was studied in a first-in-human, single dose-escalation study to evaluate the safety, tolerability, and pharmacokinetic (PK) in healthy volunteers. HB0034 was further evaluated in a multicenter, single-arm, open-label, phase Ib study to evaluate the safety and efficacy in controlling the moderate-to-severe acute GPP flare patients who received single dose of HB0034. Up to Apir 28th 2023, three patients were dosed and completed week 4 visit.

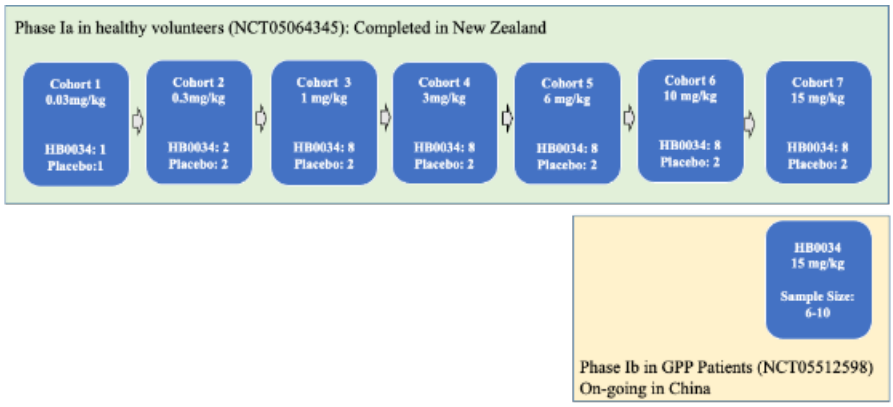

Figure 1. The design of Phase Ia and Phase Ib study of HB0034

Results:

Safety and Pharmacokinetics: Phase Ia study

44 subjects were administered HB0034 and 12 subjects were administered matching placebo. A total of 95 TEAEs were reported by 44 (78.6%) subjects who received any dose of HB0034 or placebo. Almost all TEAEs are mild, with the exception of two cases. No discernible correlation was observed between the incidence of TEAEs and the dosage administered. No deaths, serious, or severe TEAEs were reported during the study (Table 1). The clearance of HB0034 at all dose levels exhibited linear PK properties and the effective half-life of HB0034 is approximately

21-day (Figure 2).

	All Placebo (N=12) n (%) E	HB0034 0.03 mg/kg (N=1) n (%) E	HB0034 0.3 mg/kg (N=3) n (%) E	HB0034 1 mg/kg (N=8) n (%) E	HB0034 3 mg/kg (N=8) n (%) E	HB0034 6 mg/kg (N=8) n (%) E	HB0034 10 mg/kg (N=8) n (%) E	HB0034 15 mg/kg (N=8) n (%) E	Overall (N=56) n (%) E
TEAEs	9 (75.0) 25	1 (100) 2	3 (100) 4	8 (100) 20	7 (87.5) 14	4 (50.0) 7	5 (62.5) 10	7 (87.5) 13	44 (78.6) 95
Drug-related TEAEs	2 (16.7) 2	0	0	1 (12.5) 1	2 (25.0) 3	1 (12.5) 1	1 (12.5) 1	0	7 (12.5) 8
Severe TEAEs	0	0	0	0	0	0	0	0	0
Serious TEAEs	0	0	0	0	0	0	0	0	0
TEAEs Leading to Study Discontinuation	0	0	0	0	0	0	0	0	0
TEAEs Leading to Death	0	0	0	0	0	0	0	0	0

Table 1. Summary of Treatment Emergent Adverse Events in Phase Ia Study

N: Number of subjects dosed; n (%): Number and percent of subjects with TEAEs;

TEAE: Treatment-emergent adverse event; E: Event.

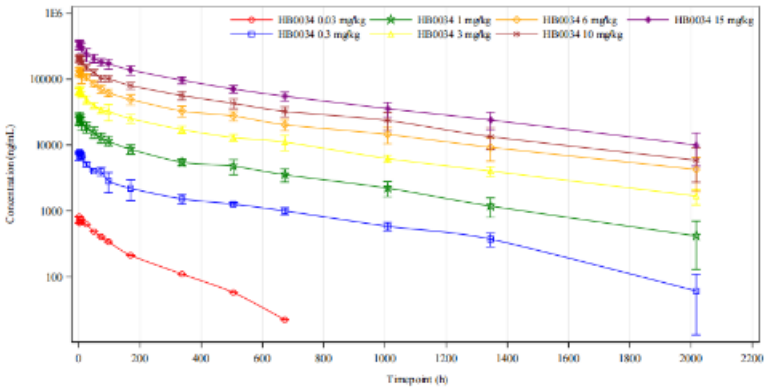

Figure 2. Mean HB0034 Serum Concentrations by Treatment (Semi-Log Scale)

Preliminary Clinical Efficacy: Phase Ib study

2(66.7%) patients achieved GPPGA 0/1(clear or almost clear) at week 1. 2(66.7%) patients achieved GPPGA pustulation subscore 0 (no visible pustules) at week 2 and week 4. GPPASI, BSA, JDA index score, PSS, DLQI and CRP were all significantly improved (Table 2). In addition,the safety was acceptable in GPP patients.

Table 2. Preliminary Efficacy of HB0034 in managing GPP flare

	Week 1	Week 2	Week 4
GPPGA 0/1*, n (%)	2(66.7)	1(33.3)	1(33.3)
GPPGA pustulation subscore 0*, n (%)	1(33.3)	2(66.7)	2(66.7)
GPPASI percentage change from baseline, mean %	- 75.17	-74.42	-72.12
Improvement in BSA of erythema with pustules, mean %	98.68	100	100
JDA index score Change from baseline, mean	- 4.5	- 6	- 6.5
PSS score change from baseline, mean	- 6.5	- 8	- 6.5
DLQI score change from baseline, mean	-7	-19.5	20.5
CRP percentage change from baseline, mean %	-72.68	-94.70	-89.55

GPPGA: Generalized Pustular Psoriasis Area and Severity Index; GPPGA: Generalized Pustular Psoriasis Physician Global Assessment; JDA: Japanese Dermatological Association; PSS: Psoriasis Symptom Scale; DLQI: Dermatology Life Quality Index.

*Patient 2 was classified as non-responsive since he received rescue treatment on Day 4 and declined to undergo disease assessments from Day 6.

Conclusion:

HB0034 demonstrated favorable safety, and PK properties in Phase Ia study. Preliminary results from on-going Phase Ib study showed promising efficacy in controlling the GPP flare and improving quality of life. However, further studies are required to determine the clinical efficacy, duration of effect, and adverse events associated with the drug.

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Abstract N°: 2312

Characteristic of clinical and dermoscopic features in nail psoriasis patients

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Introduction: Nail psoriasis is one of the clinical manifestations of psoriasis besides the skin. Skin manifestations are the most characteristic findings of psoriasis. However, nail involvement is an often-overlooked clinical symptom of the disease. While the prevalence of nail psoriasis is high, data on the basic epidemiology and clinical characteristics of nail psoriasis are scarce. Nail involvement includes that nail bed and nail matrix changes. Nail bed changes include oil drops (salmon patch), onycholysis, subungual hyperkeratosis, and splinter hemorrhage. Nail matrix changes are pitting, leukonychia, red spots in the lunula, and crumbling. Recently, dermoscopy has been recognized as an effective tool in the diagnosis and a helpful tool for better visualization of nail diseases. In this study, we investigated detailed nail features and dermoscopic features among patients with nail psoriasis.

Materials & Methods: This was a descriptive study with a cross-sectional approach that involved 207 nail psoriasis subjects. This study was conducted in the Polyclinic of Dermatology and Venereology Department of two Hospitals. It included a consecutive sampling method involving psoriasis patients who have nail disorders. Only the clinically visible psoriatic fingernails were selected, and toenails were excluded because of anticipated gross nail dystrophies due to trauma and other causes that could interpret with clinical and dermoscopic evaluation. All the participants gave written informed consent. Psoriasis patients who had nail disorders caused by dermatological diseases and systemic diseases were excluded from the study. Demographic variables (age and sex) were recorded. All samples were obtained by examining subjects, which included assessing clinical features of nail psoriasis and dermoscopic features of nail psoriasis. The collected data were tabulated descriptively to see the frequency distribution of the characteristics based on the manifestations of nail psoriasis by clinical features and dermoscopic features.

Results: There was a total of 207 nail psoriasis, including 156 (75.4%) male and 51 (24.6%) female. The mean age of subjects was 43.87±13.98 years, ranging from 19 to 76 years. The most common nail change in our study was nail pitting (69.1%), followed by onycholysis (60.9%), splinter hemorrhage (17.9%), leukonychia (15.5%), crumbling (11.1%), and oil drops (salmon patch) (7.2%). The least nail changes included a red spot in the lunula and subungual hyperkeratosis (1.4%). The most common dermoscopic findings of nail psoriasis in our study included onycholysis (78.3%), pitting (77.8%), splinter hemorrhage (27.5%), leukonychia (16.4%), crumbling (13.5%), oil drops (salmon patch) (13.5%), red spot in the lunula (2.4%), and subungual hyperkeratosis (1.9%).

Conclusion: We observed psoriasis patients who have nail disorders.** Nail pitting, onycholysis, and splinter hemorrhage occupied the top three common nail changes in psoriatic patients in our study. The most common dermoscopic findings included onycholysis, pitting, and splinter hemorrhage. Dermoscopy in nail psoriasis can be a helpful guide to assess nail abnormalities, there are several clinical nail psoriasis that can visualize the subtle changes in the nail plate such as onycholysis. This study presents preliminary evidence for the use of dermoscopy as a first step in the diagnosis of nail psoriasis.

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Abstract N°: 2332

Efficacy and safety of a small molecule with innovative inhibition of TNFR1 signalling in plaque psoriasis: A double-blind, randomized, placebo-controlled study

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Introduction & Objectives: Tumor necrosis factor (TNF) is an inflammatory cytokine involved in the pathogenesis of psoriasis. SAR441566 is an orally administrated small molecule that selectively inhibits TNF signaling through the TNF receptor 1 (TNFR1). In contrast to injectable TNF inhibitors, SAR441566 preserves signalling through TNF receptor 2 (TNFR2), a pathway that plays a role in immune homeostasis, regulatory T- cell expansion and function, tissue regeneration, and host defence against pathogens. This proof of mechanism study in adults with mild-to-moderate plaque psoriasis evaluated the safety, tolerability, and clinical response of SAR441566 compared to placebo through 4-weeks of treatment.

Materials & Methods: This phase 1, double-blind, placebo-controlled study evaluated male participants with chronic mild-to-moderate plaque psoriasis with at least two lesions of a Target Lesion Severity Score (TLSS) >4 at baseline. Patients were randomized 2:1 to SAR441566 200 mg twice a day (BID) or placebo for 4 weeks. Clinical efficacy was evaluated using the percent change from baseline to Week 4 in Psoriasis Area and Severity Index (PASI) and TLSS.

Results: A total of 38 male participants with comparable demographic characteristics were randomized; 26 participants received oral SAR441566 and 12 received placebo (**Table 1**). Patients who received SAR441566 had a statistically significant improvement from baseline in PASI compared to those who received placebo at Week 2 (17.73% versus 4.12%, p= 0.005) and Week 4 (35.09% versus 15.71%, p=0.009) (adjusted mean % improvement from baseline, p-value for one-sided test at 5% significance level) (**Figure 1**). Consistent with these findings, patients who had received SAR441566 also had a significant improvement in TLSS compared to placebo at Week 2 (17.06% versus 6.29%, p= 0.032) and Week 4 (38.18% versus 20.44%, p= 0.012) (**Figure 1**). Furthermore, separate analyses of patients with mild (PASI<10) or moderate psoriasis (PASI≥10 and <16) at baseline demonstrated improvement for SAR441566 versus placebo at Week 2 (mild: 20.9% vs 8.5%; moderate: 10.9% vs 0%) and Week 4 (mild: 37.0% vs 22.3%; moderate: 39.7% vs 15.0%), despite disease severity. Treatment with 200 mg BID of SAR441566 over 28 days was safe and well-tolerated, with no serious adverse events (AEs), severe treatment emergent AEs or AE of special interest (AESI) being reported.

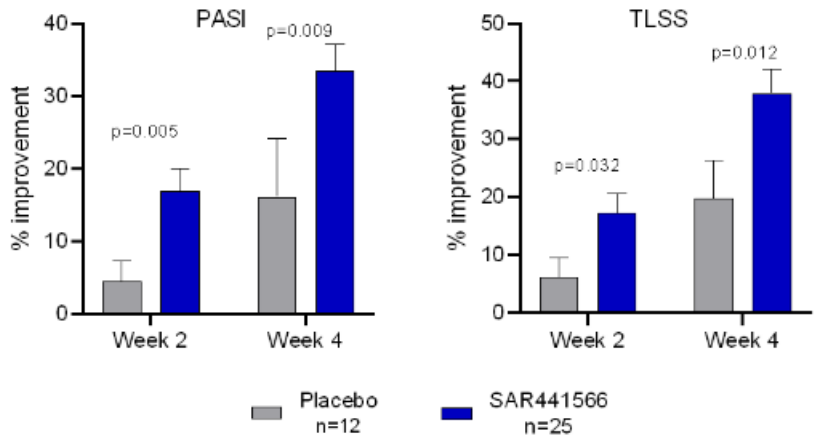
Conclusion: SAR441566, a specific inhibitor of TNFR1 signalling, demonstrated clinical efficacy in mild-to-moderate psoriasis over a 4-week treatment period. This novel oral therapy was safe and well-tolerated. The results support the mechanism of action of SAR441566, a small molecule inhibitor of TNFR1 signalling and warrants further clinical evaluation in psoriasis. **Keywords:** psoriasis, TNF inhibitor, TNF, Clinical trial

Table 1: Demographics and Baseline Characteristics

Baseline Characteristics	Placebo (n=12)	SAR441566 (n=26)
Age, mean (±SD), years	40.5 (12.5)	44.2 (9.7)
BMI, mean (±SD), kg/m^2	25.98 (2.92)	26.45 (2.97)
TLSS, mean (±SD)	7.42 (1.40)	6.83 (1.60)
PASI, mean (±SD)	7.86 (2.53)	8.91 (3.73)
PASI score, n (%)		
< 10 (mild psoriasis)	8 (66.7)	17 (65.4)
≥ 10 and <16 (moderate psoriasis)	4 (33.3)	9 (34.6)

Figure 1: PASI and TLSS improvement from baseline to week 2 and 4.

Adjusted mean % improvement from baseline using a Mixed Model with Repeated Measurement with SE and p-value. p-value for one sided test comparing the adjusted means of the two groups, SE=standard error, PASI=Psoriasis Area and Severity Index, TLSS=Target Lesion Severity score



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Abstract N°: 2354

Ixekizumab Trough Concentrations in Psoriasis: Paving the Way towards Personalized Therapy - A Cohort Study

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Introduction & Objectives: biologics for psoriasis demonstrate varying clinical outcome in daily practice, implying potential under- and over exposure.

In this study, we aimed to: 1) develop and validate an IXE in-house sandwich-type enzyme-linked immunosorbent assay (ELISA), 2) explore whether there is an exposure-response relationship for ixekizumab (IXE) in psoriasis patients, and 3) to evaluate whether patient factors influence IXE exposure and clinical outcome.

Materials & Methods: this was a prospective, multicentric, real-world cohort study (BIOLOPTIM-IXE) that included adult psoriasis patients treated with IXE according to standard dosing regimen (80 mg every 4 weeks). Blood samples were collected right before the next scheduled drug administration to measure the IXE trough concentration (TC). Disease activity was assessed at the same day as the blood sampling by Psoriasis Area and Severity Index (PASI). Optimal and suboptimal clinical response were defined as an absolute PASI ≤ 2 and > 2, respectively. Scatterplots, Spearman rank correlations, boxplots, and Mann-Whitney U tests were used for exploratory analysis. Receiver operator characteristic analysis and index of union were used to determine an optimal threshold IXE TC at steady-state.

Results: using MA-IXE117E12 and MA-IXE100F5-biotin as the capture and detection antibodies, respectively, an ELISA was developed with an exposure-response curve ranging from 10 ng/mL to 0.16525 ng/mL. One hundred fifteen serum samples collected throughout steady-state (≥ 22 weeks of treatment) from 48 patients (17 [35.4%] bio-experienced; median body weight, 81.5 [range, 70.0-92.8] kg) were included. Median cohort IXE TC was 4.1 [2.8-6.1] µg/mL. Patients with optimal response (PASI ≤ 2) had significantly higher TCs than subjects with suboptimal response (PASI > 2) (median TCs, 4.4 µg/mL and 3.0 µg/mL, respectively; P = 0.026). An optimal effective steady-state IXE TC of 3.4 µg/mL was identified for clinical outcome defined by absolute PASI. Median TCs and absolute PASI were significantly lower and worse, respectively, in patients weighing ≥ 90 kg (P < 0.001 and P = 0.013, respectively) and in biologic experienced subjects (P < 0.001 and P = 0.029, respectively).

Conclusion: These results suggest an exposure-response relationship for IXE in standard maintenance dose in real-world, adult psoriasis patients, and propose an optimal effective steady-state TC of 3.4 µg/mL, revealing the potential role of therapeutic drug monitoring in optimizing IXE use.

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Abstract N°: 2360

Healthcare Resource Utilization and Costs Among Patients with Generalized Pustular Psoriasis: A US Claims Analysis

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Introduction & Objectives: Generalised pustular psoriasis (GPP) is a rare, chronic, neutrophilic skin disease that is clinically and genetically distinct from plaque psoriasis (PsO). GPP is characterised by recurring flares of widespread erythema, oedema, coalescing pustules, and possible systemic symptoms. GPP flares recur throughout a patient's lifetime, may require hospitalisation, and can be life-threatening. There are limited data to describe the healthcare resource utilisation (HCRU) and costs incurred by patients with GPP. This analysis compared all-cause HCRU and all-cause cost between patients with GPP, patients with PsO, and patients with co-morbid GPP+PsO.

Materials & Methods: Inovalon Insights real-world claims data was used to identify four cohorts (All GPP, GPP with comorbid PsO [GPP+PsO], GPP Only, and PsO) based on the International Classification of Diseases, Tenth Revision (ICD-10) codes over a 4-year period (Jan 1, 2016 to Dec 31, 2019). GPP Only, GPP+PsO, and PsO were mutually exclusive cohorts. All GPP was defined as GPP Only (excluding PsO) and GPP+PsO cohorts together. After index, patients were followed until censoring or the end of the study period. Greedy propensity score matching was used to match cohorts 2:1 (PsO:GPP). All-cause HCRU and all-cause cost outcomes were split into 4 categories each: inpatient, emergency room (ER), office, and outpatient visits; and total cost, inpatient/ER costs, outpatient/office costs, and prescription costs. Adjusted mean all-cause HCRU and all-cause costs were calculated using a binomial regression model adjusted for index year, age, sex, payer type, region, and Charlson Comorbidity Index (CCI). Adjusted mean difference was calculated by subtracting adjusted means.

Results: The GPP cohort had higher CCI scores compared to the PsO cohort (Table 1). The All GPP and GPP+PsO cohorts had significantly more all-cause inpatient stays, ER visits, office visits, and outpatient visits over the study period compared to the PsO cohort. While the GPP Only cohort had significantly more all-cause inpatient stays, ER visits, and outpatient visits over the study period compared to the PsO cohort, there was no significant difference in the mean number of office visits (Table 2). The All GPP and GPP+PsO cohorts had significantly higher inpatient/ER costs and outpatient/office costs compared to the PsO cohort; however, prescription costs were not significantly different. Total all-cause costs were significantly higher for the GPP+PsO cohort than the PsO cohort. All-cause outpatient/office costs were significantly higher for GPP Only compared to the PsO cohort, however, all-cause total costs and all-cause prescription costs were significantly lower. There was no significant difference in all-cause inpatient/ER costs for the GPP Only cohort compared to PsO only (Table 3).

Conclusion: The GPP cohorts in this analysis experienced higher all-cause HCRU compared to the PsO cohort. Relative to the PsO cohort, the All GPP and GPP+PsO cohorts had higher inpatient/ER costs. However, the GPP Only cohort had lower all-cause total costs, primarily driven by lower all-cause prescription costs. This is possibly due to a lack of approved GPP treatments and use of older generic drugs to treat GPP in the US during the study period and limitations of the dataset in capturing discharge diagnoses. Nonetheless, this analysis fills an important gap in the existing literature, highlighting the unmet need and economic burden among GPP cohorts.

Table 1. Unmatched Cohort Demographics

Variable	GPP Only	Comorbid GPP+PsO	All GPP	PsO Only
N	1,246	1,384	2,630	127,540
Index Year				
2016	520 (41.7%)	618 (44.7%)	1,138 (43.3%)	57,234 (44.9%)
2017	259 (20.8%)	333 (24.1%)	592 (22.5%)	30,043 (23.6%)
2018	260 (20.9%)	233 (16.8%)	493 (18.7%)	22,926 (18.0%)
2019	207 (16.6%)	200 (14.5%)	407 (15.5%)	17,337 (13.6%)
Gender; n (%)				
Female	776 (62.3%)	867 (62.6%)	1,643 (62.5%)	67,548 (53.0%)
Male	470 (37.7%)	517 (37.4%)	987 (37.5%)	59,992 (47.0%)
Insurance Type; n (%)				
Commercial	683 (54.8%)	795 (57.4%)	1,478 (56.2%)	93,308 (73.2%)
Medicaid	376 (30.2%)	430 (31.1%)	806 (30.6%)	21,910 (17.2%)
Medicare Advantage	187 (15.0%)	159 (11.5%)	346 (13.2%)	12,322 (9.7%)
Region; n (%)				
Midwest	334 (26.8%)	337 (24.3%)	671 (25.5%)	36,928 (29.0%)
Northeast	256 (20.5%)	279 (20.2%)	535 (20.3%)	27,179 (21.3%)
South	457 (36.7%)	533 (38.5%)	990 (37.6%)	38,963 (30.5%)
West	199 (16.0%)	235 (17.0%)	434 (16.5%)	24,470 (19.2%)
Age at Index				
Mean (SD)	53.9 (17.4)	52.9 (16.4)	53.3 (16.9)	50.8 (16.6)
Age Group; n (%)				
18-24	28 (2.2%)	38 (2.7%)	66 (2.5%)	6,923 (5.4%)
25-34	99 (7.9%)	115 (8.3%)	214 (8.1%)	13,114 (10.3%)
35-44	177 (14.2%)	226 (16.3%)	403 (15.3%)	21,330 (16.7%)
45-54	288 (23.1%)	326 (23.6%)	614 (23.3%)	30,512 (23.9%)
55-64	446 (35.8%)	464 (33.5%)	910 (34.6%)	37,761 (29.6%)
65-74	139 (11.2%)	166 (12.0%)	305 (11.6%)	12,641 (9.9%)
75+	69 (5.5%)	49 (3.5%)	118 (4.5%)	5,259 (4.1%)
CCI (Total)				
Mean (SD)	1.48 (2.18)	1.53 (2.16)	1.51 (2.17)	0.94 (1.71)

Abbreviations: CCI: Charlson Comorbidity Index; GPP: generalised pustular psoriasis; PsO: plaque psoriasis; SD: standard deviation

Table 2. All-Cause Health Care Resource Utilization (Maximum Follow-up)

Comparison Populations	N	Mean Difference Per Patient*	IRR (95% CI)	P-Value
All GPP vs PsO				
Inpatient Stays	7,890	0.26	1.63 (1.45, 1.84)	**<0.001**
ER Visits		0.82	1.48 (1.36, 1.60)	**<0.001**
Office Visits		4.36	1.12 (1.06, 1.16)	**<0.001**
Outpatient Visits		4.74	1.51 (1.42, 1.62)	**<0.001**
Comorbid GPP+PsO vs PsO				
Inpatient Stays	4,152	0.25	1.65 (1.40, 1.93)	**<0.001**
ER Visits		0.87	1.54 (1.36, 1.72)	**<0.001**
Office Visits		11.13	1.28 (1.22, 1.36)	**<0.001**
Outpatient Visits		5.96	1.63 (1.49, 1.79)	**<0.001**
GPP Only vs PsO				
Inpatient Stays	3,738	0.29	1.72 (1.45, 2.05)	**<0.001**
ER Visits		0.65	1.36 (1.21, 1.54)	**<0.001**
Office Visits		-1.99	0.95 (0.90, 1.01)	0.090
Outpatient Visits		3.95	1.43 (1.30, 1.58)	**<0.001**

*Negative binomial regression controlled for index year, age, sex, insurance type, region, and CCI
Abbreviations: CCI: Charlson Comorbidity Index; CI: confidence interval; ER: emergency room; GPP: generalised pustular psoriasis; IRR: incidence rate ratio; PsO: plaque psoriasis

Table 3. All-Cause Cost

Comparison Populations	N	Mean Difference Per Member Per Month*	P-Value
All GPP vs PsO			
Total Costs	7,890	-$56	0.09
Inpatient/ER Costs	1,682	$278	**<0.001**
Outpatient/Office Visit Costs	7,812	$67	**<0.001**
Prescription Costs	3,345	-$171	0.12
Comorbid GPP+PsO vs PsO			
Total Costs	4,152	$117	**0.02**
Inpatient/ER Costs	883	$429	**<0.001**
Outpatient/Office Visit Costs	4,119	$111	**<0.001**
Prescription Costs	1,730	$126	0.47
GPP Only vs PsO			
Total Costs	3,783	-$310	**<0.001**
Inpatient/ER Costs	779	$22	0.551
Outpatient/Office Visit Costs	3,695	$33	**0.008**
Prescription Costs	1,605	-$609	**<0.001**

*Negative binomial regression controlled for index year, age, sex, insurance type, region, and CCI
Abbreviations: CCI: Charlson Comorbidity Index; ER: emergency room; GPP: generalised pustular psoriasis; PsO: plaque psoriasis

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Abstract N°: 2364

Single-cell RNA-seq reveals increased and activated post-capillary venule endothelial cells in erythrodermic psoriasis

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Introduction & Objectives:

Erythrodermic psoriasis (EP) is a life-threatening variant of psoriasis and vascular endothelial cells (ECs) is active participants in intercellular crosstalk of cutaneous inflammation. The study aimed to figure out the role of ECs in developing EP and provide promising targets for its therapy.

Materials & Methods:

Here, taking psoriasis vulgaris (PV) as a control, we explore vascular ECs characteristics in EP lesions by single-cell RNA-seq and immunofluorescence.

Results:

We exhibit single-cell transcriptional atlas of skin samples from 4 patients with EP and 2 with PV. Our results verified increased and activated ECs in EP, especially post-capillary venules (PCV) subpopulation with abundant gene expression relative to angiogenesis, leukocyte adhesion and antigen presentation. Functional analysis revealed that up-regulated genes in EP PCV involved in response to cytokine or hypoxia and cell growth. Trajectory analysis of ECs from EP indicated a more differentiated status dominated by PCV and CAP.1. Communication analysis identified more intensified interactions between PCV and other cells through VEGF and Notch signaling in EP. Both elevated and activated PCVs with intensified EGR1 were identified in biopsies from EP or PV with EP history.

Conclusion:

We provided a systematic analysis of EC heterogeneity in EP at single-cell resolution. In addition, we identified an increased and activated PCV subpopulation with rising EGR1 involved in adhesion molecules over-expression and angiogenesis in EP or PV with EP history.

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Abstract N°: 2369

Roflumilast foam 0.3% in patients with scalp and body psoriasis in the phase 3 ARRECTOR trial: Efficacy, patient-reported outcomes, and safety

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Roflumilast foam 0.3% in patients with scalp and body psoriasis in the phase 3 ARRECTOR trial: Efficacy, patient-reported outcomes, and safety

Introduction & Objectives: Roflumilast is a nonsteroidal, highly potent phosphodiesterase 4 inhibitor under investigation as a once-daily foam formulation for treatment of scalp and body psoriasis. A phase 3 randomized controlled trial (NCT05028582) was conducted in patients ≥12 years old with scalp and body psoriasis, minimum Scalp-Investigator Global Assessment (S-IGA) score of Moderate, and minimum Body-IGA (B-IGA) of Mild.

Materials & Methods: Eligible patients had an overall body surface area affected by psoriasis of ≤25% (including ≤20% for non-scalp areas, not including palms/soles). Patients were randomized 2:1 to apply roflumilast foam 0.3% (n=281) or vehicle (n=151) once-daily for 8 weeks. All affected body locations (and any new areas that developed during the study) were treated, including the scalp, face, trunk, and intertriginous areas. The co-primary efficacy endpoints were S-IGA and B-IGA Success (S-IGA/B-IGA of Clear [0] or Almost Clear [1] plus ≥2-grade improvement from baseline) at Week 8. Secondary endpoints included improvements in Psoriasis Area and Severity Index (PASI) and patient-reported outcomes including Scalp Itch-Numerical Rating Score (SI-NRS), Worst Itch-NRS (WI-NRS), and Psoriasis Symptom Diary (PSD).

Results: At Week 8, significantly more roflumilast- than vehicle-treated patients achieved S-IGA Success (66.4% vs 27.8%; P<0.0001), B-IGA Success (45.5% vs. 20.1%; P<0.0001), and PASI-75 (50.1% vs 16.8%; P<0.0001). Additionally, 40.0% and 27.8% of roflumilast-treated patients achieved S-IGA and B-IGA of Clear, respectively (P<0.0001; nominal for B-IGA). At Week 8, more patients treated with roflumilast than vehicle achieved WI-NRS Success, a ≥4 grade improvement in patients with baseline score ≥4 (63.1% vs 30.1%; P<0.0001), and SI-NRS Success (65.3% vs 30.3%; P<0.0001). Significant improvement in Least Squares (LS) mean change from baseline in SI-NRS was demonstrated at 24 hours after the first application (P=0.0164). More roflumilast- than vehicle-treated patients reported a PSD total score of 0 at Week 8 (19.6% vs 7.1%; P=0.0012) and a score of 0 for PSD items of severity of psoriasis-related scaling (41.5% vs 13.6%; P<0.0001), itch (31.7% vs 10.0%; P<0.0001), and pain (64.9% vs 40.3%; P<0.0001). A statistically significant greater reduction from baseline at Week 8 was observed for roflumilast- than vehicle-treated patients in the LS mean aggregate score of PSD items relating to

itch/pain/scaling severity (-10.87 vs -5.75; P<0.0001). Safety and local tolerability were favorable and rates of discontinuation of study drug due to adverse events were low and similar among patients treated with roflumilast (2.5%) and vehicle (1.3%).

Conclusion: Once-daily, nonsteroidal roflumilast foam 0.3% provided improvement across multiple efficacy endpoints, including patient-reported outcomes, while demonstrating favorable safety and local tolerability in patients with scalp and body psoriasis. Sponsored by Arcutis Biotherapeutics, Inc.

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Abstract N°: 2379

Successful treatment with bimekizumab of a psoriatic patient undergoing hemodialysis

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Successful treatment with bimekizumab of a psoriatic patient undergoing hemodialysis

Introduction & Objectives:

In the treatment of psoriasis patients, it is crucial to consider potential underlying complications/comorbidities as they could impact the selection of appropriate therapy. In this case, we present a patient with end-stage kidney disease (ESKD) who is undergoing hemodialysis (HD) and was effectively and safely treated with Bimekizumab. As far as we are aware, this is the first documented case of successful treatment with an anti-IL-17A/IL-17F antibody in a psoriasis patient undergoing HD.

Materials & Methods:

A 43-year-old man with a history of psoriasis presented to our outpatient clinic with a widespread rash that was unresponsive to topical treatment. The patient had been diagnosed with end-stage kidney disease due to hypertensive nephropathy about four years prior and was currently undergoing hemodialysis treatment three times per week at a separate facility and was awaiting organ transplantation. Physical examination revealed erythematous desquamative plaques on the upper and lower limbs with smaller lesions located on the trunk and back; the patient reported itching, while joint pain was not present (PASI: 11; BSA: 30; NRS pruritus: 6; NRS pain: 0; DLQI: 18). After ruling out infections and organ abnormalities through screening and consulting with the patient's nephrologist colleagues Bimekizumab a monoclonal antibody targeting IL-17A and IL-17F was prescribed. This decision was based on existing literature on other drugs in the same class, which showed positive outcomes and efficacy in treating psoriasis patients with similar comorbidities1,2,3,4.

Results:

Following the initial administration of the drug, the patient reported a significant improvement in pruritus (pNRS: 2) and a minor improvement in skin lesions (PASI: 4.4) after one week. One month later the patient achieved complete clearance of skin lesions and improvement in overall quality of life (PASI: 0; BSA: 0; NRS pruritus: 3; DLQI: 4). The patient's positive response to Bimekizumab therapy was sustained for eight months following the start of treatment, with no significant changes observed in renal function as assessed by regular evaluations performed by the patient's HD center. Studies show that drugs used to treat psoriasis have similar efficacy and safety in patients with chronic kidney disease compared to those with normal kidney function. Pharmacokinetics are also comparable. Furthermore, hemodialysis does not appear to significantly impact drug clearance in these patients5. Antibody-based drugs, such as Bimekizumab, are not expected to be cleared by hemodialysis or affected by renal impairment because these drugs are typically broken down through intracellular catabolism, which means their biological half-life is around 14 to 21 days, and they are not cleared through the kidney or liver. Secondly, biological agents are large, high molecular weight proteins that are unlikely to be cleared by HD due to their size3.

Conclusion:

This appears to be the first reported case of using Bimekizumab to treat psoriasis in patients undergoing dialysis. The results indicate that Bimekizumab may be effective for treating severe psoriasis in this population. However, additional cases and studies are needed to better understand the drug's safety and efficacy in this context.

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Abstract N°: 2409

Patient preference for cream or foam fixed-dose combination of calcipotriene (a vitamin D analog) and betamethasone dipropionate: Results of a split body and scalp study in patients with mild to moderate plaque psoriasis.

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Introduction & Objectives:

A topical fixed combination cream formulation of calcipotriene 0.005% (Cal) and betamethasone dipropionate 0.064% (BDP) is now available. Previously, only fixed combination ointment, foam and topical suspension/gel were available. The cream features a moisturizing aqueous base and a specialized multimolecular technology that encapsulates the active ingredients in oil droplets designed to allow efficient drug delivery.

This randomized, split-body study, in which subjects were blinded to brand names, was undertaken in 150 patients with mild to moderate plaque psoriasis to investigate comparative patient satisfaction between Cal/BDP foam and Cal/BDP cream formulations.

Materials & Methods:

Study cream was dispensed in measured fashion, and subjects applied it to an area on one side of the body and/or scalp. The study foam was similarly applied to the contralateral side.

Results:

Mean overall Vehicle Preference Measure (VPM) scores were higher for the cream than the foam ($p = 0.0043$), as were individual scores for ease of application, feeling to the touch, smell, and feeling on the skin ($p < 0.03$). With respect to overall satisfaction, the majority of subjects preferred the cream (55%), while 8% scored the cream and foam equally, and 37% preferred the foam.

Conclusion:

Results of this study suggest that patients may prefer Cal/BDP cream over Cal/BDP foam for the management of plaque psoriasis on the body and on the scalp. Cal/BDP cream outperformed Cal/BDP foam on mean overall and several individual scores of vehicle preference, and in overall satisfaction measures.

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Abstract N°: 2445

Secukinumab in treatment of moderate to severe psoriasis: skin condition and nail dystrophy within 12 weeks.

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Secukinumab in treatment of moderate to severe psoriasis: skin condition and nail dystrophy within 12 weeks.

I.Blaha, O.Aleksandruk

Introduction & Objectives: Psoriasis remains one of the most widespread diseases among chronic dermatoses. Chronic relapsing course of the disease, produced damage to the skin, nails, and joints require further investigations for treatment approach. In fact, immunobiological therapy allows obtaining significant and stable clinical results in patients with moderate and severe psoriasis. Different targets for immunobiological treatments seem to produce different treatment results.

The aim of our observation was to investigate the efficacy of 12 weeks of treatment with secukinumab, a monoclonal antibody that inhibits interleukin (IL)-17A, on the course of psoriatic onychodystrophy in patients with moderate to severe psoriasis.

Materials & Methods: Overall, we monitored 23 patients with moderate to severe psoriasis and accompanying psoriatic onychodystrophy. 9 of them were receiving 150 mg of secukinumab once per week weekly and then once on 1, 2, 3, 4, 8, and 12 weeks. The rest 14 patients were receiving 300 mg of secukinumab with the same intervals. To assess the Severity of psoriasis and psoriatic onychodystrophy were assessed Psoriasis Area and Severity Index (PASI) and Nail Psoriasis Severity Index (NAPSI) values at the beginning and at the 12th week of treatment.

Results: at the beginning of treatment, in 9 patients the PASI index was 5-10 (corresponding to the moderate degree of severity), the NAPSI scale was in the range of 30-51, and in 14 patients, the PASI index was above 10 (severe course of psoriasis), the NAPSI scale was in the range of 48- 92. At the 12th week of treatment with secukinumab, a significant skin improvement was observed, which was reflected in a reliable decrease in the PASI scale ($p<0,001$) by 67.1% in patients receiving 300 mg of secukinumab and by 53.1% in those receiving 150 mg of the drug. Patients demonstrated pronounced positive changes of the nail plates condition, a significant decrease in the NAPSI scale ($p<0,05$) by 63.8% and 50.5% when using secukinumab at a dose of 300 mg and 150 mg, respectively.

Conclusion: 12 weeks treatment of psoriasis with secukinumab produces significant improvement in skin and nail condition. We observed significantly more evident results of the treatment in patients with severe psoriasis than in patients with moderate course of the disease, that was reflected in PASI and NAPSI scales regression.

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Abstract N°: 2490

Molecular effects in the skin of psoriasis patients after oral treatment with orismilast

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Introduction & Objectives:

Orismilast is a potent phosphodiesterase-4B and -4D inhibitor.1 Efficacy and safety of orismilast modified-release tablets were demonstrated in a 16-week, phase 2b, double-blinded, placebo-controlled, dose-finding study (20mg, 30mg and 40mg BID) in patients with moderate-to-severe psoriasis (IASOS).2 Here, we report skin biomarker data based on tape strip samples from patients in the IASOS study. The primary objective of the biomarker study was to evaluate the effect of orismilast on a broad spectrum of inflammatory markers in psoriatic skin lesions and constitutes the first report of measuring skin protein levels of psoriasis patients using tape strips as a non-invasive sampling technology combined with the Olink® technology. The biomarker data and conclusions will be presented and discussed.

Materials & Methods:

Tape strips were collected from lesional and nonlesional skin at baseline and lesional skin at week 16 of each patient. The biomarker population is a subpopulation of the ITT population. Protein extracts from patients treated with 20mg orismilast BID (N=22/48) and 30mg orismilast BID (N=27/50) were analyzed using the Olink® technology (Target 96 Inflammation panel) and IL-23 ELISA (V-Plex MSD).

Results:

The focus of the analysis has been on comparing change in biomarker levels in the psoriatic lesions (baseline vs week 16) after treatment with oral orismilast (20 or 30 mg BID). In short, a broad immunomodulatory effect was observed for patients treated with orismilast as demonstrated by a significant reduction in key proteins related to:

- Th17 (e.g. IL-23, IL-17A, CCL20 and IL-12B)
- Th1 (e.g. TNFa, IFNg, CXCL9 and CXCL10)
- Innate immunity (e.g. IL-6 and IL-17C)

Furthermore, several risk proteins associated with subclinical atherosclerosis (CCL4, CDCP1 and VEFG-A) were also significantly reduced at week 16.

Conclusion:

This biomarker evaluation, based on tape strip skin samples from psoriasis patients in the Ph2b IASOS study, clearly demonstrate a reduced level of several key disease driving biomarkers of psoriasis and supports the clinical

efficacy observed for orismilast. In addition, markers related to the increased risk of atherosclerotic cardiovascular disease are also reduced. Finally, the study underlines tape strip sampling of the skin as a powerful, non-invasive technology to obtain data on protein changes using the Olink® technology.

References

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\2) IASOS study: NCT05190419. Presented as an oral late breaker at AAD 2023 by Prof. Lars E. French.*Manuscript in preparation*.

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Abstract N°: 2494

Patient-reported outcomes in the randomized, double-blind, placebo-controlled phase 2b trial of the oral TYK2 inhibitor TAK-279 in moderate-to-severe psoriasis

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Introduction & Objectives:

TAK-279 is a highly selective, oral, allosteric inhibitor of tyrosine kinase 2 (TYK2). Increased activation of proinflammatory enzymes in the Janus kinase–signal transducer and activator of transcription pathway (including TYK2) is associated with several autoimmune diseases, including psoriasis. The phase 2b study of TAK-279 in psoriasis met its primary efficacy endpoint, with 67% of patients achieving a Psoriasis Area and Severity Index (PASI) 75 response at the highest dose (30 mg). Here, we report patient-reported outcomes (PROs) from this study.

Materials & Methods:

In this randomized, double-blind, placebo-controlled study (NCT04999839), patients with moderate-to-severe plaque psoriasis were randomly assigned (1:1:1:1:1) to one of four doses of TAK-279 (2 mg, 5 mg, 15 mg, 30 mg) or placebo, administered orally once daily for 12 weeks. PRO endpoints included: change from baseline in Dermatology Life Quality Index (DLQI) score; change from baseline in pruritus numeric rating scale (NRS); proportion of patients with a baseline pruritus NRS score ≥ 4 achieving at least a 4-point reduction from baseline. Changes from baseline in DLQI and pruritus NRS were analysed using a mixed model with repeated measures, which included treatment, visit, treatment-by-visit interaction and prior biologic treatment as fixed effects, and baseline score as a covariate.

Results:

In total, 259 patients were randomized and treated, with ~50 patients per arm (mean [standard deviation] baseline DLQI and pruritus NRS scores: 12.0 [6.95] and 6.5 [2.57], respectively). At Week 12, DLQI scores had decreased in all TAK-279 groups, with significant differences versus placebo for all doses except 2 mg, and evidence of a dose–response at the 15 mg and 30 mg doses (Table 1). Reductions in pruritus NRS were also observed at Week 12, with significantly greater reductions in all TAK-279 groups versus placebo, except for the 2 mg dose (Table 1). The proportion of patients with a baseline pruritus NRS score ≥ 4 (n=219) achieving a ≥ 4-point improvement in pruritus NRS was also greater in the TAK-279 groups: 34.8%, 48.8% (non-significant [NS] versus placebo), 54.5% (NS), 66.0% (p=0.003) and 68.3% (p=0.002) for placebo, 2 mg, 5 mg, 15 mg and 30 mg, respectively.

Conclusion:

TAK-279 treatment was associated with significant improvements in patient-reported quality of life (DLQI) and signs/symptoms of psoriasis (pruritus NRS) compared with placebo at doses ≥ 5 mg over 12 weeks, with the greatest responses seen in the higher dose groups. These significant and positive PRO findings, together with the previously reported efficacy of TAK-279 on skin responses (where TAK-279 doses ≥ 5 mg were all associated with significantly higher PASI 75/90/100 responses compared with placebo), provide evidence of investigator and

patient satisfaction in reducing the signs and symptoms of psoriasis.

Study/writing funding:

Nimbus Discovery, Inc./Takeda Development Center Americas, Inc.

Table 1. Least-squares (LS) mean change from baseline at Week 12 in Dermatology Life Quality Index and pruritus numeric rating scale scores for TAK-279 versus placebo

	Placebo	TAK-279			
		2 mg	5 mg	15 mg	30 mg
Dermatology Life Quality Index					
LS mean change from baseline	−4.9	−5.3	−7.9	−8.5	−8.9
(SE)	(0.75)	(0.78)	(0.75)	(0.74)	(0.75)
p-value versus placebo	–	0.693	0.003	<0.001	<0.001
Pruritus numeric rating scale					
LS mean change from baseline	−2.0	−3.0	−3.1	−4.4	−4.3
(SE)	(0.38)	(0.39)	(0.38)	(0.37)	(0.38)
p-value versus placebo	–	0.065	0.039	<0.001	<0.001

Analysed using a mixed model with repeated measures (MMRM). The model included treatment, visit (Weeks 4, 8 and 12), treatment-by-visit interaction and prior treatment with biologics as fixed effects, and baseline score as covariate. p-values were nominal and were based on the comparison of each dose of TAK-279 versus placebo. SE, standard error.

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Abstract N°: 2505

Efficacy and safety results from the randomized, double-blind, placebo-controlled phase 2b trial of the oral TYK2 inhibitor TAK-279 in moderate-to-severe psoriasis

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Introduction & Objectives:

TAK-279 is a highly selective, oral, allosteric inhibitor of tyrosine kinase 2 (TYK2) that mediates signaling from cytokines involved in the pathology of psoriasis and other immune-mediated diseases.

Materials & Methods:

In this phase 2b, randomized, double-blind, placebo-controlled study (NCT04999839), adult patients with moderate-to-severe plaque psoriasis were randomly assigned (1:1:1:1:1) to receive one of four doses of TAK-279 (2 mg, 5 mg, 15 mg, 30 mg) or placebo, all administered orally once daily for 12 weeks. The primary endpoint was the proportion of patients achieving Psoriasis Area and Severity Index (PASI) 75 (75% improvement in PASI score from baseline) at Week 12. Secondary endpoints included PASI 90 and 100 responses. All analyses were conducted in the modified intent-to-treat analysis set (all patients randomized who received at least one dose of study treatment), with non-response imputed for missing data. The proportion of patients achieving PASI responses was compared between treatment groups using a Cochran–Mantel–Haenszel test, with prior biologic treatment included as a stratification factor.

Results:

In total, 259 patients were randomized and received treatment. At Week 12, a significantly greater proportion of patients achieved PASI 75 at doses ≥ 5 mg (44%, 68%, 67% for 5 mg, 15 mg, 30 mg, respectively) versus placebo (6%; $p<0.001$). Consistent with the primary endpoint, secondary endpoints were also successfully achieved at TAK-279 doses ≥ 5 mg at Week 12, with the PASI 100 response not plateauing at the highest dose (PASI 90: 21%, 45%, 46% for 5 mg, 15 mg, 30 mg, respectively, versus 0% for placebo [$p<0.001$]; PASI 100: 10%, 15%, 33% for 5 mg, 15 mg, 30 mg, respectively, versus 0% for placebo [$p<0.001$ at 30 mg]). Adverse event (AE) frequency was 53–62% in TAK-279 treatment arms with no clear dose dependence, and 44% in the placebo group. The most common AEs (≥ 5% and higher than placebo) were infections, acne/acneiform dermatitis and diarrhoea. One patient in the 30 mg group experienced two serious adverse events (SAEs) (pleural effusion and pericardial effusion) that were considered unrelated to treatment; there were no other SAEs and no deaths. Changes in laboratory parameters were consistent with TYK2 inhibition, including creatine kinase increases, although they were not dose dependent. There was no imbalance in the occurrence of cytopenia across groups.

Conclusion:

TAK-279 demonstrated significantly greater skin clearance versus placebo at oral doses ≥ 5 mg once daily with PASI 100 reaching 33% at Week 12 at the highest dose. The safety profile of TAK-279 was acceptable at all doses, supporting further studies in psoriasis.

Study/writing funding:

Nimbus Discovery, Inc./Takeda Development Center Americas, Inc.

Previous abstract submission:

Annual Meeting of the American Academy of Dermatology 2023.

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Abstract N°: 2519

The Registry of Psoriasis Health Outcomes: A Longitudinal Real-World Collaboration Study (RePhlect) – North American Registry Design

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Introduction & Objectives: Deucravacitinib is an oral, selective inhibitor of tyrosine kinase 2 (TYK2) approved in the US, EU, and other countries for treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. In pivotal phase 3 randomized trials, deucravacitinib demonstrated superiority over placebo and apremilast for multiple efficacy endpoints and patient reported outcome measures, as well as a well-tolerated safety profile. The Registry of Psoriasis Health Outcomes: A Longitudinal Real-world Collaboration Study (RePhlect) assesses the use of deucravacitinib in a diverse, real-world, global population of patients with psoriasis. The North American registry will determine the comparative effectiveness of deucravacitinib versus apremilast over 5 years in adult patients in clinical practices in the US and Canada.

Materials & Methods: Data for the North American cohort of RePhlect will be collected through the CorEvitas Psoriasis Registry, a prospective, observational, real-world study of adult patients with dermatologist-diagnosed psoriasis who started or switched to an approved systemic therapy for the treatment of psoriasis. Data on socio-demographics and lifestyle factors, psoriasis disease characteristics, current and prior psoriasis treatments, disease activity, and patient reported outcome measures are collected from both patients and their dermatology providers during routine dermatology visits occurring approximately every 6-months. Currently the CorEvitas Registry enrolls psoriasis patients across 263 private and academic clinical sites from 596 physicians in 40 US states and 7 Canadian provinces (Figure). The RePhlect cohort will enroll and prospectively follow patients diagnosed with plaque psoriasis who initiate deucravacitinib or apremilast. The target enrollment over 4 years for deucravacitinib and apremilast initiators is 1000 and 500 patients, respectively. Under the guidance of the North American RePhlect Steering Committee, a comprehensive statistical analysis plan to compare the effectiveness of deucravacitinib and apremilast over up to 5 years was developed based on the following primary outcomes: change in BSA, IGA 0/1, DLQI 0/1, and drug survival. Additional outcomes will include PASI 75, achievement of PASI ≤5, PASI ≤3 and NPF target/acceptable response, change in IGA, change in DLQI, achievement of DLQI ≤5, and change in itch and other patient-reported measures.

Results: The first RePhlect patient was enrolled in September 2022, and, as of April 2023, 148 deucravacitinib and 84 apremilast initiations are included.

Conclusion: RePhlect is a global, collaborative effort to understand the real-world evidence of the effectiveness of deucravacitinib in comparison to other systemic treatment options among patients with psoriasis, complementing the existing deucravacitinib clinical trials evidence. This abstract showcases the design and approach for the RePhlect North American region.

Figure. CorEvitas Psoriasis Registry sites from inception of the registry

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Abstract N°: 2524

Efficacy of deucravacitinib, an oral, selective tyrosine kinase 2 inhibitor, in Asian patients with moderate to severe plaque psoriasis: findings from the phase 3 POETYK PSO-1 trial

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Introduction & Objectives: Deucravacitinib, an oral, selective tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. In the global phase 3 POETYK PSO-1 trial (NCT03624127), deucravacitinib was superior to placebo and to apremilast in patients with moderate to severe plaque psoriasis on multiple clinical endpoints, including the coprimary endpoints, ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) and static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1) at Week 16. This subanalysis evaluated the efficacy of deucravacitinib in Asian patients who participated in the POETYK PSO-1 trial.

Materials & Methods: POETYK PSO-1 was a 52-week, double-blind, active- and placebo-controlled trial in patients with moderate to severe plaque psoriasis. Patients were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily. Patients receiving placebo switched to deucravacitinib at Week 16. Patients receiving apremilast who did not achieve PASI 50 by Week 24 switched to deucravacitinib. Primary clinical endpoints were PASI 75 and sPGA 0/1. Efficacy outcomes in the deucravacitinib group were compared with those in the placebo and apremilast groups at Week 16 and the apremilast group at Week 24; additional findings through Week 52 are reported for deucravacitinib-treated patients only. Adverse events (AEs) were reported for all treatment groups. This subanalysis includes participants from mainland China, Taiwan, South Korea, and Japan.

Results: The POETYK PSO-1 trial enrolled 666 patients, including 106 Asian patients (mean [SD] age 46.1 [12.8] years; 25.5% female). Overall, baseline characteristics were balanced across treatment groups and consistent with the full PSO-1 population, with the exception of weight (mean [SD], 74.7 [17.8] kg in Asians vs 88.1 [21.7] kg in the full population). PASI 75 rates were numerically higher among patients treated with deucravacitinib versus placebo and apremilast at Week 16 (74.0% vs 9.7% and 28.0%, respectively) and versus apremilast at Week 24 (74.0% vs 32.0%). At Week 52, 76.0% of patients in the deucravacitinib group achieved PASI 75, including 33 (89.2%) of 37 patients who had PASI 75 at Week 24. For context, in the full PSO-1 population, PASI 75 rates with deucravacitinib at Weeks 16, 24, and 52 were 58.4%, 69.3%, and 65.1%, respectively. A greater proportion of patients achieved sPGA 0/1 with deucravacitinib versus placebo and apremilast at Week 16 (72.0% vs 6.5% and 40.0%, respectively) and versus apremilast at Week 24 (72.0% vs 36.0%); 62% of patients in the deucravacitinib group had sPGA 0/1 at Week 52. At Week 16, AEs occurred in 70.0%, 56.7%, and 64.0% of patients receiving deucravacitinib, placebo, and apremilast, respectively, and serious AEs occurred in 6.0%, 6.7%, and 4.0%. AEs leading to treatment discontinuations were reported in 3.4% of deucravacitinib patients by Week 52. No deaths were reported. Additional findings from secondary efficacy endpoints, patient-reported outcomes, and safety

through Week 52 will be presented.

Conclusion: Deucravacitinib was effective and safe in Asian patients with moderate to severe plaque psoriasis through 52 weeks. Findings in the Asian subgroup were consistent with results in the overall POETYK PSO-1 population.

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Abstract N°: 2525

Association Between Disease Duration and Treatment Response in Patients With Moderate-to-Severe Plaque Psoriasis Treated With Biologics in a Real-world Setting: Results at Week 12 From the Psoriasis Study of Health Outcomes (PSoHO)

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Introduction & Objectives:

Patient demographics and disease characteristics may influence clinical response to biologic treatment in patients with moderate-to-severe plaque psoriasis (PsO). Previous studies show no effect of longer disease duration on treatment response yet do not evaluate patients with a shorter disease duration (Lynde C, 2023). This analysis addresses this gap by comparing the association between shorter or longer disease duration and effectiveness of a range of approved biologics at Week 12 in a real-world setting.

Materials & Methods:

Psoriasis Study of Health Outcomes (PSoHO) is an ongoing 3-year, international, prospective, noninterventional study comparing the effectiveness of anti-interleukin (IL)-17A biologics (ixekizumab [IXE] and secukinumab) relative to other approved biologics, as well as IXE versus other individual biologics. Patients were categorized into subgroups according to shorter (<2, <5 and <10 years) or longer (≥2, ≥5 or ≥10 years) PsO disease duration. The primary endpoint was the proportion of patients who achieved ≥90% improvement in Psoriasis Area Severity Index score (PASI 90) and/or a static Physician Global Assessment score of 0/1. Other outcomes were PASI 90 and PASI 100. Unadjusted PASI 100 response rates were reported descriptively. Patients with missing outcomes were imputed as non-responder imputation (NRI). Adjusted pairwise treatment comparisons were performed using frequentist model averaging (FMA) for each disease duration subgroup.

Results:

Of 1981 patients, 39.0% (n=773) received anti-IL-17A biologics and 61.0% (n=1208) received other biologics. More than 90% of patients had a disease duration of ≥2 years. Patient baseline characteristics across the 2 cohorts stratified by disease duration of <2 and ≥2 years were similar, with few exceptions such as frequency of comorbid psoriatic arthritis or prior exposure to biologics (**Table 1**).

At Week 12, unadjusted response rates were numerically higher for the anti-IL-17A cohort than for the other biologics cohort, irrespective of a disease duration of <2 or ≥2 years. The PASI 100 response rate was 36.7% (<2 years subgroup) and 35.8% (≥2 years subgroup) for the anti-IL-17A cohort versus 21.8% (<2 years subgroup) and 21.9% (≥2 years subgroups) for the other biologics cohort. Among individual biologics, IXE showed the

highest numerical response rate for PASI 100 at Week 12 in patients with a disease duration of <2 years (42.1%) and ≥2 years (38.3%) (**Fig. 1a**). In patients with a disease duration of <2 years, the adjusted odds ratios (95% CI) of achieving a PASI 100 response at Week 12 in the anti-IL-17A cohort versus the other biologics cohort was 2.0 (1.0, 4.1) (**Fig. 1b**). Similar results were observed for other study endpoints and disease duration subgroups.

Conclusion:

Disease duration does not impact response rates regardless of the treatment at Week 12. Patients across most disease duration subgroups in the anti-IL-17A cohort had higher odds of achieving high level skin clearance at Week 12 versus the other biologics cohort in a real-world setting. Irrespective of disease duration, patients treated with IXE showed numerically higher response rates relative to other individual biologics.

Table 1. Demographics and baseline disease characteristics of patients in the anti-IL-17A and the other biologics cohorts stratified by disease duration (<2 and ≥2 years).

	Anti-IL-17A biologics (N=773)		Other biologics (N=1208)	
	<2 years (n=60)	≥2 years (n=713)	<2 years (n=78)	≥2 years (n=1130)
Age, years	42.0 (13.7)	47.2 (13.6)	41.5 (14.7)	44.6 (13.4)
Male, n (%)	32 (53.3)	410 (57.5)	43 (55.1)	658 (58.2)
Weight, kg	82.2 (21.7)	85.8 (20.7)	81.7 (24.5)	84.8 (21.0)
Disease duration, median years	1.0	15.8	1.1	15.0
PASI	17.6 (10.2)	14.4 (8.3)	15.1 (8.4)	14.4 (8.6)
Percentage of BSA	23.5 (22.2)	20.9 (16.8)	21.1 (17.5)	21.5 (17.7)
DLQI[a]	13.8 (8.1)	12.9 (7.6)	12.9 (7.9)	12.6 (7.5)
Any comorbidities reported, n (%)[b]	34 (56.7)	385 (54.0)	43 (55.1)	578 (51.2)
Psoriatic arthritis, n (%)[c]	13 (21.7)	214 (30.0)	6 (7.7)	228 (20.2)
Nail psoriasis, n (%)[d]	22 (36.7)	283 (39.7)	20 (25.6)	425 (37.6)
Any previous conventional therapy, n (%)	51 (85.0)	522 (73.2)	57 (73.1)	935 (82.7)
Prior treatment with biologics, n (%)	5 (8.3)	286 (40.1)	14 (17.9)	401 (35.5)

Data are expressed as mean (standard deviation), unless otherwise indicated. The n (%) may not equal the group total due to missing patient data.
BSA = body surface area; DLQI = Dermatology Life Quality Index; IL = interleukin; PASI = Psoriasis Area and Severity Index.
[a]DLQI was measured on a 0 to 30 scale, higher scores denote greater impairment of quality of life.
[b]Comorbidities were captured based on a predefined list.
[c]A diagnosis of psoriatic arthritis was recorded by dermatologists based on the medical history and/or information provided by the patient.
[d]Recorded as a yes/no question (investigator assessed).

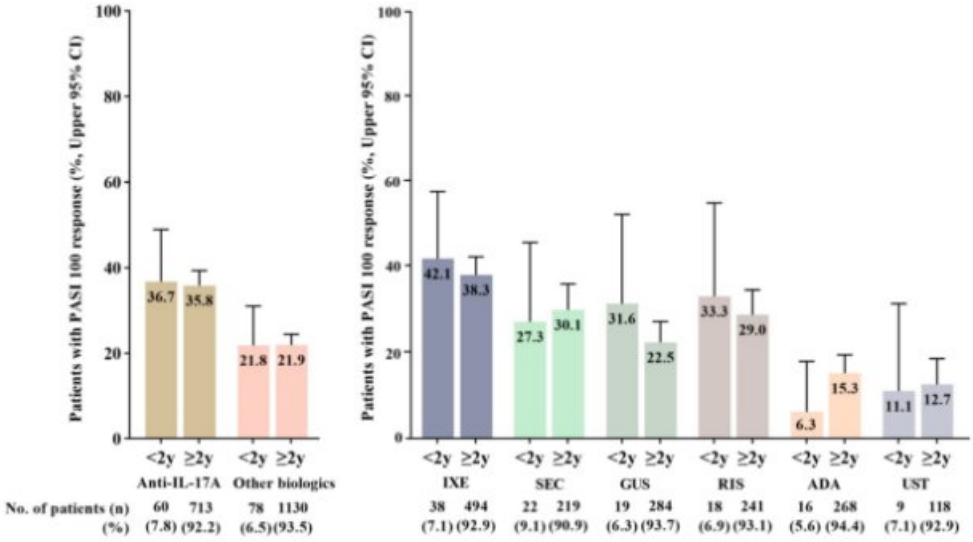

Figure 1a. PASI 100 unadjusted response rates across different treatment cohorts (anti-IL-17A, other biologics, and individual biologics) at Week 12 among patients with psoriasis stratified by <2 years and ≥2 years disease duration. (Percentages were calculated as n/N*100). Error bars represent the upper limit of the 95% confidence interval.
ADA = adalimumab; CI = confidence interval; GUS = guselkumab; IL = interleukin; IXE = ixekizumab; PASI = Psoriasis Area and Severity Index; RIS = risankizumab; SEC = secukinumab; UST = ustekinumab; y = years.

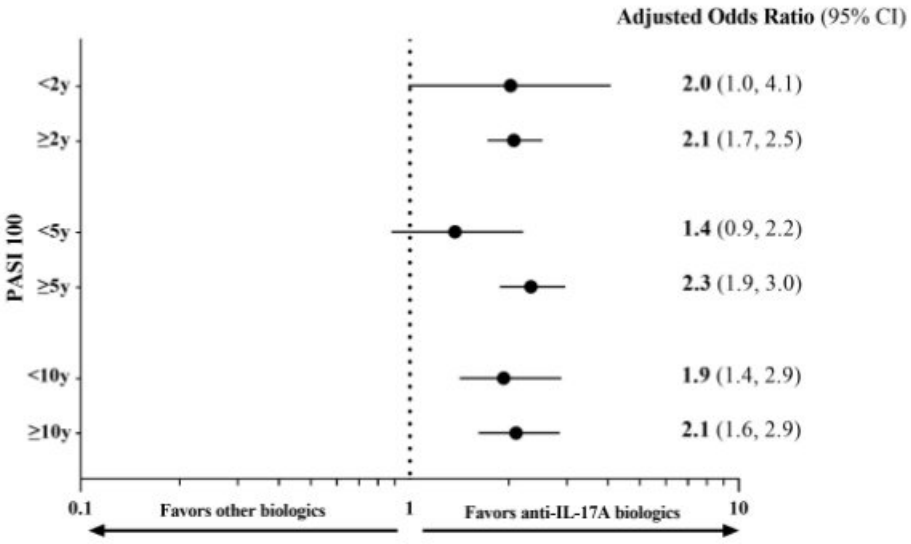

Figure 1b. Comparative adjusted analysis of PASI 100 response rates in the anti-IL-17A biologics cohort versus the other biologics cohort across patients with psoriasis categorized based on disease duration. The results show adjusted odds ratio (95% CI) at Week 12.

CI = confidence interval; IL = interleukin; PASI = Psoriasis Area and Severity Index; y = years.

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Abstract N°: 2528

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with moderate to severe plaque psoriasis: absolute Psoriasis Area and Severity Index outcomes in the phase 3 POETYK PSO-3 trial

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. The phase 3 POETYK PSO-3 trial (NCT04167462) demonstrated the superiority of deucravacitinib versus placebo at Week 16 in ≥75% reduction from baseline in PASI (PASI 75; 68.8% vs 8.1%, respectively) and static Physicians Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1; 55.6% vs 6.8%, respectively). This study further examined PASI improvements with deucravacitinib treatment in the POETYK PSO-3 trial.

Materials & Methods: The 52-week, phase 3, double-blind POETYK PSO-3 trial evaluated deucravacitinib in patients with moderate to severe plaque psoriasis in mainland China, Taiwan, and South Korea. Eligible adult patients were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily. Patients randomized to placebo crossed over to deucravacitinib at Week 16; all patients then continued treatment through 52 weeks. Mean change and mean percentage change from baseline in PASI were assessed through Week 52. Proportions of patients achieving treat-to-target outcomes of absolute PASI scores of ≤1, ≤3, and ≤5 through Week 52 were evaluated. An analysis of covariance model was used with stratification factors of country and prior biologic use as fixed effects and the baseline value as a covariate.

Results: A total of 220 patients were randomized to deucravacitinib (n=146) and placebo (n=74). Mean baseline PASI was similar in patients receiving deucravacitinib (24.6) and placebo (24.4). Adjusted mean change in PASI from baseline at Week 16 was significantly greater with deucravacitinib versus placebo (−16.8 vs −0.4, respectively; *P*<0.0001). Improvements in PASI were maintained through Week 52 in patients initially randomized to deucravacitinib. Higher proportions of patients receiving deucravacitinib versus placebo achieved clinically meaningful outcomes of absolute PASI ≤1 (17.1% vs 0%), ≤2 (35.6% vs 0%), ≤3 (49.3% vs 1.4%), ≤4 (59.6% vs 5.4%), and ≤5 (64.4% vs 6.8%) at Week 16; improvements were maintained through Week 52. Patients who crossed over to deucravacitinib from placebo after Week 16 showed similar improvements at Week 52 as those treated with deucravacitinib from Day 1.

Conclusion: These results show that Asian patients with moderate to severe plaque psoriasis treated with deucravacitinib achieved clinically meaningful absolute PASI outcomes that were superior to placebo.

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Abstract N°: 2546

Real-life experience on effectiveness and safety of Risankizumab in psoriasis.

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Introduction & Objectives: Risankizumab, an IL-23 inhibitor, has been approved for the treatment of moderate-to-severe plaque psoriasis. The long-term efficacy and safety has been demonstrated in clinical trials, but only in a few real-world studies.

We report our experience on effectiveness of Risankizumab on psoriasis characteristics after 4-, 12- and 24-week treatment in 64 patients. Drug survival rate and safety data were also collected.

Materials & Methods: We retrospectively analysed 64 patients from Son Espases Hospital who received treatment with biologic therapy with Risankizumab for moderate-to-severe plaque psoriasis. We included baseline characteristics, comorbidities, previous therapies and Psoriasis Area and Severity Index (PASI) score. The proportion of patients achieving a 75%, 90% and complete resolution (PASI 75, PASI 90, PASI 100) after 4, 12 and 24 weeks was analysed.

Results: A total of 40 men and 24 women were enrolled in our analysis. The mean age of onset of psoriasis was 35 years, and the mean absolute PASI score was 15. Of our patients, 85,9% were previously treated with classic systemic agents, and 76,5% had received at least 1 biologic treatment previously. After 24 weeks, 98,2% of patients achieved PASI 75, 89,3% achieved PASI 90 and 55,4% achieved PASI 100. Only 3 patients discontinued treatment, all of them due to inefficacy, no severe adverse events were identified.

Conclusion: In our experience, Risankizumab was effective and safe in a real-world setting, even in a population who failed to multiple previous treatments.

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Abstract N°: 2553

Long-term Safety and Efficacy of Risankizumab for the Treatment of Moderate-to-Severe Plaque Psoriasis: Interim Analysis of the LIMMitless Open-label Extension Trial Beyond 5.5 Years of Follow-up

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Introduction & Objectives:

Psoriasis is a chronic, inflammatory skin disease that often requires long-term management for optimal disease control. Risankizumab (RZB) is a humanized IgG1 monoclonal antibody that specifically inhibits interleukin 23 by binding to its p19 subunit and is approved for the treatment of moderate-to-severe plaque psoriasis in adults. Here, long-term safety and efficacy of RZB treatment beyond 5.5 years were evaluated.

Materials & Methods:

In the ongoing LIMMitless study (open-**L**abel extension study to assess the safety and efficacy of r**I**sankizu**M**ab for **M**a**I**n**T**enance in moderate-to-severe p**L**aqu**E** type p**S**oria**S**is; NCT03047395), patients initially randomized to receive RZB 150 mg and who completed a double-blind, phase 2/3 base study (UltIMMa1/NCT02684370, UltIMMa2/NCT02684357, SustaIMM/NCT03000075, NCT03255382, or IMMvent/NCT02694523) were eligible to continue open-label RZB 150 mg every 12 weeks for up to 5 additional years. This interim analysis evaluated safety through the data cutoff date (March 08, 2023, up to 324 weeks of treatment) and efficacy through 304 weeks of continuous RZB therapy. Safety was assessed by monitoring adverse events (AEs), which are reported as the number of events per 100 patient-years. Efficacy was assessed by the proportion of patients who achieved ≥ 90%/100% improvement from baseline in Psoriasis Area and Severity Index (PASI 90/PASI 100), static Physician's Global Assessment of clear or almost clear (sPGA 0/1), Dermatology Life Quality Index of no effect on patient's life (DLQI 0/1), and mean improvement in PASI from baseline. Efficacy was analyzed using 3 methods to impute missing data (modified nonresponder imputation [mNRI], last observation carried forward [LOCF], and observed cases).

Results:

Of the 955 patients randomized to receive RZB 150 mg in the base studies, 897 continued into the LIMMitless study; 644 were still ongoing at the time of data cutoff. Through week 324, rates of AEs, AEs leading to discontinuation, and AEs of safety interest were low (**Table 1**) and consistent with those observed in the 16-week short-term safety analyses (primary psoriasis safety pool). Patients experienced rapid improvements in efficacy outcomes within 12−28 weeks of the base studies, which were maintained long-term with continuous RZB therapy; at week 304, 86.0% of patients achieved PASI 90, 54.3% achieved PASI 100, and 84.7% achieved sPGA 0/1 (mNRI; **Table 2**). Patients also experienced substantial improvements in health-related quality of life with continuous RZB therapy; 76.1% of patients achieved DLQI 0/1 (mNRI) at week 304. Starting at week 28 of the base studies, mean improvement in PASI from baseline was 95.6% through week 304 (LOCF).

Conclusion:

Long-term continuous treatment with RZB was well tolerated beyond 5.5 years, with a safety profile consistent with that observed in previous short-term studies; no new safety findings were reported. RZB consistently demonstrated high durable efficacy and health-related quality-of-life improvements for up to 5.5 years of continuous therapy.

Table 1. Treatment-Emergent Adverse Event Summary

	Primary Psoriasis Safety Pool 16 weeks[a]		LIMMitless Study ≤ 324 weeks
Events (E/100 PYs)	RZB 150 mg N = 1306 PYs = 402.2	Placebo N = 300 PYs = 92.0	Continuous RZB 150 mg N = 897 PYs = 4891.9
Any AE	1279 (318.0)	261 (283.7)	6960 (142.3)
Serious AE	40 (9.9)	16 (17.4)	331 (6.8)
AE leading to discontinuation of RZB	11 (2.7)	9 (9.8)	86 (1.8)
Deaths	2 (0.5)	0	9 (0.2)[b]
TEAEs of safety interest			
Adjudicated MACE	1 (0.2)	1 (1.1)	23 (0.5)[c]
Serious infections	7 (1.7)	1 (1.1)	52 (1.1)[c]
Systemic *Candidiasis*	0	0	0
Active tuberculosis	0	1 (1.1)	0
Malignant tumors (including NMSC)	6 (1.5)	1 (1.1)	46 (0.9)[c]
NMSC	3 (0.7)	1 (1.1)	19 (0.4)
Excluding NMSC	3 (0.7)	0	27 (0.6)[d]
Serious hypersensitivity reactions	0	0	4 (< 0.1)[e]
Inflammatory bowel disease			
Crohn's disease	0	0	0
Ulcerative colitis	0	0	1 (< 0.1)

[a]Primary psoriasis safety pool includes UltIMMa-1, UltMMa-2, IMMhance, and IMMvent, and NCT0205448110 studies.

[b]Due to natural causes (n = 1), accident (n = 1), cardiopulmonary event (n = 1), cardiac arrest (n = 1), sudden cardiac death (n = 1), cause unknown (n = 3), and COVID-19 infection (n = 1); no deaths were related to study drug.

[c]Rates were consistent with previously published benchmarks in the Psoriasis Longitudinal Assessment and Registry.

[d]Malignancy types excluding NMSC were colorectal (n = 7), skin (n = 5), breast (n = 4), prostate (n = 3), urothelial (n = 3), uterine (n = 2), brain (n = 1), gastric (n = 1), and head and neck (n = 1).

[e]Serious hypersensitivity reactions (all considered unrelated to study drug) were paraphenylenediamine allergy (n = 1; mild, attributed to hair dye application), generalized microbial eczema (n = 1; moderate, attributed to prolonged duration of generalized eczema and lack of response to treatment with hydrocortisone), Stevens-Johnson syndrome (n = 2; severe, attributed to addition of chlorpromazine [n = 1] and attributed to addition of Bactrim [n = 1]).

AE, adverse event; E, event; NMSC, nonmelanoma skin cancer; PYs, patient-years; RZB, risankizumab.

Table 2: Long-term Efficacy of Continuous RZB 150-mg Treatment

Key Efficacy Outcomes	Continuous RZB (N = 897)				
	Week 16	Week 52	Week 148	Week 232	Week 304
PASI 90, % (95% CI)[a]	75.8 (73.0, 78.6)	86.3 (84.0, 88.5)	83.8 (81.4, 86.2)	85.2 (82.8, 87.5)	86.0 (83.7, 88.2)
PASI 100, % (95% CI)[a]	41.1 (37.9, 44.4)	58.2 (55.0, 61.4)	58.1 (54.9, 61.3)	56.4 (53.2, 59.7)	54.3 (51.0, 57.6)
Improvement in PASI, mean, % (SE)[b]	92.2 (0.5)	95.3 (0.4)	95.5 (0.3)	95.5 (0.3)	95.6 (0.3)
sPGA 0/1, % (95% CI)[a]	87.4 (85.2, 89.6)	88.7 (86.7, 90.8)	84.3 (81.9, 86.7)	83.9 (81.5, 86.3)	84.7 (82.4, 87.1)
DLQI 0/1, % (95% CI)[a]	66.3 (63.2, 69.4)	77.8 (75.1, 80.5)	77.4 (74.6, 80.1)	79.6 (77.0, 82.2)	76.1 (73.4, 78.9)

[a]Results were computed using the mNRI method for missing data imputation.

[b]Results were computed using the LOCF method for missing data imputation.

DLQI 0/1, Dermatology Life Quality Index of clear (0) or almost clear (1); LOCF, last observation carried forward; mNRI, modified nonresponder imputation; PASI, Psoriasis Area and Severity Index; RZB, risankizumab; sPGA 0/1, static Physician's Global Assessment of clear (0) or almost clear (1).

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Abstract N°: 2556

Impact of oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, deucravacitinib, on psoriasis in patients with active psoriatic arthritis: results from a phase 2 trial

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Introduction & Objectives: Tyrosine kinase 2 (TYK2) mediates signaling of cytokines (eg, IL-23) involved in plaque psoriasis (PsO) and psoriatic arthritis (PsA) pathogenesis. Deucravacitinib (DEUC), an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe PsO who are candidates for systemic therapy. The approval was based on the superiority of DEUC to apremilast and placebo (PBO) in a variety of PsO disease activity measures in two phase 3 trials in patients with moderate to severe PsO. In addition, DEUC was efficacious on multiple measures of arthritis severity compared with PBO in a phase 2 trial in patients with active PsA who had ≥1 PsO lesion (≥2 cm). In patients with body surface area (BSA) involvement ≥3% at baseline (80% of patients in this trial), a greater proportion of patients achieved a ≥75% reduction in Psoriasis Area and Severity Index (PASI 75) with DEUC treatment (6 mg QD: 42.4%, *P*=0.01; 12 mg QD: 59.6%, *P*<0.0001) vs PBO (20.4%) at week 16. This analysis further evaluated the impact of DEUC on PsO in patients with PsA in the phase 2 trial (NCT03881059).

Materials & Methods: The phase 2 double-blind PsA trial randomized patients (N=203) 1:1:1 to PBO, DEUC 6 mg once daily (QD), or DEUC 12 mg QD. After week 16 (Part A), patients could enroll in an optional, double-blind period until week 52 (Part B). In Part B, patients receiving DEUC who achieved minimal disease activity at week 16 continued DEUC treatment to week 52. Measurements of PsO disease activity, including mean BSA, mean PASI score, and achievement of BSA and PASI thresholds, were assessed.

Results: At baseline, PsO characteristics were generally comparable across treatment groups, with most patients (≥74%) having BSA ≥3% to <10% or PASI ≤12 (**Table**). At week 16, significant decreases from baseline in mean PASI score were observed with DEUC treatment vs PBO both in patients with baseline BSA ≥3% to <10% or PASI ≤12 as well as in those with baseline BSA ≥10% and PASI >12 (**Figure**). These significant changes in PASI were observed in the baseline BSA ≥3% to <10% or PASI ≤12 population even with very low baseline PASI scores. Significant decreases in PASI from baseline were observed with DEUC treatment vs PBO in both patients with background conventional synthetic disease-modifying antirheumatic drug (csDMARD) use (DEUC 6 mg, -4.0 and 12 mg, -4.9 vs PBO, -2.3; *P*<0.05 for both) and those without csDMARD use (-3.7 and -4.0 vs -2.5, respectively; *P*<0.001 for both). At week 16, a greater proportion of patients treated with DEUC vs PBO achieved PASI ≤1 in patients with baseline BSA ≥3% (DEUC 6 mg, 32.2% and 12 mg, 44.2% vs PBO, 18.5%) and in patients with baseline BSA ≥10% and PASI >12 (23.1% and 28.6% vs 0.0%, respectively). In patients with baseline BSA ≥3%, decreases in mean PASI score at week 16 were maintained through week 52 in patients who continued treatment with DEUC 6 mg (absolute PASI score, week 16: 2.39, week 52: 1.22) and 12 mg (week 16: 0.64, week 52: 0.24).

Conclusion: Treatment with DEUC significantly improved PsO in patients with PsA, regardless of baseline PsO severity and background csDMARD use. Of note, improvement in the subgroup of patients with baseline BSA ≥10% and PASI >12 in this trial was comparable to that observed in the phase 3 POETYK PSO-1 trial in patients

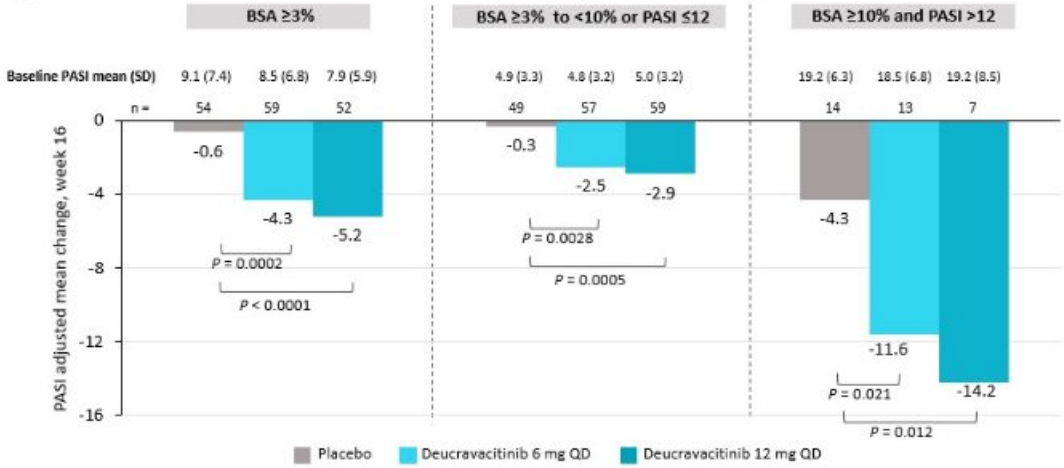
with baseline BSA ≥10% and PASI >12.

Table. Baseline psoriasis characteristics

		Placebo (n = 66)	Deucravacitinib 6 mg QD (n = 70)	Deucravacitinib 12 mg QD (n = 67)
BSA severity	BSA <3%, n (%)	9 (14)	11 (16)	14 (21)
	BSA ≥3%–<10%, n (%)	32 (49)	37 (53)	29 (43)
	BSA ≥10%, n (%)	22 (33)	22 (31)	23 (34)
PASI severity	PASI ≤5, n (%)	30 (46)	33 (47)	29 (43)
	PASI >5–≤12, n (%)	18 (27)	23 (33)	30 (45)
	PASI >12, n (%)	15 (23)	14 (20)	7 (10)
	Not reported, n (%)	3 (5)	0	1 (2)
BSA ≥3%	n (%)	54 (82)	59 (84)	52 (78)
BSA ≥3% to <10% or PASI ≤12	n (%)	49 (74)	57 (81)	59 (88)
BSA ≥10% and PASI >12	n (%)	14 (21)	13 (19)	7 (10)

BSA, body surface area; PASI, Psoriasis Area and Severity Index; QD, once daily.

Figure. PASI mean change from baseline at week 16 by psoriasis severity at baseline



Modified baseline observation carried forward method was used to handle missing data. Adjusted means and nominal *P* values were derived from an analysis of covariance model with factors for body weight and TNFi use and the baseline value as a covariate. BSA, body surface area; PASI, Psoriasis Area and Severity Index; PsO, plaque psoriasis; QD, once daily; SD, standard deviation; TNFi, tumor necrosis factor inhibitor.

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Abstract N°: 2557

Deucravacitinib long-term efficacy in patients originally randomized to placebo: 2-year results from the POETYK PSO program

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. In the pivotal POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials in moderate to severe plaque psoriasis, deucravacitinib demonstrated superiority to placebo and apremilast. Here, long-term outcomes were assessed in patients who crossed over from placebo to deucravacitinib in PSO-1 or PSO-2 and entered the POETYK long-term extension (LTE) trial (NCT04036435).

Materials & Methods: Patients were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast twice daily; placebo patients crossed over to deucravacitinib at Week 16. At Week 52, patients could enter the LTE and receive deucravacitinib for up to 240 weeks. Efficacy outcomes included ≥75% and ≥90% reductions from baseline in Psoriasis Area and Severity Index (PASI 75/90) and static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1). Efficacy is reported using modified nonresponder imputation (mNRI); patients who had not reached the Week 112 assessment or had not discontinued as of October 1, 2021, were excluded. As-observed data and treatment failure rule imputation will be presented.

Results: Of the 421 patients originally randomized to placebo, 298 completed PSO-1 or PSO-2 and entered the LTE. The mNRI population included 249 patients. At Week 112 (96 weeks of continuous deucravacitinib), response rates were 79.9% (PASI 75), 53.2% (PASI 90), and 59.1% (sPGA 0/1).

Conclusion: Deucravacitinib is associated with durable efficacy with up to 96 weeks of continuous treatment. Findings are comparable to patients who started deucravacitinib on Day 1 of PSO-1 or PSO-2.

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Abstract N°: 2558

Deucravacitinib long-term efficacy with continuous treatment in plaque psoriasis: 2-year results from the phase 3 POETYK PSO-1 and POETYK LTE trials

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. In the phase 3, 52-week, double-blind POETYK PSO-1 (NCT03624127) trial, deucravacitinib demonstrated superior efficacy versus placebo and apremilast in patients with psoriasis. Here, long-term efficacy after ≈2 years of deucravacitinib exposure is reported.

Materials & Methods: In POETYK PSO-1, patients were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily (QD), or apremilast 30 mg twice daily; at Week 52, patients could enter the POETYK long-term extension (LTE; NCT04036435) where they received deucravacitinib 6 mg QD. This analysis focused on patients randomized to deucravacitinib on Day 1 who continued treatment in the POETYK LTE. Efficacy endpoints were assessed with modified nonresponder imputation (mNRI) and included ≥75% reduction from baseline in Psoriasis Area and Severity Index of (PASI 75), ≥90% reduction from baseline in PASI (PASI 90), and static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with ≥2-point improvement from baseline (sPGA 0/1). Maintenance of response was assessed in patients who achieved PASI 75 at Week 24.

Results: In the mNRI population, 262 patients randomized to deucravacitinib on Day 1 of POETYK PSO-1 continued treatment in the POETYK LTE, including 200 who had achieved PASI 75 at Week 24. At Week 112, response rates for PASI 75, PASI 90, and sPGA 0/1 with deucravacitinib were 82.4%, 55.2%, and 66.5%, respectively. Among Week 24 PASI 75 responders, efficacy was maintained from Week 24 (PASI 75, 100%; PASI 90, 64.5%; sPGA 0/1, 83.5%) to Week 112 (PASI 75, 91.4%; PASI 90, 64.5%; sPGA 0/1, 73.7%).

Conclusion: Clinical efficacy was maintained for up to 112 weeks with continuous deucravacitinib treatment.

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Abstract N°: 2559

Non-clinical evaluations of deucravacitinib and Janus kinase inhibitor specificity in inflammatory or homeostatic pathways

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. TYK2 mediates signaling of select inflammatory pathways compared with Janus kinase (JAK)1/2/3, which also control cytokines required for homeostasis. Deucravacitinib minimizes nonspecific activity against JAK1/2/3 and has shown clinical efficacy in psoriasis, PsA, and SLE. JAK inhibitors (JAKi) typically have changes in clinical laboratory parameters and decrease hemoglobin and leukocytes, including NK and neutrophils—changes that have not been observed with deucravacitinib. In vitro functional assays may improve understanding of clinical and pharmacodynamic changes over basic signal transduction assays. This study evaluated deucravacitinib and JAKi in functional assays for cytokine activity related to the JAKi profile.

Materials & Methods: Hematopoietic stem cells were cultured using MethoCult™ and MegaCult™ for erythroid and megakaryocyte progenitors in the presence of deucravacitinib or JAKi; colony formations were enumerated. PBMCs from normal healthy volunteers (NHV) were treated at indicated inhibitor concentration and duration with IL-2, IL-7, or IL-15 and evaluated by FACS for signaling and functional outputs. NHV mDCs were compared for IFN-I inhibition by ELISA in the presence of inhibitors. Estimated whole blood inhibitor potencies were determined by blood:plasma ratios and drug-free fraction.

Results: In assays of JAK2-mediated hematopoiesis, the IC50 of deucravacitinib was >5000 nM. However, JAKi inhibited with IC50 of 150-693 nM for erythroid, 181-647 nM for myeloid, and 938-4368 nM for megakaryocyte colony formation (**Table 1**). Assessing cell signaling and cellular functions requiring the JAK1/3 pair, deucravacitinib weakly inhibited IL-15-induced NK cell pSTAT, CD107a expression, and proliferation with IC50 of 936 nM, 916 nM, and 711 nM, respectively. Conversely, JAKi were very potent (**Table 2**) in these assays with a range of IC50 of 17-41 nM (pSTAT), 21-34 nM (CD107a), and 24-31 nM (proliferation). IFNα-mediated CXCL9/10 production through the JAK1/TYK2 pair was more potently inhibited by deucravacitinib (4 and 9 nM) than JAKi (7-54 and 60-375 nM) in mDCs (**Table 3**).

Conclusion: Functional assays of target pathways may provide improved predictions of in vivo effects of drugs compared with more proximal signal transduction assays. In hematopoietic and functional cell models of JAK or TYK2 signaling, deucravacitinib was highly selective for TYK2 signaling pathways and did not inhibit JAK-dependent hematopoietic assays at clinically relevant concentrations. Conversely, JAKi blocked JAK1/3 pair-dependent signaling and functions and JAK2 pair-dependent colony formation. Deucravacitinib has high specificity and potency against TYK2, supporting further development in inflammatory diseases.

Table 1. Potency of deucravacitinib and JAK inhibitors against JAK 2-mediated functional differentiation of hematopoietic stem cells

	Total erythroid colonies		Myeloid progenitor colonies		Megakaryocyte progenitor colonies	
Compound	Measured IC_{50} (nM)	95% CI	Measured IC_{50} (nM)	95% CI	Measured IC_{50} (nM)	95% CI
Deucravacitinib	>10,000	NA	5091	3487-6886	9568	7076->10,000
Tofacitinib	693	548-881	647	516-793	4368	3183-5842
Baricitinib	150	115-201	181	157-211	938	807-1141
Upadacitinib	308	225-409	198	147-270	1335	1009-2161

CI, confidence interval; IC_{50}, half maximal inhibitory concentration; JAK, Janus kinase; NA, not applicable.

Table 2. Potency of deucravacitinib and JAK inhibitors against IL-15 signaling and function in NK cells

	NK cell proliferation		NK cell CD107a expression		NK cell pSTAT5 expression	
Compound	Measured IC_{50} (nM)	95% CI	Measured IC_{50} (nM)	95% CI	Measured IC_{50} (nM)	95% CI
Deucravacitinib	711	516-905	916	473-1359	936	435-1436
Tofacitinib	31	13-50	34	15-52	41	<1-81
Baricitinib	24	9-39	22	5-39	35	<1-89
Upadacitinib	27	14-40	21	8-34	17	2-32

CD107a, cluster of differentiation 107a; CI, confidence interval; IC_{50}, half maximal inhibitory concentration; IL, interleukin; JAK, Janus kinase; NK, natural killer; pSTAT, signal transducer and activator of transcription phosphorylation.

Table 3. Potency of deucravacitinib and JAK inhibitors against IFNα functional outputs in mDCs

	CXCL9 production		CXCL10 production	
Compound	Measured IC_{50} (nM)	95% CI	Measured IC_{50} (nM)	95% CI
Deucravacitinib	4	1-6	9	4-14
Tofacitinib	54	36-72	375	59-691
Baricitinib	26	10-42	214	40-388
Upadacitinib	7	3-11	60	15-104

CI, confidence interval; CXCL9/10, chemokine ligand 9/10; IC_{50}, half maximal inhibitory concentration; IFN, interferon; JAK, Janus kinase; mDC, monocytic dendritic cell.

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Abstract N°: 2560

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in scalp, nail, and palmoplantar psoriasis in Japanese patients with plaque psoriasis: subset analysis of the phase 3 POETYK PSO-4 trial

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. The open-label, phase 3 POETYK PSO-4 trial (NCT03924427) evaluated deucravacitinib 6 mg once daily for 52 weeks in Japanese patients with moderate to severe plaque psoriasis. Efficacy was assessed in the current analysis based on measures of scalp, fingernail, and palmoplantar psoriasis.

Materials & Methods: In this single-arm, open-label trial, adult Japanese patients with moderate to severe plaque psoriasis received deucravacitinib 6 mg once daily. Endpoints included scalp-specific Physician's Global Assessment score of 0 or 1 (ss-PGA 0/1) and Psoriasis Scalp Severity Index (PSSI) in patients with moderate to severe scalp psoriasis (ss-PGA ≥3) at baseline, PGA-Fingernails (PGA-F) 0/1 and modified Nail Psoriasis Severity Index (mNAPSI) in patients with moderate to severe fingernail psoriasis (PGA-F ≥3) at baseline, and palmoplantar PGA (pp-PGA) 0/1 and palmoplantar Psoriasis Area and Severity Index (pp-PASI) in patients with moderate to severe palmoplantar psoriasis (pp-PGA ≥3) at baseline.

Results: Among a total of 63 patients, there were 35 (55.6%) with scalp psoriasis, 10 (15.9%) with fingernail psoriasis, and 4 (6.3%) with palmoplantar psoriasis, all with moderate to severe involvement. At Week 16, improvements were observed in scalp (ss-PGA 0/1, 91.2%; mean change in PSSI, −30.2 [baseline, 32.4]), fingernail (PGA-F 0/1, 20.0%; mean change in mNAPSI, −9.4 [baseline, 29.7]), and palmoplantar (pp-PGA 0/1, 75.0%; mean change in pp-PASI, −19.9 [baseline, 24.0]) outcomes. Response rates were maintained through Week 52 (ss-PGA 0/1, 87.5%; PSSI, −28.7; PGA-F 0/1, 40.0%; mNAPSI, −15.4; pp-PGA 0/1, 75.0%; pp-PASI, −22.7).

Conclusion: In Japanese patients with moderate to severe plaque psoriasis, deucravacitinib substantially improved measures of scalp, fingernail, and palmoplantar disease.

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Abstract N°: 2561

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with moderate to severe plaque psoriasis: improvement in body surface area involvement in the phase 3 POETYK PSO-3 trial

Jianzhong Zhang[1], Yangfeng Ding[2], Ping Wang[3], Linfeng Li[4], Weili Pan[5], Yan Lu[6], Leona Liu[7], Renata M. Kisa[7], Kim Hoyt[7], Subhashis Banerjee[7]

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. In the global phase 3 POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials, deucravacitinib demonstrated superiority to placebo. This study evaluated the efficacy of deucravacitinib over 52 weeks in Asian patients from mainland China, Taiwan, and South Korea based on body surface area (BSA) involvement, BSA by static Physician's Global Assessment (BSA × sPGA), and sPGA.

Materials & Methods: The phase 3 POETYK PSO-3 trial (NCT04167462) examined deucravacitinib in Asian patients from mainland China, Taiwan, and South Korea. Adult patients were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily. Patients receiving placebo crossed over to deucravacitinib at Week 16, and patients randomized to deucravacitinib on Day 1 continued treatment for 52 weeks. Endpoints included BSA involvement and a convenient measure of overall severity, BSA × sPGA, in POETYK PSO-3 at Weeks 16 and 52.

Results: Mean baseline scores were similar for patients randomized to placebo (n = 74; BSA, 33.4%; BSA × sPGA, 109.1) and deucravacitinib (n = 146; BSA, 34.1%; BSA × sPGA, 110.3). In patients receiving placebo, BSA involvement at Week 16 increased by 12.9% and BSA × sPGA increased by 8.3% versus a decrease of 68.2% and 78.1%, respectively, in deucravacitinib-treated patients. At Week 16, 10.8% of patients receiving placebo achieved a ≥75% improvement from baseline in BSA × sPGA, versus 76% of patients treated with deucravacitinib. Improvements in all measures were maintained at Week 52 for patients continuously treated with deucravacitinib; comparable results were observed in placebo patients who crossed over to deucravacitinib at Week 16.

Conclusion: These results demonstrate that deucravacitinib treatment was associated with marked improvements in BSA and BSA × sPGA by Week 16 that were sustained through 52 weeks in Asian patients with moderate to severe plaque psoriasis.

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Abstract N°: 2563

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with scalp, palmoplantar, and nail psoriasis: subgroup analysis of the phase 3 POETYK PSO-3 trial

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib mediates cytokine signaling (interleukin-23 and Type I interferons) involved in psoriasis pathogenesis. In two global phase 3 trials, POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751), deucravacitinib demonstrated superiority to placebo in patients with moderate to severe scalp, palmoplantar, and nail psoriasis. This study evaluated the efficacy of deucravacitinib in Asian patients from mainland China, Taiwan, and South Korea with moderate to severe scalp, nail, and palmoplantar psoriasis in the phase 3 POETYK PSO-3 trial (NCT04167462).

Materials & Methods: Adult patients were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily. Patients receiving placebo crossed over to deucravacitinib at Week 16, and patients randomized to deucravacitinib continued treatment for 52 weeks. Endpoints included scalp-specific, palmoplantar, and fingernail Physician's Global Assessment scores of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (ss-PGA 0/1, pp-PGA 0/1, and PGA-F 0/1, respectively), ≥90% improvement in Psoriasis Scalp Severity Score (PSSI 90), and ≥75% improvement in modified Nail Psoriasis Severity Index (mNAPSI 75) in patients with moderate to severe scalp (ss-PGA ≥3), palmoplantar (pp-PGA ≥3), or fingernail (PGA-F ≥3) involvement, respectively, at baseline.

Results: Of the 220 patients randomized (deucravacitinib, n=146; placebo, n=74), 106 (72.6%), 15 (10.3%), and 46 (31.5%) treated with deucravacitinib and 51 (68.9%), 7 (9.5%), and 24 (32.4%) receiving placebo had baseline ss-PGA ≥3, pp-PGA ≥3, and PGA-F ≥3, respectively. At Week 16, ss-PGA 0/1, PSSI 90, and pp-PGA 0/1 rates were significantly higher in patients treated with deucravacitinib (62.9%, 51.4%, and 66.7%, respectively) versus placebo (9.8%, 5.9%, and 0%; $P \leq 0.01$ for all). PGA-F 0/1 and mNAPSI 75 responses were numerically higher with deucravacitinib (19.6% and 10.9%, respectively) than placebo (4.2% and 4.2%). Response rates were improved or maintained with continued deucravacitinib through Week 52.

Conclusion: Deucravacitinib improved scalp, palmoplantar, and nail disease burden in Asian patients with moderate to severe plaque psoriasis.

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Abstract N°: 2564

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with moderate to severe plaque psoriasis: onset of action and maintenance of response in the phase 3 POETYK PSO-3 trial

Jianzhong Zhang[1], Yangfeng Ding[2], Ping Wang[3], Linfeng Li[4], Weili Pan[5], Yan Lu[6], Leona Liu[7], Renata M. Kisa[7], Kim Hoyt[7], Subhashis Banerjee[7]

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was well tolerated and efficacious in two global phase 3 trials, POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751), as well as in POETYK PSO-3 (NCT04167462), a phase 3 trial in patients from mainland China, Taiwan, and South Korea. Here, we report onset of action and maintenance of response to deucravacitinib in POETYK PSO-3.

Materials & Methods: In the 52-week phase 3 POETYK PSO-3 trial, adult patients were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily. Patients receiving placebo crossed over to deucravacitinib at Week 16, and patients randomized to deucravacitinib continued treatment for 52 weeks. Onset of action was evaluated by Psoriasis Area and Severity Index (PASI), body surface area (BSA) involvement, and BSA × static Physician's Global Assessment (BSA×sPGA). Achievement of a ≥75% reduction from baseline in PASI (PASI 75) and patient-reported outcomes including Dermatology Life Quality Index (DLQI) and Psoriasis Symptoms and Signs Diary (PSSD) were also assessed. Maintenance of response was assessed by achievement of PASI 75, sPGA 0/1, DLQI, and PSSD with continuous deucravacitinib treatment and patients crossing over from placebo at Week 16 through Week 52.

Results: Deucravacitinib (n=146) was associated with significantly larger mean changes from baseline vs placebo (n=74) by Week 1 in PASI and the more convenient measure in clinic, BSA×sPGA (−2.8, $P<0.002$ and −10.1, $P<0.04$, respectively) and by Week 2 in BSA involvement (−3.3, $P<0.0007$). Achievement of PASI 75 and an sPGA score of 0 (clear) or 1 (almost clear) with ≥2-point improvement from baseline (sPGA 0/1) was significantly higher with deucravacitinib vs placebo by Week 4 ($P<0.006$ and $P<0.0006$, respectively). Responses were maintained through 52 weeks with continuous deucravacitinib treatment; patients who crossed over from placebo at Week 16 had comparable results at Week 52. Patient-reported outcomes (PSSD, DLQI 0/1) were improved as early as Week 2 with deucravacitinib vs placebo; improvements were maintained through Week 52.

Conclusion: Deucravacitinib displayed a rapid onset of action by Week 1 and sustained maintenance of response in Asian patients with moderate to severe plaque psoriasis.

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Abstract N°: 2565

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with moderate to severe plaque psoriasis: safety findings from the phase 3 POETYK PSO-3 trial

Jianzhong Zhang[1], Yangfeng Ding[2], Ping Wang[3], Linfeng Li[4], Weili Pan[5], Yan Lu[6], Hao Cheng[7], Xian Jiang[8], Ji-Chen Ho[9], Shuping Guo[10], Seong Jun Seo[11], Leona Liu[12], Elizabeth Colston[12], Arkendu Chatterjee[12], Renata M. Kisa[12], Subhashis Banerjee[12]

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. In two global phase 3 studies, POETYK PSO-1 and PSO-2, deucravacitinib showed superior efficacy versus placebo and apremilast with acceptable safety and tolerability. Here, we report safety results from the phase 3 POETYK PSO-3 trial (NCT04167462) of deucravacitinib in patients with moderate to severe plaque psoriasis in mainland China, Taiwan, and South Korea.

Materials & Methods: Adults with moderate to severe plaque psoriasis were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily. Patients receiving placebo crossed over to deucravacitinib at Week 16; patients randomized to deucravacitinib continued treatment for 52 weeks. Safety outcomes were assessed over 52 weeks. After completing the study, patients were able to enroll in a long-term, open-label extension trial; patients who did not enter the extension underwent 4 weeks of safety surveillance.

Results: A total of 220 patients were randomized to deucravacitinib (n=146) and placebo (n=74). At Week 52, the exposure-adjusted incidence rates (EAIRs) per 100 person-years (PY) for deucravacitinib versus placebo, respectively, were 319.9 versus 364.7 for adverse events (AEs), 6.5 versus 4.5 for serious AEs, and 2.7 versus 0 for AEs leading to discontinuation. No deaths were reported during the trial. AEs with EAIRs ≥10/100 PY with deucravacitinib included upper respiratory tract infection (25.9/100 PY) and nasopharyngitis (23.6/100 PY). No cases of influenza, COVID-19, opportunistic infection, tuberculosis, malignancy, major adverse cardiovascular event, or venous thromboembolism were reported over the 52-week trial. Five cases of localized herpes zoster (deucravacitinib, n=5; placebo, n=0) were reported over 52 weeks (2.7/100 PY). No case of herpes zoster was serious, disseminated, or led to discontinuation.

Conclusion: Deucravacitinib was generally safe and well tolerated over 52 weeks in Asian patients with moderate to severe plaque psoriasis.

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Abstract N°: 2566

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with moderate to severe plaque psoriasis: laboratory parameters from the phase 3 POETYK PSO-3 trial

Jianzhong Zhang[1], Yangfeng Ding[2], Ping Wang[3], Linfeng Li[4], Weili Pan[5], Yan Lu[6], Hao Cheng[7], Xian Jiang[8], Ji-Chen Ho[9], Shuping Guo[10], Seong Jun Seo[11], Leona Liu[12], Elizabeth Colston[12], Arkendu Chatterjee[12], Renata M. Kisa[12], Subhashis Banerjee[12]

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. In the phase 3 global POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials, deucravacitinib showed superiority versus placebo and apremilast across multiple endpoints and was well tolerated. This study compared the effects of deucravacitinib versus placebo on multiple laboratory parameters in patients with moderate to severe plaque psoriasis from mainland China, Taiwan, and South Korea in the POETYK PSO-3 trial (NCT04167462).

Materials & Methods: Patients with stable moderate to severe plaque psoriasis (Psoriasis Area and Severity Index ≥12, static Physician's Global Assessment ≥3, body surface area involvement ≥10%) were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily in the 52-week, phase 3, double-blind POETYK PSO-3 trial. Patients receiving placebo crossed over to deucravacitinib at Week 16. Changes from baseline levels for standard hematologic parameters (lymphocytes, neutrophils, platelets, hemoglobin) and chemistry parameters, including lipids (total cholesterol, high- and low-density lipoprotein cholesterol, triglycerides) and serum creatine phosphokinase, were evaluated. Shifts in Common Terminology Criteria for Adverse Events (CTCAE; version 5.0) severity grade of laboratory abnormalities between baseline and Weeks 16 and 52 were also assessed.

Results: A total of 220 patients (deucravacitinib, n=146; placebo, n=74) were randomized and analyzed. Overall, no clinically meaningful changes from baseline levels in mean values were observed in any laboratory parameter over the placebo-controlled period (Weeks 0-16). Additionally, no clinically relevant changes from baseline levels were observed up to Week 52 with continued deucravacitinib treatment. The majority of patients remained within normal limits in laboratory parameters throughout the trial; shifts of ≥2 CTCAE grades from baseline were balanced overall and infrequent in both treatment groups. There were no discontinuations due to laboratory abnormalities.

Conclusion: Deucravacitinib did not result in clinically significant laboratory abnormalities in Asian patients with moderate to severe plaque psoriasis.

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Abstract N°: 2571

Treatment choice and clinical progression of plaque psoriasis: An observational, retrospective cohort study using the French EGB database

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Introduction: Psoriasis (PsO) is a chronic heterogeneous skin disease that substantially affects patient quality of life. Current treatments are tailored to severity and zones affected by PsO ranging from topical treatments to systemic therapies (STs) and biologics. This national scale study provides insights into how patients with plaque PsO have been treated in France and the clinical progression of the dermatosis from 2014 to 2019.

Methods: An observational retrospective cohort study was conducted using the *Echantillon Généraliste des Bénéficiaires* (EGB) database. Included patients were those: i) with a primary, associated or related PsO diagnosis in this database and/or ii) with a long-term disease status record from the national health insurance, and/or iii) prescribed with topical treatments, STs and biologics. Excluded patients were: i) under six-year-olds, ii) with a filled associated diagnosis of PsO in the PMSI database without treatment reimbursement, and iii) prescribed rheumatological STs/biologics or methotrexate (MTX) only. Variables included clinical progression, comorbidity prevalence and days off work. Patient characteristics, therapy modifications, prescriber specialty and prescribed calcipotriene and betamethasone dipropionate (Cal/BD) were described.

Results: Although 5,366 patients were identified, 485 patients received MTX alone (96% prescribed by rheumatologists). Out of the 4,881 patients included, 86% identified as mild PsO patients, 11% moderate, and 3% severe. The mean age was 52 years and 51% of patients were male. The most prescribed treatment was at least one Cal/BD (85%) followed by dermocorticosteroids only (60%), STs (10%) and biologics (2%). For 4,213 mild PsO patients, 86% received specific topical treatments (including a fixed dose Cal/BD) and 14% received dermocorticosteroids only. For 541 moderate PsO patients, 20% received STs only, while 60% received STs combined with specific topical treatments. Most ST prescriptions were MTX. For 127 severe PsO patients, 36% were treated with biologics only and 38% with combined conventional STs and biologics. Cardiometabolic pathologies & risk factors were the most prevalent comorbidity type (42%, 39% and 35% for mild, moderate and severe PsO respectively) followed by anxiety/depression mostly affecting patients with severe PsO (28%). The clinical progression of mild PsO in relation to patient comorbidities as well as for those treated with topical treatments was statistically significant. Overall, patients with mild severity (7%) switched to conventional STs [95%CI: 5 to 8] and patients with moderate severity (7%) transitioned to biologics [95%CI: 5 to 9] over the five-year follow up. Since 2018, Cal/BD prescriptions were mostly given alone (62%) followed by combined therapy with dermocorticosteroids (30%), and increased from 24% to 34% in 2019 for patients that were previously treated with dermocorticosteroids. In the five years, over half of patients with mild PsO never or were no longer treated with topical treatments and corticosteroids. Around 30% of patients with moderate PsO were no longer treated with conventional STs. In addition, 5,027 days off work were taken, mostly by patients with mild severity (n=4,113), and were prescribed by GPs, other specialty physicians and psychiatrists.

Conclusions: Our findings provide an understanding to long-term PsO treatment outcomes, with different patterns and different reasons across the three severity stages.

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Psoriasis Status and Care in the University Environment

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Psoriasis Status and Care in the University Environment

Christina Morcos, Michael Sticherling

Introduction: Psoriasis is a common chronic systemic immune-mediated inflammatory skin disorder. Approximately 2% of the population suffers from Psoriasis. Validated scores like PASI Score, DLQI, and GEPARD scores are necessary to evaluate the patients. The advantage of biological agents within the past two decades has dramatically improved the treatment of psoriasis and psoriatic arthritis.

Objectives: Our objective was to study the prevalence, epidemiology, comorbidities, severity, association with psoriatic arthritis and the different lines of treatments.

Patients and Methods: This retrospective study included 869 patients with psoriasis recruited from both the outpatient and the inpatient clinics of the Dermatology department.

The data was collected from the Soarian software system based on the clinical or histologically confirmed diagnosis of Psoriasis. Full personal and family history together with a full assessment of the psoriasis lesions both clinically and with different scores like PASI, DLQI, and GEPARD scores were documented. Skin Punch biopsies were done if necessary, and a treatment plan for every patient was done after full assessment, the patient was referred to the Rheumatology clinic if there was an associated joint pain.

Results: 40.5% of the patients have a family history and one-third of the patients got their first diagnosis between 18 and 40 years old. The mean duration of patient care in the clinic was 38.4 months. The most

common type of psoriasis was psoriasis vulgaris 79.3%, scalp psoriasis 25%, inverse psoriasis 16.2% and pustular psoriasis 9%. The most affected area was the trunk (69.3%), followed by the extremities 58.1%. 21.3% were confirmed to have Psoriasis-arthritis.

47.3% of the patients had different comorbidities, the most frequent was arterial hypertension 30.7%, adiposities (17.3%), hyperlipidemia (14.5%), hypothyroid (8.9%), and depression (6.7%). There was a significant association between nail affection and psoriasis arthritis.

45.6% of the patients were using systemic biologics, 38.2% topical therapies, 11.6% the classic systemic therapies and only 4.6% Small Molecular Antagonists. The most frequently used topical therapy was the fixed combination (Glucocorticoids with Vitamin D in 61%, followed by calcipotriol (37.4%) and Glucocorticoids Class 2-3 (35.2%). 45.2 % of the patients were receiving Ultraviolet therapy. The narrowband UVB (23.8%), followed by bath PUVA 14.8%.

Among the current systemic medications, ustekinumab was the most used (11.9%), followed by secukinumab (10.6%), adalimumab 7.1% and methotrexate (5.5%). Whereas the most frequently used systemic drugs among the drug history were methotrexate (26.2%), fumarates (24.5%) followed by ustekinumab (20.4%). ## **Conclusion:** The various evaluated clinical parameters and scores have improved over time with treatment, especially with the biological therapy.The retrospective compilation of data is a major constraint and limits further substantial conclusions. Therefore, a prospective and preferably comparative or placebo-controlled study is clearly needed.

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Excess modifiable cardiovascular risk factors among psoriasis patients with coronary artery disease

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Introduction & Objectives: Excess cardiovascular disease in psoriasis is due to multiple etiological factors. PET scans in psoriasis have demonstrated systemic inflammation is associated with widespread large-vessel inflammatory changes. Furthermore, metabolic disease increases the risk of psoriasis. This study aims to compare the presence of traditional cardiovascular (CV) risk factors on the prevalence and severity of coronary artery disease (CAD) in psoriasis patients versus those without psoriasis.

Materials & Methods: All patients were identified from the local APPROACH database that prospectively collected patient demographics, traditional CV risk factors, and the extent of vascular disease among patients who underwent cardiac catheterization. Traditional risk factors were self-reported at the pre-op visit before the cardiac catheterization. The extent of CAD was extracted from the catheterization reports. CAD was categorized into four main categories: severe, moderate, mild, and normal, based on the number of vessels involved, type of vessel, and percentage of vessel occlusion. Patients from the APPROACH cohort were identified as having psoriasis if the provincial billing code had at least one health visit under code 696 from a dermatologist. In contrast, control patients never had 696 billing codes administered. Descriptive statistics, chi-squared, and multivariate regression were used for the analysis.

Results: 442 psoriasis patients and 1724 non-psoriasis patients were identified from the APPROACH database. Severe, moderate, mild, and normal CAD were noted in 192, 149, 39, and 62 patients with psoriasis and 737, 648, 140, and 199 control patients, respectively. The average number of traditional CV risk factors in psoriasis was 3.20 compared to 2.99 for non-psoriasis patients ($p=0.0025$). Psoriasis patients with moderate to severe CAD had a significantly greater number of traditional CV risk factors than controls (3.31 vs 3.10; $p=0.0234$). Among psoriasis patients, the number of CV risk factors correlated with the extent of CAD as severe, moderate, mild, and normal CAD had 3.38, 3.23, 2.95, and 2.83 CV risk factors, respectively. Dyslipidemia, diabetes, renal insufficiency, heart failure, increasing age, and male sex predicted increased CAD in psoriasis patients ($p< 0.05$ for all factors).

Conclusion: Psoriasis patients have more risk factors than control patients; this is more evident for those with CAD. There is a direct relationship between the number of CV risk factors and the severity of CAD. Numerous modifiable risk factors predictive of CAD in psoriasis patients were identified in this study and may help lessen the burden of CAD if managed appropriately.

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A US Claims Database Analysis Estimating Risk of All-Cause Mortality in Patients with Generalised Pustular Psoriasis

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Introduction & Objectives: Generalised pustular psoriasis (GPP) is a rare, chronic, neutrophilic skin disease characterised by recurring flares of widespread erythema, oedema, coalescing pustules, and possible systemic symptoms. GPP flares may require hospitalisation and can be life-threatening. There is limited data to describe the mortality burden of GPP in the United States. The objective of this study was to compare all-cause mortality among patients with GPP to matched populations of patients with plaque psoriasis (PsO), and the general population without GPP or PsO.

Materials & Methods: Inovalon Insights real-world claims data were used to identify five cohorts (All GPP, Comorbid GPP+PsO, GPP Only, PsO Only, General Population) based on the International Classification of Diseases, Tenth Revision (ICD-10) diagnosis codes over a 4-year period (Jan 1, 2016 to Dec 31, 2019). GPP Only, PsO Only, and comorbid GPP+PsO were mutually exclusive cohorts. The All GPP group was defined by considering the GPP Only (excluding PsO) and comorbid GPP+PsO cohorts together. The General Population cohort consisted of patients meeting the inclusion criteria without a medical claim for GPP or PsO during the pre- and post-index periods. All-cause mortality was assessed during two periods: a 365-day post-index diagnosis and a maximum follow-up period for each patient (i.e., until the study period ended or a patient experienced an event). Greedy caliper propensity score matching was used to match GPP patients 1:2 to the PsO and General Population cohorts using index year, age, gender, insurance type, region, and Charlson Comorbidity Index (CCI). Risk of all-cause mortality was assessed using Cox proportional hazard models.

Results: Patients across cohorts were primarily female and commercially insured (Table 1). Patients in the GPP Only cohort were significantly older at index and had significantly higher CCI scores compared to PsO Only and General Population cohorts ($p<0.001$; Table 1), which highlights the higher severity of GPP. At 365 days of follow-up (Table 2), the All GPP cohort had a significantly higher risk of mortality compared to both the General Population (HR 4.93, 95% CI 2.24 to 10.88) and the PsO Only cohort (HR 2.31, 95% CI 1.32 to 4.04). The GPP+PsO cohort had a significantly higher mortality risk than the PsO Only cohort (HR 2.67, 95% CI 1.15 to 6.20). At 365 days follow-up the GPP Only cohort had a numerically higher risk of mortality compared to the PsO cohort. While not statistically significant at that timepoint, the higher risk was significant at the later timepoint. Indeed, at the maximum follow-up (Table 2), the risk of mortality for the All GPP cohort was almost 4 times higher than the general population (HR 3.98, 95% CI 2.92 to 5.43) and 1.5 times higher than the PsO Only cohort (HR 1.49, 95% CI 1.20 to 1.85). In both the GPP+PsO cohort and GPP Only cohort, the risk of mortality was almost 1.5 times the risk of the PsO Only cohort (HR 1.41, 95% CI 1.05 to 1.90; HR 1.49, 95% CI 1.10 to 2.03), with all comparisons at the maximum follow-up being statistically significant.

Conclusion: This study characterizing all-cause mortality in patients with GPP demonstrated a higher risk of mortality in GPP compared to both the matched PsO and General Population cohorts. These results fill a significant gap in the existing literature and reinforce the need for increased awareness of the mortality burden as well as the comorbidity burden in GPP.

Table 1. Cohort Demographics

Variable	GPP Only	Comorbid GPP+PsO	PsO Only	General Population	All GPP
N	1,246	1,384	127,540	19,641,441	2,630
Index Year; n (%)					
2016	520 (41.7%)	618 (44.7%)	57,234(44.9%)	15,935,507 (81.1%)	1,138 (43.3%)
2017	259 (20.8%)	333 (24.1%)	30,043 (23.6%)	1,288,978 (6.6%)	592 (22.5%)
2018	260 (20.9%)	233 (16.8%)	22,926 (18.0%)	656,736 (3.3%)	493 (18.7%)
2019	207 (16.6%)	200 (14.5%)	17,337 (13.6%)	1,760,220 (9.0%)	407 (15.5%)
Gender; n (%)					
Female	776 (62.3%)	867 (62.6%)	67,548 (53.0%)	10,633,411 (54.1%)	1,643 (62.5%)
Male	470 (37.7%)	517 (37.4%)	59,992 (47.0%)	9,008,030 (45.9%)	987 (37.5%)
Insurance Type; n (%)					
Commercial	683 (54.8%)	795 (57.4%)	93,308 (73.2%)	11,663,868 (59.4%)	1,478 (56.2%)
Medicaid	376 (30.2%)	430 (31.1%)	21,910 (17.2%)	5,724,463 (29.1%)	806 (30.6%)
Medicare Advantage	187 (15.0%)	159 (11.5%)	12,322 (9.7%)	2,253,110 (11.5%)	346 (13.2%)
Region; n (%)					
Midwest	334 (26.8%)	337 (24.3%)	36,928 (29.0%)	4,734,851 (24.1%)	671 (25.5%)
Northeast	256 (20.5%)	279 (20.2%)	27,179 (21.3%)	3,324,571 (16.9%)	535 (20.3%)
South	457 (36.7%)	533 (38.5%)	38,963 (30.5%)	6,427,700 (32.7%)	990 (37.6%)
West	199 (16.0%)	235 (17.0%)	24,470 (19.2%)	5,154,319 (26.2%)	434 (16.5%)
Age at Index					
Mean (SD)	53.9 (17.4)	52.9 (16.4)	50.8 (16.6)	46.7 (17.2)	53.3 (16.9)
Age Group; n (%)					
18-24	28 (2.2%)	38 (2.7%)	6,923 (5.4%)	2,663,752 (13.6%)	66 (2.5%)
25-34	99 (7.9%)	115 (8.3%)	13,114 (10.3%)	2,869,280 (14.6%)	214 (8.1%)
35-44	177 (14.2%)	226 (16.3%)	21,330 (16.7%)	3,252,043 (16.6%)	403 (15.3%)
45-54	288 (23.1%)	326 (23.6%)	30,512 (23.9%)	3,850,775 (19.6%)	614 (23.3%)
55-64	446 (35.8%)	464 (33.5%)	37,761 (29.6%)	4,063,681 (20.7%)	910 (34.6%)
65-74	139 (11.2%)	166 (12.0%)	12,641 (9.9%)	1,847,695 (9.4%)	305 (11.6%)
75+	69 (5.5%)	49 (3.5%)	5,259 (4.1%)	1,094,215 (5.6%)	118 (4.5%)
CCI (Total)					
Mean (SD)	1.48 (2.18)	1.53 (2.16)	0.94 (1.71)	0.75 (1.59)	1.51 (2.17)

Abbreviations: CCI: Charlson Comorbidity Index; GPP: Generalised pustular psoriasis; PsO: plaque psoriasis; SD: standard deviation

Table 2. Mortality Risk

Comparison Populations	Hazard Ratio	95% CI	P-value
365 Day Follow-Up			
All GPP vs General Population	4.93	2.24, 10.88	**<0.001**
All GPP vs PsO	2.31	1.32, 4.04	**0.004**
Comorbid GPP+ PsO vs PsO Only	2.67	1.15, 6.20	**0.022**
GPP Only vs PsO Only	1.90	0.88, 4.14	**0.104**
Maximum Follow-Up			
All GPP vs General Population	3.98	2.92, 5.43	**<0.001**
All GPP vs PsO	1.49	1.20, 1.85	**<0.001**
Comorbid GPP+ PsO vs PsO Only	1.41	1.05, 1.90	**0.023**
GPP Only vs PsO Only	1.49	1.10, 2.03	**0.011**

Bold indicates statistical significance

Abbreviations: CI: confidence interval; GPP: generalised pustular psoriasis; PsO: plaque psoriasis

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Abstract N°: 2633

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with moderate to severe plaque psoriasis: efficacy by baseline demographics and disease characteristics in the phase 3 POETYK PSO-3 trial

Jianzhong Zhang[1], Yangfeng Ding[2], Ping Wang[3], Linfeng LI[4], Weili Pan[5], Yan Lu[6], Hao Cheng[7], Xian Jiang[8], Shuping Guo[9], Tsen-Fang Tsai[10], Yong-Beom Choe[11], Renata M. Kisa[12], Kim Hoyt[12], Shilpa Kamat[12], Rebecca Vanlandingham[12], Subhashis Banerjee[12]

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Introduction & Objectives: Tyrosine kinase 2 (TYK2) is an intracellular enzyme that mediates signaling of cytokines (interleukin-23 and Type I interferons) involved in psoriasis pathogenesis. Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. POETYK PSO-3 (NCT04167462), a phase 3 trial in Asian patients with moderate to severe plaque psoriasis, demonstrated that deucravacitinib was superior to placebo at Week 16 and maintained efficacy through Week 52 with continuous treatment (Zhang J, et al. Presented at the 31st EADV Congress; September 7-10, 2022; Milan, Italy). Here, we report the efficacy of deucravacitinib at Week 16 by baseline patient demographic and disease characteristics in this study population.

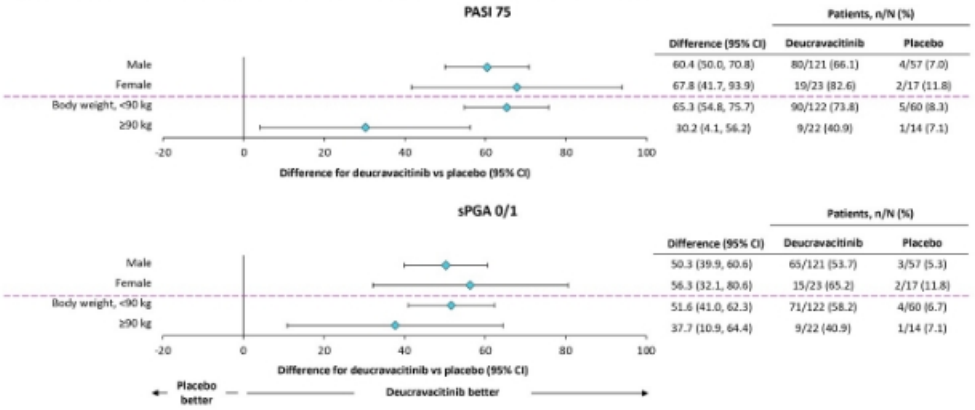
Materials & Methods: Adults (age ≥18 y) from mainland China, Taiwan, or South Korea with moderate to severe plaque psoriasis (baseline Psoriasis Area and Severity Index [PASI] ≥12, static Physician's Global Assessment [sPGA] ≥3, and body surface area involvement ≥10%) were randomized 1:2 in a blinded manner to oral placebo or deucravacitinib 6 mg once daily. Coprimary endpoints at Week 16 were the proportion of patients achieving ≥75% reduction from baseline in PASI (PASI 75) and the proportion achieving sPGA score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1). Prespecified subgroup analyses of PASI 75 and sPGA 0/1 response rates at Week 16 were performed by sex, body weight, disease severity, disease duration, and age at disease onset at baseline. Differences (95% confidence interval [CI]) between groups were obtained using a Cochran-Mantel-Haenszel test stratified by region (mainland China vs non-mainland China) and prior biologic therapy per randomization. Nonresponder imputation was used for missing data.

Results: In the deucravacitinib (n=146) and placebo (n=74) groups, respectively, baseline demographic (male, 84.2% vs 77.0%; mean body weight, 77.5 kg vs 74.5 kg) and disease characteristics (mean PASI score, 24.6 vs 24.4; mean disease duration, 13.1 y vs 13.9 y; mean age at disease onset, 27.9 y vs 28.1 y) were comparable. At Week 16, significantly higher proportions of patients in the overall population treated with deucravacitinib versus placebo achieved PASI 75 (68.8% vs 8.1%, respectively; difference [95% CI], 60.7% [50.9%, 70.6%]; $P<0.0001$) and sPGA 0/1 (55.6% vs 6.8%; 48.9% [38.9%, 58.9%]; $P<0.0001$) (Zhang J, et al. 2022). Subgroup analyses of PASI 75 and sPGA 0/1 response rates at Week 16 indicated that deucravacitinib was more efficacious than placebo, regardless of sex and body weight (**Figure 1**), and disease severity, disease duration, and age at disease onset

(**Figure 2**).

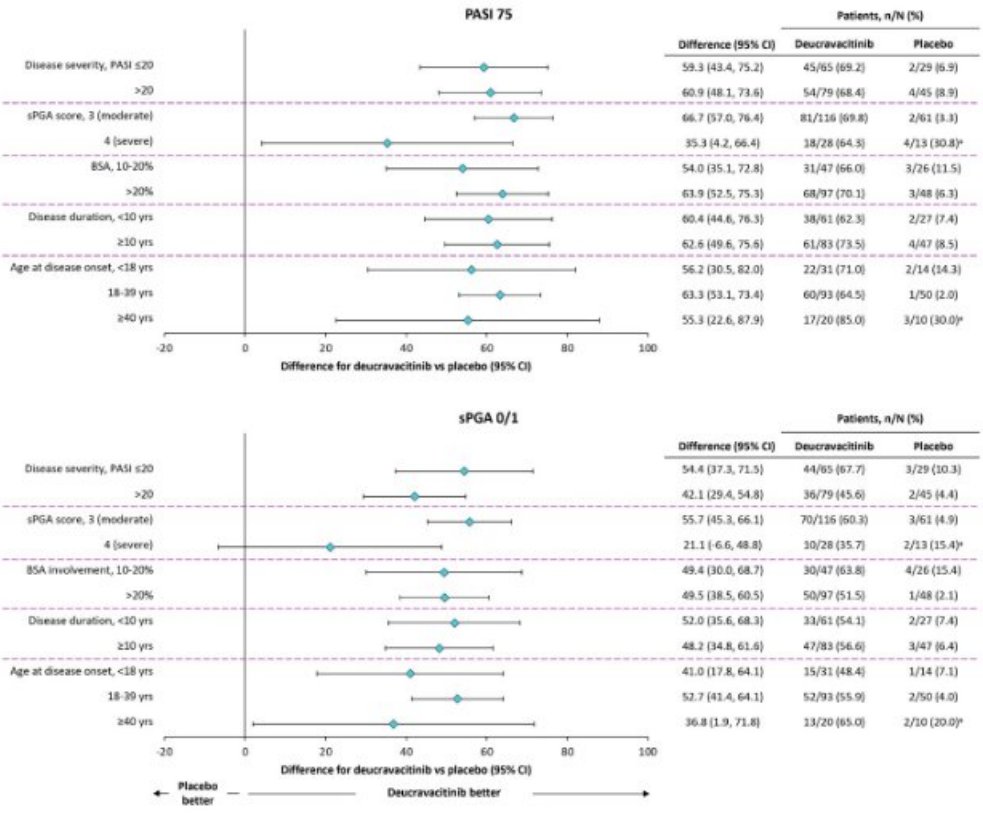
Conclusion: Deucravacitinib was more efficacious than placebo at Week 16 in Asian adults with moderate to severe plaque psoriasis across all baseline subgroups stratified by sex, body weight, disease severity, disease duration, and age at disease onset. Higher efficacy rates observed with deucravacitinib versus placebo across baseline subgroups were consistent with those reported in the overall population. These findings provide additional support for deucravacitinib, a once-daily oral drug, as an efficacious therapeutic option for Asian adults with moderate to severe plaque psoriasis.

Figure 1. PASI 75 and sPGA 0/1 responses at Week 16 by baseline patient demographics



CI, confidence interval; PASI 75, ≥75% reduction from baseline in the Psoriasis Area and Severity Index; sPGA 0/1, static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline.

Figure 2. PASI 75 and sPGA 0/1 responses at Week 16 by baseline disease characteristics



*High response rates were observed in the placebo group.
BSA, body surface area; CI, confidence interval; PASI 75, ≥75% reduction from baseline in the Psoriasis Area and Severity Index; sPGA 0/1, static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline.

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Abstract N°: 2637

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with moderate to severe plaque psoriasis: efficacy by prior treatment in the phase 3 POETYK PSO-3 trial

Jianzhong Zhang[1], Yangfeng Ding[2], Ping Wang[3], Linfeng Li[4], Weili Pan[5], Yan Lu[6], Hao Cheng[7], Xian Jiang[8], Shuping Guo[9], Tsen-Fang Tsai[10], Sang-Woong Youn[11], Renata M. Kisa[12], Shilpa Kamat[12], Rebecca Vanlandingham[12], Kim Hoyt[12], Subhashis Banerjee[12]

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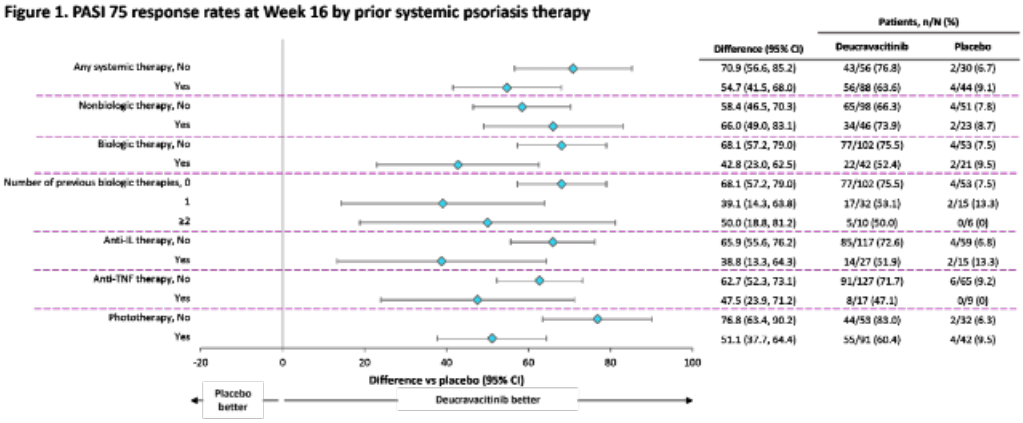
Introduction & Objectives: Tyrosine kinase 2 (TYK2) is an intracellular enzyme that mediates signaling of cytokines (interleukin-23 and Type I interferons) involved in psoriasis pathogenesis. Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, Japan, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. POETYK PSO-3 (NCT04167462), a phase 3 trial in Asian patients with moderate to severe plaque psoriasis, demonstrated that deucravacitinib was superior to placebo at Week 16 and maintained efficacy through Week 52 with continuous treatment (Zhang J, et al. Presented at the 31st EADV Congress; September 7-10, 2022; Milan, Italy). Here, deucravacitinib efficacy, stratified by prior systemic psoriasis therapy, is reported in this study population.

Materials & Methods: Adults (aged ≥18 years) from mainland China, Taiwan, or South Korea with moderate to severe plaque psoriasis (baseline Psoriasis Area and Severity Index [PASI] ≥12, static Physician's Global Assessment [sPGA] ≥3, body surface area involvement ≥10%) were randomized 1:2 in a blinded manner to oral placebo or deucravacitinib 6 mg once daily. Coprimary endpoints at Week 16 were the proportion of patients achieving ≥75% reduction from baseline in PASI (PASI 75) and the proportion achieving a sPGA score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1). Prespecified baseline subgroup analyses of PASI 75 and sPGA 0/1 response rates at Week 16 were performed based on prior systemic psoriasis therapies. Differences (95% confidence interval [CI]) between groups were obtained using a Cochran-Mantel-Haenszel test stratified by region (mainland China or non-mainland China) and prior biologic therapy use at randomization. Nonresponder imputation was used for missing data.

Results: Baseline patient demographics and disease characteristics were comparable in the deucravacitinib (n=146) and placebo (n=74) groups by prior systemic therapy (61.6% vs 59.5%, respectively), biologic treatment (28.8% vs 28.4%), anti-interleukin (anti-IL) treatment (18.5% vs 20.3%), anti-tumor necrosis factor (anti-TNF) treatment (11.6% vs 12.2%), nonbiologic treatment (32.9% vs 31.1%), and phototherapy (63.7% vs 56.8%). At Week 16, significantly higher proportions of patients in the overall population treated with deucravacitinib versus placebo achieved PASI 75 (68.8% vs 8.1%, respectively; difference [95% CI], 60.7% [50.9%, 70.6%]; $P<0.0001$) and sPGA 0/1 (55.6% vs 6.8%; 48.9% [38.9%, 58.9%]; $P<0.0001$) (Zhang J, et al. 2022). Subgroup analyses of PASI 75 (**Figure 1**) and sPGA 0/1 (**Figure 2**) response rates at Week 16 indicated that deucravacitinib was more efficacious than placebo, regardless of type of prior systemic psoriasis therapy use.

Conclusion: Deucravacitinib was more efficacious than placebo at Week 16 in Asian adults with moderate to severe plaque psoriasis across all baseline subgroups stratified by any prior use of systemic, biologic (including anti-IL and anti-TNF), and nonbiologic agents, as well as phototherapy. Higher efficacy rates observed with deucravacitinib versus placebo across baseline subgroups were consistent with those reported in the overall population. These findings provide additional support for deucravacitinib, a once-daily oral drug, as an efficacious therapeutic option for Asian adults with moderate to severe plaque psoriasis.

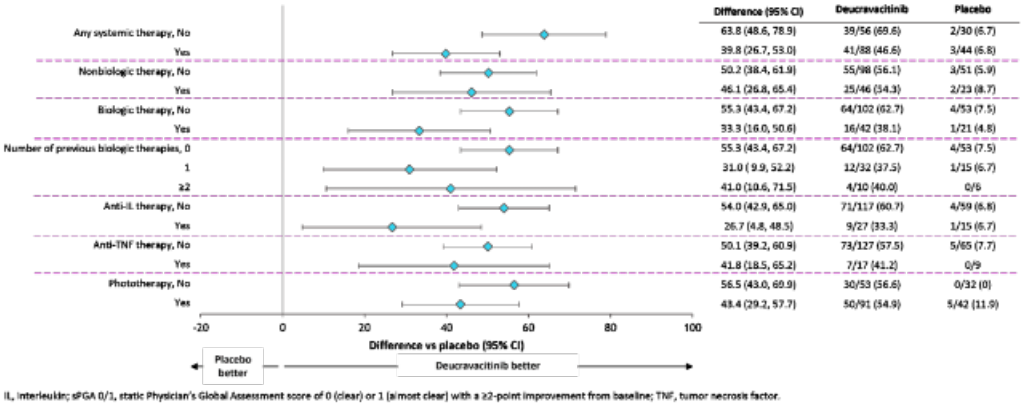
Figure 1. PASI 75 response rates at Week 16 by prior systemic psoriasis therapy



	Difference (95% CI)	Patients, n/N (%)	
		Deucravacitinib	Placebo
Any systemic therapy, No	70.9 (56.6, 85.2)	43/56 (76.8)	2/30 (6.7)
Yes	54.7 (41.5, 68.0)	56/88 (63.6)	4/44 (9.1)
Nonbiologic therapy, No	58.4 (46.5, 70.3)	65/98 (66.3)	4/51 (7.8)
Yes	66.0 (49.0, 83.1)	34/46 (73.9)	2/23 (8.7)
Biologic therapy, No	68.1 (57.2, 79.0)	77/102 (75.5)	4/53 (7.5)
Yes	42.8 (23.0, 62.5)	22/42 (52.4)	2/21 (9.5)
Number of previous biologic therapies, 0	68.1 (57.2, 79.0)	77/102 (75.5)	4/53 (7.5)
1	39.1 (14.3, 63.8)	17/32 (53.1)	2/15 (13.3)
≥2	50.0 (18.8, 81.2)	5/10 (50.0)	0/6 (0)
Anti-IL therapy, No	65.9 (55.6, 76.2)	85/117 (72.6)	4/59 (6.8)
Yes	38.8 (13.3, 64.3)	14/27 (51.9)	2/15 (13.3)
Anti-TNF therapy, No	62.7 (52.3, 73.1)	91/127 (71.7)	6/65 (9.2)
Yes	47.5 (23.9, 71.2)	8/17 (47.1)	0/9 (0)
Phototherapy, No	76.8 (63.4, 90.2)	44/53 (83.0)	2/32 (6.3)
Yes	51.1 (37.7, 64.4)	55/91 (60.4)	4/42 (9.5)

IL, interleukin; PASI 75, ≥75% reduction from baseline in Psoriasis Area and Severity Index; TNF, tumor necrosis factor.

Figure 2. sPGA 0/1 response rates at Week 16 by prior systemic psoriasis therapy



	Difference (95% CI)	Patients, n/N (%)	
		Deucravacitinib	Placebo
Any systemic therapy, No	63.8 (48.6, 78.9)	39/56 (69.6)	2/30 (6.7)
Yes	39.8 (26.7, 53.0)	41/88 (46.6)	3/44 (6.8)
Nonbiologic therapy, No	50.2 (38.4, 61.9)	55/98 (56.1)	3/51 (5.9)
Yes	46.1 (26.8, 65.4)	25/46 (54.3)	2/23 (8.7)
Biologic therapy, No	55.3 (43.4, 67.2)	64/102 (62.7)	4/53 (7.5)
Yes	33.3 (16.0, 50.6)	16/42 (38.1)	1/21 (4.8)
Number of previous biologic therapies, 0	55.3 (43.4, 67.2)	64/102 (62.7)	4/53 (7.5)
1	31.0 (9.9, 52.2)	12/32 (37.5)	1/15 (6.7)
≥2	41.0 (10.6, 71.5)	4/10 (40.0)	0/6
Anti-IL therapy, No	54.0 (42.9, 65.0)	71/117 (60.7)	4/59 (6.8)
Yes	26.7 (4.8, 48.5)	9/27 (33.3)	1/15 (6.7)
Anti-TNF therapy, No	50.1 (39.2, 60.9)	73/127 (57.5)	5/65 (7.7)
Yes	41.8 (18.5, 65.2)	7/17 (41.2)	0/9
Phototherapy, No	56.5 (43.0, 69.9)	30/53 (56.6)	0/32 (0)
Yes	43.4 (29.2, 57.7)	50/91 (54.9)	5/42 (11.9)

IL, interleukin; sPGA 0/1, static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline; TNF, tumor necrosis factor.

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Abstract N°: 2641

Effect of Apremilast on Imaging, Patient-Reported, and Dermatological Clinical Outcomes in Patients With Psoriatic Arthritis: Results From the MOSAIC Study

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Introduction & Objectives: Psoriatic arthritis (PsA) is associated with a negative impact on quality of life and physical function, as well as potentially progressive joint destruction. Clinical joint assessments and imaging are important to recognize and diagnose patients (pts) with early PsA. Apremilast (APR) is an oral phosphodiesterase 4 inhibitor with a unique immunomodulatory mechanism of action that is approved for the treatment of PsA and/or psoriasis. MRI is a sensitive tool that allows for the assessment of inflammation and structural changes in PsA. The objective of the MOSAIC study was to evaluate the impact of APR on inflammation using MRI, patient-reported, and dermatological clinical outcomes in pts with PsA.

Materials & Methods: MOSAIC (NCT03783026) was a phase 4, multicenter, single-arm, open-label study in pts with active PsA (met CASPAR criteria for PsA; ≥3 months but ≤5 years since diagnosis). Pts received APR 30 mg BID (either monotherapy or with stable methotrexate) for 48 weeks. Contrast-enhanced MRI of the hand was performed at baseline (BL), Week 24, and Week 48. Experienced blinded readers adjudicated all images. The primary endpoint was change from BL in the composite score of bone marrow edema (osteitis), synovitis, and tenosynovitis, as assessed using the validated PsA MRI score (PsAMRIS*) scoring system, at Week 24 (score range: 0–216). Secondary and exploratory endpoints included change from BL in the PsAMRIS composite score at Week 48, change from BL in the 12-item PsA Impact of Disease (PsAID-12†) score at Weeks 24 and 48, the achievement of ≥50% or ≥75% reduction from BL in Psoriasis Area and Severity Index (PASI) score (PASI-50 or PASI-75) in pts with BL affected body surface area (BSA) >3% at Weeks 24 and 48, the change from BL in total PASI score at Weeks 24 and 48. Safety was evaluated.

Results: A total of 122 pts were enrolled and received APR treatment. The mean age was 46.6 years and 54.9% were women (**Table 1**). The mean duration of PsA was 1.9 years, and the mean (SD) PsAMRIS composite score at BL was 18.5 (17.8). At Week 24, the least-squares (LS) mean change from BL in the PsAMRIS composite score was −2.3 (95% CI: −4.7, 0.1; **Figure 1**); at Week 48, the LS mean change was −2.9 (95% CI: −5.5, −0.4). Mean change from BL in PsAID-12 score was −1.4 (95% CI: −1.7, −1.0) at Week 24 and −1.6 (95% CI: −2.0, −1.3) at Week 48 (**Figure 2**). Of the 122 pts, 24 (19.7%) had a BSA >3% at BL and had PASI assessments. At Weeks 24 and 48, 42.9% and 50.0% of pts on APR had achieved PASI-50, respectively (**Figure 3**). PASI-75 was achieved by 33.3% of evaluable pts at Week 24 and by 31.3% at Week 48. Mean (95% CI) percent change from BL in PASI score was −29.1% (−61.3, 3.1) at Week 24 and −43.6% (−73.5, −13.7) at Week 48. The most common treatment-emergent adverse events were diarrhea (33.6%), nausea (12.3%), and headache (10.7%). There were no new safety signals.

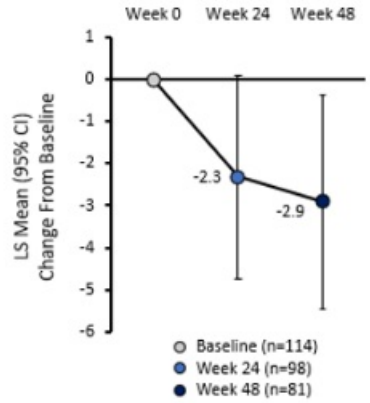
Conclusions: APR treatment led to improvements in MRI, patient-reported, and dermatological clinical outcomes in pts with ≤5-year history of PsA. Inflammation of the hand was reduced at Week 24, as measured by the PsAMRIS composite score, with further reduction at Week 48. The impact of PsA symptoms on daily life was lessened following APR treatment, as measured by PsAID-12. Pts with BSA >3% at BL experienced improvement in skin symptoms, as measured by PASI. Taken together, results from MOSAIC highlight the benefit of APR across PsA and psoriasis endpoints, as well as the value of using MRI and PsAMRIS to monitor inflammatory disease and response to treatment.

Table 1. Demographics and Baseline Disease Characteristics

Characteristic	N=122
Age, mean (SD), years	46.6 (12.9)
Women, n (%)	67 (54.9)
BMI, mean (SD), kg/m^2	29.6 (6.8)
Duration of psoriatic arthritis, mean (SD), years	1.9 (1.7)
BSA %, mean (SD)	4.5 (12.2)
PsAMRIS* composite score of bone marrow edema, synovitis, and tenosynovitis, mean (SD)	18.5 (17.9)
PsAID-12† score, mean (SD)	4.8 (1.9)
PASI score, mean (SD)	10.6 (12.4)‡

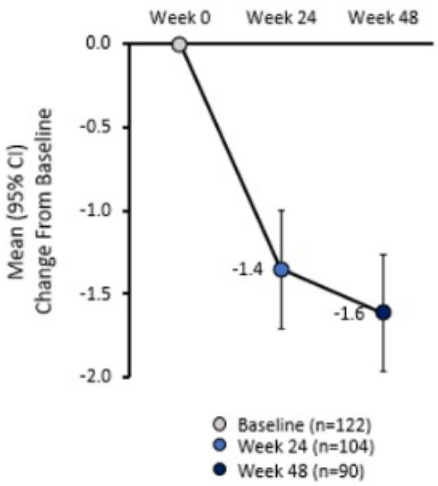
*PsAMRIS is a validated scoring system used to assess the images from the MRI of the most affected hand. †PsAID-12 contains 12 physical and psychological domains perceived by patients as particularly important for their health, each based on a 0–10 numerical rating scale and with a different weight. ‡Reported for patients with a baseline BSA >3% (n=24).
BMI=body mass index; BSA=body surface area; PASI=Psoriasis Area and Severity Index; PsA=psoriatic arthritis; PsAID-12=12-item PsA Impact of Disease; PsAMRIS=PsA MRI score.

Figure 1. Primary Endpoint: Change From Baseline in PsAMRIS Composite Score of Bone Marrow Edema (Osteitis), Synovitis, and Tenosynovitis With Apremilast Treatment



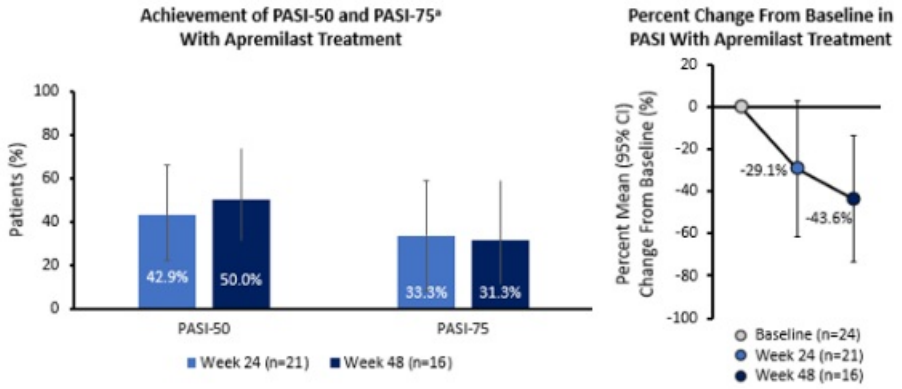
Includes patients from the full analysis set (defined as all enrolled patients who received ≥1 dose of study medication) with a composite score at baseline and at the specified timepoint. Based on the mixed-effect model for repeated measures with change from baseline as the response variable, including scanner type and time as fixed effects and baseline composite score as a covariate.
LS=least squares; PsAMRIS=PsA MRI score.

Figure 2. Change From Baseline in PsAID-12 Score With Apremilast Treatment



Includes patients from the full analysis set (defined as all enrolled patients who received ≥1 dose of study medication) with a PsAID-12 score at baseline and at the specified timepoint (patients with a baseline score of 0 were excluded). Two-sided 95% CI of mean changes from baseline and mean percentage changes from baseline are derived based on t-statistics.
PsAID-12=Psoriatic Arthritis Impact of Disease 12-domain Questionnaire.

Figure 3. Effect of Apremilast Treatment on PASI



Includes patients from the full analysis set (defined as all enrolled patients who received ≥1 dose of study medication) with baseline BSA >3% and a PASI score at baseline and at the specified timepoint.
ªError bars represent two-sided 95% CI, based on the Clopper-Pearson Method.
PASI=Psoriasis Area Severity Index; PASI-50/PASI-75=a ≥50%/75% reduction from baseline in PASI score.

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Abstract N°: 2644

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in Asian patients with plaque psoriasis: maintenance of response in the phase 3 POETYK PSO-3 trial

Jianzhong Zhang[1], Yangfeng Ding[2], Ping Wang[3], Linfeng Li[4], Weili Pan[5], Yan Lu[6], Hao Cheng[7], Xian Jiang[8], Ji-Chen Ho[9], Shuping Guo[10], Seong Jun Seo[11], Leona Liu[12], Elizabeth Colston[12], Arkendu Chatterjee[12], Renata M. Kisa[12], Subhashis Banerjee[12]

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib mediates intracellular signaling of cytokines (interleukin-23 and Type I interferon) involved in psoriasis pathogenesis. Two global, phase 3 clinical trials in moderate to severe plaque psoriasis, POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751), demonstrated that deucravacitinib was superior to placebo based on the coprimary endpoints of ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) and static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1) at Week 16, as well as superiority to apremilast on multiple endpoints. A third phase 3 clinical trial, POETYK PSO-3 (NCT04167462), demonstrated the superiority of deucravacitinib versus placebo based on PASI 75 and sPGA 0/1 at Week 16 in Asian patients from mainland China, Taiwan, and South Korea with moderate to severe plaque psoriasis. Here, the maintenance of response was evaluated over 52 weeks in deucravacitinib-treated patients who achieved a response at Week 16 in POETYK PSO-3.

Materials & Methods: Patients ≥18 years of age with moderate to severe plaque psoriasis (baseline PASI ≥12, sPGA ≥3, and body surface area involvement ≥10%) were randomized 1:2 in a blinded manner to oral placebo or deucravacitinib 6 mg once daily. Patients randomized to deucravacitinib received continuous treatment from baseline to Week 52, while patients on placebo crossed over to deucravacitinib at Week 16. Nonresponder imputation was used for missing data.

Results: A total of 146 patients** were randomized to deucravacitinib. Response rates with deucravacitinib were high at Week 16 (PASI 75, 68.8%; sPGA 0/1, 55.6%) and at Week 24 (PASI 75, 72.4%; sPGA 0/1, 60.7%). Most patients who achieved a response at Week 16 maintained response at Week 52 (PASI 75, 87.8%; sPGA 0/1, 73.4%).

Conclusion: Deucravacitinib maintained clinical efficacy over 52 weeks in Asian patients with moderate to severe plaque psoriasis.

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Abstract N°: 2646

Deucravacitinib in plaque psoriasis: 3-year safety and efficacy results from the phase 3 POETYK PSO-1 and PSO-2 trials

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was superior to placebo and apremilast in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) trials in moderate to severe plaque psoriasis. Upon completion of the parent trials, patients could enroll in the ongoing POETYK long-term extension (LTE) (NCT04036435) trial. As previously reported, patients treated with deucravacitinib maintained long-term efficacy responses through 2 years with no new safety signals compared with Year 1. Here, we report safety and efficacy of deucravacitinib up to 3 years (Week 148) through the cutoff date (June 15, 2022).

Materials & Methods: PSO-1 and PSO-2 randomized patients 1:2:1 to oral placebo, deucravacitinib 6 mg once daily (QD), or apremilast twice daily. At Week 52, patients enrolled in the LTE trial received open-label deucravacitinib 6 mg QD. Safety was evaluated in patients who received ≥1 dose of deucravacitinib. Exposure-adjusted incidence rate (EAIR) per 100 person-years (PY) is calculated as 100*(# of patients with an adverse event [AE])/(total exposure time for all patients at risk [time to initial AE occurrence for patients with AE + total exposure time for patients without AE]). Efficacy outcomes included ≥75%/≥90% reduction from baseline in Psoriasis Area and Severity Index (PASI 75/90) and static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1). Efficacy was reported using modified nonresponder imputation (mNRI) in patients who received continuous deucravacitinib treatment from Day 1 of the parent trial and were enrolled and treated in the LTE trial. As-observed data and results by treatment failure rule imputation were also analyzed.

Results: A total of 1519 patients received ≥1 dose of deucravacitinib, with 513 patients receiving continuous deucravacitinib treatment from Day 1 in PSO-1/PSO-2 and who were enrolled and treated in the LTE trial. Cumulative exposure from parent trial randomization was 3294.3 PY for these safety analyses. EAIRs/100 PY were similar, or decreased, from the 2-year to 3-year cumulative period, respectively, for AEs (154.4, 144.8), serious AEs (6.1, 5.5), discontinuation due to AEs (2.8, 2.4), herpes zoster (0.7, 0.6), malignancies (0.9, 0.9), major adverse cardiovascular events (0.4, 0.3), venous thromboembolism (0.1, 0.1), and deaths (0.4, 0.3). Clinical response rates

were maintained at Week 148 by mNRI (PASI 75, 73.2% [95% CI, 68.7, 77.8]; PASI 90, 48.1% [95% CI, 43.2, 53.1]; sPGA 0/1, 54.1% [95% CI, 49.1, 59.1]), with similar results regardless of data imputation methodology.

Conclusion: Deucravacitinib demonstrated a consistent safety profile through 3 years with no increases in AE or serious AE rates over time and no emergence of new or long-term safety signals. Efficacy was sustained through 3 years in patients treated continuously with deucravacitinib from Day 1 in the parent trials. Since it is important to provide long-term safety for this new class of drugs, these findings provide additional support for deucravacitinib having a consistent safety profile and durable efficacy for up to 3 years of use.

EA DV CONGRESS
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 2659

Deucravacitinib in plaque psoriasis: maintenance of response over 3 years in the phase 3 POETYK PSO-1 and PSO-2 trials

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was superior to placebo and apremilast in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials in moderate to severe plaque psoriasis. Upon completion of these trials, patients could enroll in the ongoing POETYK long-term extension (LTE) (NCT04036435) trial. Deucravacitinib maintained long-term efficacy through 2 years with no new safety signals. Here, we report clinical efficacy for up to 3 years (148 weeks) in the POETYK LTE trial in a subset of patients who received continuous deucravacitinib treatment from Day 1 in the parent trials and entered the POETYK LTE trial.

Materials & Methods: In POETYK PSO-1 and PSO-2, patients were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily (QD), or apremilast 30 mg twice daily. At Week 52, patients could enter the POETYK LTE trial where they received open-label deucravacitinib 6 mg QD. This analysis evaluated the efficacy of deucravacitinib through Week 148 in patients from the pooled POETYK PSO-1 and PSO-2 populations who received continuous deucravacitinib from Day 1, achieved ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) at Week 16 (primary endpoint) or at Week 24 (peak response), and enrolled in the POETYK LTE trial. Maintenance of response was assessed through the cutoff date of June 15, 2022, and included PASI 75 and PASI 90 (≥90% reduction from baseline in PASI). sPGA 0/1 (static Physician's Global Assessment of 0 [clear] or 1 [almost clear] with a ≥2-point improvement from baseline) was also assessed. Efficacy was reported using modified nonresponder imputation. The Clopper-Pearson method was used to calculate 95% confidence intervals (CIs).

Results: A total of 513 patients completed 52 weeks in the parent trials and received continuous deucravacitinib treatment from Day 1, including 313 (61.4%) patients (95% CI, 57.0%, 65.6%) who achieved PASI 75 at Week 16 and 336 (66.5%) patients (95% CI, 62.2%, 70.6%) who achieved PASI 75 at Week 24. Among these patients, PASI 75 response rates were maintained from Week 52 (the start of the POETYK LTE trial) to Week 148 (**Table**). PASI 90

response rates were maintained in more than half of this population from the start of the POETYK LTE trial (**Table**). sPGA 0/1 response rates were also maintained from Week 52 to Week 148 in these patients (**Table**).

Conclusion: Clinical efficacy was maintained for up to 148 weeks with continuous deucravacitinib treatment in most of the patients who were Week 16 and Week 24 PASI 75 responders from the parent trials and enrolled in the POETYK LTE trial. These findings further support the long-term use of once-daily oral deucravacitinib as an effective treatment for patients with moderate to severe plaque psoriasis.

Table. PASI 75, PASI 90, and sPGA 0/1 response rates with continuous deucravacitinib in Week 16 (n = 313) and Week 24 (n = 336) PASI 75 responders

	PASI 75 responders at Week 16, % (95% CI)			PASI 75 responders at Week 24, % (95% CI)		
Parameter	Week 16 (n = 277)	Week 52 (n = 277)	Week 148 (n = 277)	Week 24 (n = 305)	Week 52 (n = 305)	Week 148 (n = 305)
PASI 75	100 (NE, NE)	87.0 (NE, NE)	84.5 (79.8, 89.2)	100 (NE, NE)	90.2 (NE, NE)	86.0 (81.6, 90.3)
PASI 90	57.8 (NE, NE)	60.6 (NE, NE)	60.0 (53.9, 66.1)	63.3 (NE, NE)	61.6 (NE, NE)	60.4 (54.6, 66.3)
sPGA 0/1	84.1 (NE, NE)	70.8 (NE, NE)	62.8 (56.7, 68.9)	83.0 (NE, NE)	74.1 (NE, NE)	64.5 (58.7, 70.3)

CI, confidence interval; NE, nonestimable; PASI 75/90, ≥75%/90% reduction from baseline in PASI; sPGA 0/1, static Physician's Global Assessment score of 0 (clear) or 1 (almost clear), with a ≥2-point improvement from baseline.

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Abstract N°: 2682

Adherence to general national dietary guidelines and risk of psoriasis: results from a general population study of 96,960 individuals

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Introduction & Objectives:

The impact of diet on risk of psoriasis is currently an emerging and debated topic. Patients believe it matters; however, evidence is scarce. Ongoing and previous studies have focused on specific diets such as the Mediterranean diet, anti-inflammatory diet, hypocaloric diet, gluten-free diet, intermittent fasting, and supplementation with micronutrients. Long-term adherence to these diets can be challenging and therefore, we tested if adherence to simple general national dietary guidelines is associated with risk of moderate to severe psoriasis in a prospective cohort study from the general population.

Materials & Methods:

We included 105,332 individuals from the general population, aged 20-100 years, randomly invited from 2003 to 2015. Identification of psoriasis was made using ICD-10 codes L40, corresponding to moderate to severe psoriasis. Adherence to general national dietary guidelines was grouped into low, intermediate, and high based on a food frequency questionnaire. Information on potential confounders was obtained from clinical examination, self-reported lifestyle questionnaire, and blood samples at baseline.

Results:

Of the 105,332 individuals included in this study, 580 had a diagnosis of psoriasis at the time of enrolment and 640 received a diagnosis during a median follow-up of 9 years. Risk of having moderate to severe psoriasis increased according to non-adherence to general national dietary guidelines in a stepwise manner with an age- and sex adjusted odds ratio of 1.70 (95% confidence interval 1.26-2.30) in individuals with low adherence compared to individuals with high adherence to dietary guidelines. After adjustment for hypertension, smoking, alcohol consumption, physical activity, and low educational level the odds ratio was 1.43 (1.05-1.94). However, in the prospective analyses we could not find an increased risk of developing moderate to severe psoriasis in individuals with low or intermediate adherence compared to high adherence to general dietary guidelines (P for trend: 0.45).

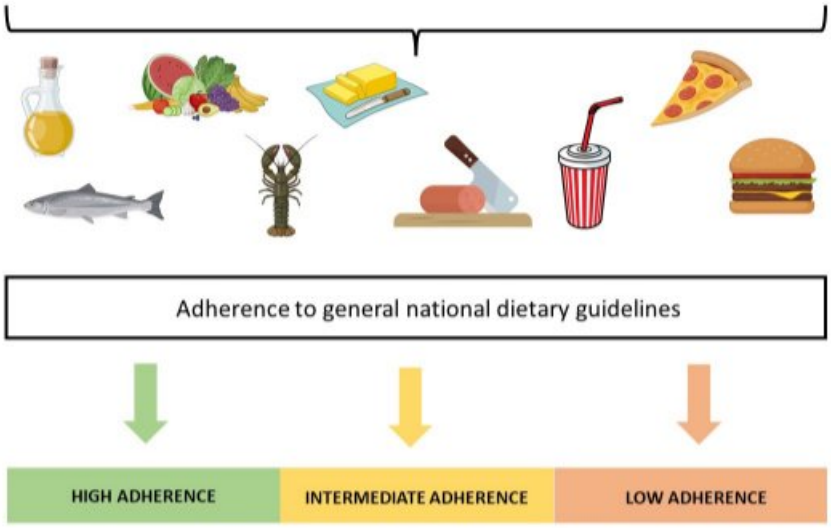
Conclusion:

In this prospective cohort study, we find that individuals with moderate to severe psoriasis have an unhealthier diet compared to individuals without moderate to severe psoriasis. However, an unhealthy diet does not appear to increase the risk of developing psoriasis.

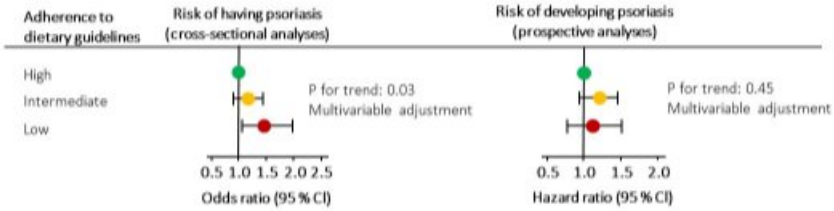
Summarizing figure

Study population and methods

- 105,332 individuals from the general population
- Food frequency questionnaire at study inclusion



Results



Conclusion

Individuals with moderate to severe psoriasis have an unhealthier diet compared to individuals without moderate to severe psoriasis. However, an unhealthy diet does not appear to increase the risk of developing psoriasis.

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Abstract N°: 2687

Evaluating Serum Protein Profiles during Different Hormonal Life Stages of Psoriasis Patients

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Introduction & Objectives:

Little is known about the potential link between hormonal life stages and systemic disease severity in psoriasis, as research is limited. Here we investigated the differences between the blood of pre- or post-menopausal female psoriasis patients, and matched males, at the proteomic level.

Materials & Methods:

Liquid chromatography mass spectrometry (LC-MS/MS) was used in conjunction with a 500-reference protein panel to analyse the serum of 29 patients (13 female, 16 male) with severe psoriasis (PASI > 10), from the University Hospital of Zurich's Dermatology Biobank. High abundant proteins were depleted using mini spin-columns to improve detection of low abundant proteins. Patients had not received previous systemic antibody treatments, did not have psoriatic arthritis, were not severely over or underweight (BMI > 20 and < 30), had normal CRP levels (< 5 mg/L), and had not received clinically relevant co-medication at the time of sampling. For analysis, patients were grouped into pre- and post-menopausal age groups of 18 – 42 years and 51 years and older, respectively.

Results:

Using LC-MS/MS, we detected 394 proteins (79% recovery). Two-way statistical analysis revealed significantly increased immunoglobulin superfamily containing leucine-rich repeat protein, fibronectin, gal-3-binding protein, cadherin-1, ICAM1 and cartilage oligomeric matrix protein in older compared to younger female patients. Subsequent network analysis identified among others platelet degranulation and activation pathways, which have been linked to increased cardiovascular disease risk (CVD) in psoriasis. When comparing age-matched female to male patients, pro-platelet basic protein (PPBP), Insulin-like growth factor II and Insulin-like growth factor-binding protein 4 were more highly expressed in young females. Notably, PPBP is a potent chemoattractant and activator of neutrophils, which have been implicated in psoriatic disease severity. In contrast, Apolipoprotein C-II and C-III were lower in young females, which may positively affect CVD risk. In older female patients, Galectin-3-binding protein and Extracellular matrix protein 1 were more highly expressed, both of which are also active in platelet degranulation and activation pathway.

Conclusion:

Using a highly specific 500-reference protein panel, we could show that there are significant differences in the serum proteins between female and male psoriasis patients based on their hormonal life cycle. Pathway analysis revealed platelet degranulation to be enriched in younger females, which may relate to vascular inflammation and CVD risk in psoriatic patients. Since psoriasis severity is currently mainly diagnosed visually, this may lead to underestimation of systemic inflammation in certain patient groups. **

Table 1. Baseline patient characteristics.

	Female ("Pre")	Female ("Post")	Male ("Pre"-Matched)	Male ("Post"-Matched)
N	8	5	10	6
Age	33±7,0	69±8,0	35±6,0	58±6,0
Age: min. - max.	22 - 42	52 – 78	26 - 43	51 - 66
BMI	25,7±3,3	24,4±2,1	25,0±3,3	26,6±0,4
PASI	13,4±3,6	10,5±0,9	14,0±4,1	11,1±0,5

"Pre": pre-menopausal; "Post": post-menopausal; "Pre-/Post"-matched: age matched male cohort; BMI: Body Mass Index; PASI: Psoriasis Area Severity Index

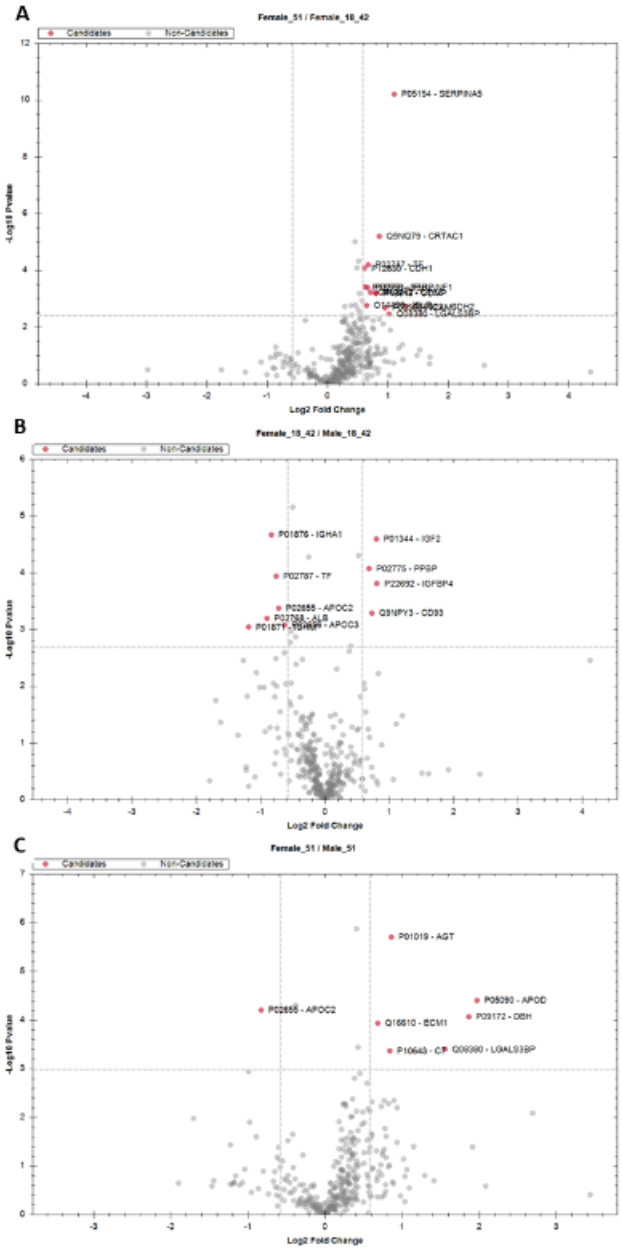

Figure 1. Differential expression between ***A)*** *18 – 42 year old female and 51 year old and older female patients,* ***B)*** *51 year old and older female and age matched male patients,* ***C)*** *18 – 42 year old female and age matched male patients using the PQ500 standard panel. Figures show volcano plots processed in Biognosys SpectroDive software, with –log10 transformed P-value as a function of the difference between groups. Red dots indicate differentially expressed protein candidates.*

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Abstract N°: 2754

PICASSO: ProspectIve Cohort psoriASiS fOllow-up

Heleen Cokelaere[1], Vanhoutvin Tine[1], Dorien Hunin[1], Tom Hillary[1]

[1]Leuven, Dermatology, Leuven, Belgium

PICASSO: ProspectIve Cohort psoriASiS fOllow-up

Introduction & Objectives:

Psoriasis is a common inflammatory disorder that occurs in up to 3% of the Western population. It is associated with multiple comorbidities, among which the metabolic syndrome (MetS) whose prevalence is increased up to three times compared to the general population.1 The causal relationship between psoriasis and MetS or other comorbidities remains to be elucidated. The orofecal and cutaneous microbiome have been suggested to trigger systemic inflammation, although data on this topic are limited.2, 3 It remains unclear to what extent these comorbidities and host environment facilitate or slow down disease progression. While detailed understanding of the pathophysiology has enabled the development of highly targeted and efficient treatment options, to date no hard evidence of predictive markers for disease evolution or treatment response in cutaneous psoriasis is available.4

We aim to create a prospective cohort and biobank, including 200 psoriasis patients with recent onset of disease (Figure 1). Every 2.5 years, disease characteristics and evolution are mapped and biological samples are collected to identify bio- and genetic markers that predispose to moderate or severe disease and development of comorbidities.

Materials & Methods:

In this prospective monocentric cohort, patients with a disease duration of less than three years, presenting at or referred to our dermatology department will be proposed to participate in the project.

Conclusion:

Here we present the PICASSO-project for the first time: in this unique cohort including psoriasis patients with recent onset of disease, we prospectively collect clinical data and bio-material. Ultimately, these insights could enable patient stratification and personalized treatment. In this poster we provide details on the extensive bio-sampling and goals of the PICASSO-project. Furthermore we provide an update on patient inclusion and patient characteristics.

This work was supported by research grants by Abbvie, Almirall, Amgen, Eli-Lilly, Janssen, Leo Pharma, Novartis, UCB.

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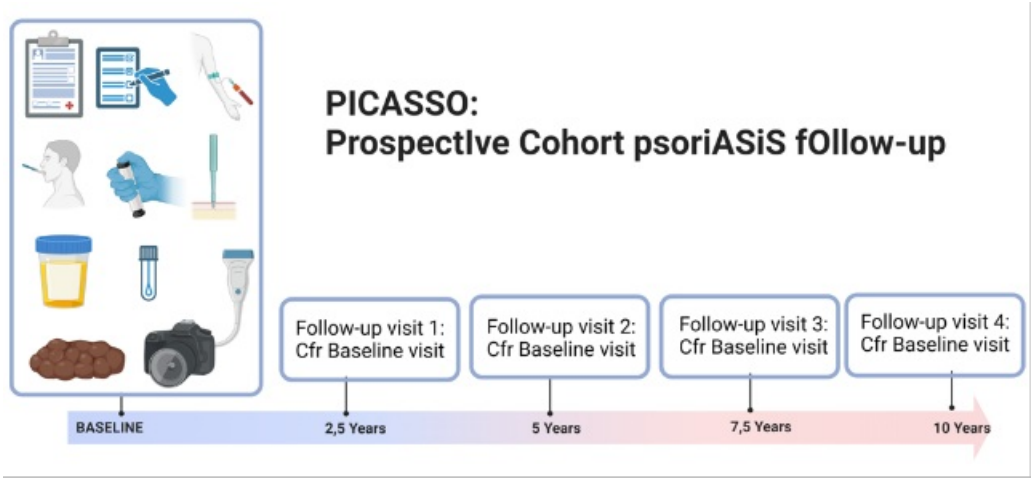

Figure 1: Flowchart of the PICASSO-project. Genetic and biological samples are collected at baseline (disease duration less than 3 years) and 4 follow-up visits every 2.5 years. Sampling includes blood, saliva, nails, faeces, urine, skin swabs, tape stripping, skin biopsies and hair. Carotid intima media thickness is measured via ultrasound. Clinical parameters (e.g. disease severity, treatment and patient reported outcome measures) are assessed at every time point. Created with BioRender.com.

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Abstract N°: 2765

Type I/II immunity and cytotoxicity signature genes mark transcriptional programs of peripheral γδ T cells in untreated psoriasis vulgaris.

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Introduction & Objectives: Psoriasis vulgaris (PV) is a chronic erythematosquamous dermatosis mediated by the accumulation of inflammatory cells in the skin. Much of the inflammatory infiltrate consists of innate immune cell effectors, including the most numerous innate-like T cell compartment of γδ lymphocytes. Current evidence points to altered proportions of peripheral γδ T subpopulations in blood and skin of untreated psoriatic patients, but the intrinsic changes that guide their compositional, phenotypic, and functional perturbations in PV are still largely unknown.

Materials & Methods: Here, we investigated an immunotranscriptome of peripheral blood CD3+γδTCR+ T cells in a well-characterized cohort of 12 affected (type I PV, median PASI 7.4) and 11 matched control individuals. Mean age, CMV status and BMI were similar in both groups. High-quality RNA samples from flow-sorted bulk γδT cells (CD3ε, panTCRγδ, TCRVδ1/δ2, FACS Canto II/BioRadS3e) were used for targeted RNA sequencing of 395 genes associated with various biomarkers of immune cell differentiation, proliferation, effector function and trafficking (AmpliSeq Immune Response Panel, Illumina Miniseq sequencer). Differential gene expression analysis was performed using BaseSpace RNA Amplicon and DeSeq2 pipelines (false discovery rate q<0.05, llog-ratiol>0.25). Gene Ontology and KEGG were used for pathway analysis.

Results: Compared to healthy controls, γδT cells from PV patients differentially expressed 36 genes, 30 of which were upregulated, including the Th1/2 lineage defining transcription factors *STAT6* and *TBX21. IRF1* (the master regulator of interferon/IFN signalling) and the IFNγ-inducible targets were overrepresented as well (*ISG20, CD40, KLRK1, GPR18, IL2RB*, q=2.1E-9, gene set enrichment analysis), together with the genes related to cytotoxicity (*PRF1, GZMA, NKG7, SRGN, HLA-E*, q=1.1E-9), cell trafficking (*KLF2, CXCR4, GPR18, MIF, CORO1A*, q=5.9E-11), and cell-cell adhesion (*SELL, CD47, ITGAL*, q=1.3E-7). Genes encoding members of the TCR signalosome (*CD3D/E/G, ZAP70, CD247*, q=1.7E-6) were also overexpressed, while the levels of *IFI44L* (a feedback regulator of IFN response), *IL23A*, and *MTOR* (which encodes the major nutrient-sensitive regulator of cell metabolism and stress response) were reduced. Disease activity (PASI, DLQI) had no effect on target gene expression.**

Conclusion: Our data revealed significant transcriptional alterations in the peripheral γδT cell pool of PV patients, providing evidence of enhanced activation and cytotoxic capacity in PV settings. The recovered biomarkers warrant further evaluation of their prognostic and therapeutic significance.

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Abstract N°: 2802

Examining the lived-experience of psoriasis in Brazil: findings from an online Global Psoriasis Atlas survey

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Introduction & Objectives: Psoriasis occurs commonly in Brazil, but** there is limited knowledge of the burden of psoriasis on individuals. We surveyed people with psoriasis to better understand their lived experience.

Materials & Methods: We developed an** online survey and recruited adults with psoriasis in Brazil via email through patient organisations and social media. The survey assessed 5 domains for severity and impact: well-being, disease state, treatment, comorbidities, and work impact. Spearman's correlation (Rho) was used to test the correlation between self-assessed disease severity (using the Simplified Psoriasis Index [SPI] extent score; range 0 [clear/minor] to 40 [widespread/severe]) and health-related quality of life (QoL, using the Hernandez EQ-5D utility score) and capability (ICECAP) scores. Multivariable linear regression was used to identify predictors of QoL and ICECAP.

Results: Between May 2022 and January 2023, 563 people with psoriasis were surveyed. The mean age of participants was 42.1±12.4 years, females represented 73.5%, with 67.5% identifying as white, 25.9% mixed, 5.3% Black, 0.9 % Asian, and 0.4% other. Most participants had been diagnosed for >10 years (67%), 88% were non-smokers and 47% did not consume alcohol. In the past year, 46% of respondents experienced 1 psoriasis flare and 27% experienced multiple flares. Whilst 83% of respondents were receiving prescribed medications (topicals, injectables and oral) or used other treatments including UV exposure, diet modification and alternative treatments, less than half found their treatments effective. Comorbidities such as anxiety/depression, arthritis or back/joint problems, hypertension, kidney or liver disease, and type 2 diabetes were prevalent, with 52% of respondents reporting at least one other long-term condition.

The average self-assessed SPI was 7.8±8.6 with most respondents reporting mild psoriasis (68%). Self-assessed SPI was found to be moderately negatively correlated with health-related QoL ($r=-0.49$, $P<0.05$) and capability ($r=-0.44$, $P<0.05$). Significant predictors of poorer QoL included increased SPI, being female, Black or Asian ethnicity (compared to White), unemployed, number of comorbidities, number of flares and use of oral, injectable, or alternative treatments; SPI, comorbidities, flares, and gender were the strongest predictors. Significant predictors of reduced capability included increased SPI, being female, Black ethnicity, lower educational attainment, not in full-time employment, number of comorbidities, number of flares and use of injectable or alternative treatments; SPI, comorbidities, employment status, flares, and gender were the strongest predictors.

When respondents were asked to describe their experience of living with psoriasis, 4 recurrent themes were identified: (1) feelings of stigma/prejudice, (2) a lack of public awareness, (3) feeling trapped by the disease, and (4) difficulty obtaining appropriate specialist care and treatment.

Conclusion: We found that psoriasis, its clinical features, severity, and associated comorbidities, negatively impact health-related quality of life and capability in the surveyed Brazilian population. This is accompanied by feelings of social stigma and prejudice and inadequate availability of specialist physicians and treatment which highlight a need for better access to care, and awareness of the disease, to improve the lives of people living with psoriasis.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 2804

Interest of a novel dermocosmetic shampoo in the management of scalp psoriasis

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Introduction & Objectives:

Scalp psoriasis (SP) is a chronic disease presenting thick scales on clearly-defined, erythematous skin. It can also cause severe itching. Even though, the hair frequently covers lesions, flaking may impact the subject's quality of life. Currently, SP treatment includes topical therapy, intralesional therapy, systemic therapy, and photochemotherapy.

The present studies assessed the non-delipidating and protective effect as well as the clinical benefit and safety of a novel dermocosmetic shampoo containing salicylic acid, juniper and zanthoxylum extracts, and forskoline for mild to moderate SP.

Materials & Methods:

Two open-labelled, intra-individual clinical studies were conducted. The first study assessed, 1 and 4 hours after a single application, the non-delipidating and protective effect of the shampoo by assessing transepidermal water loss (TEWL) and sebum quantity on the face of 10 healthy adult female subjects with oily skin (cutaneous sebum rate $\geq$140µg/cm^2).

The second study assessed in 18 subjects aged >18 years with mild to moderate untreated SP, the clinical benefit, local tolerability and cosmetic acceptability of the shampoo during 56 days. Subjects applied the shampoo every 2 days during 21 days and then twice a week during 35 days. The investigator assessed the investigator global score (IGA, from 0=none to 4=severe), the scalp surface area (SSA), the psoriasis scalp severity index (PSSI from 0=none to 72=very severe) and the overall benefits (0=very poor to 4=very good) on baseline, Day 28 (D28) and 56 (D56). Subjects assessed the intensity of pruritus on D28 and D56 and the cosmetic acceptability on Day 56.

Results:

A variation compared to the non-treated area of the TEWL and the cutaneous sebum rate was observed 1 and 4h after a single application. In the clinical study, subjects had a mean age of 36.0±10 years, 72% were males, 50% had phototype V, 33 a phototype IV and 6% each had a phototype II, III or VI. 66% had a SP starting more than 6 years prior to the study and 61% had a psoriasis family history. After 28 days, the SSA had decreased by 20.2% ($p<0.001$) and the PSSI by 29.7% ($p<0.01$); the IGA decrease was not significant. After 56 days, the IGA had decreased by 24.2% ($p<0.05$), the SSA by 38.9% and the PSSI by 56.3% (both $p<0.001$). Overall, investigators rated the dermocosmetic shampoo being beneficial in 67% of subjects. The pruritus score had decreased by 34% at D28 and by 57% at D56 (both $p<0.001$). Subjects highly appreciated the cosmetic properties of the shampoo which was very well tolerated.

Conclusion:

The dermocosmetic shampoo is non-delipidating, does not affect the skin barrier and is highly beneficial and well tolerated by subjects with mild to moderate scalp psoriasis as early as after 28 days.

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Abstract N°: 2810

Efficacy and safety of biological drugs in the treatmens of moderate-to-severe psoriasis in elderly patients

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Introduction & Objectives:

To date, data published in the literature regarding the efficacy and safety of biologic drug therapy for moderate and severe psoriasis in the elderly is rather limited. Randomized clinical trials have tended to include a small proportion of participants older than 65 years, and the few retrospective studies targeting the elderly population are based on small cohorts of patients.

Materials & Methods:

We retrieved the data of over-65 patients referred to the Psoriasis Severe outpatient clinic. The efficacy and safety of currently available biologic drugs were evaluated: TNF-α inhibitors (etanercept, adalimumab and certolizumab), IL-12/23 inhibitors (ustekinumab), IL-17 inhibitors (brodalumab, secukinumab and ixekizumab) and inhibitors of IL-23 (guselkumab, risankizumab and tildrakizumab). Monitoring of clinical data (PASI, BSA, DLQI and NAPSI) was carried out at the start of treatment (baseline) and then at weeks 12, 24, 36, 48 and 60 (endpoint of the study). A descriptive analysis and an inferential analysis (Student's t-test for paired samples and multivariate logistic analysis) were performed.

Results:

The mean PASI value steadily decreased over the course of therapy, from 11.67 at baseline to 0.95 at week 60. 67.19% of the patients achieved the PASI-100 at the end of the observation period. Among the patients in the study, 24 also had nail involvement, with a mean value of NAPSI at T0 of 35.29, reduced to 4.21 at week 60. Multivariate analysis showed that the number of comorbidities of the patients did not significantly influence significantly on the achievement of the treatment goal ($p<0.05$).

Conclusion:

The results of the present analysis are in line with those of clinical trials randomised clinical trials in the general population and with those of retrospective studies in the elderly population. The data obtained support the hypothesis of the effectiveness of biologic drugs even in patients over 65 and support the appropriateness of their use in clinical practice.

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Abstract N°: 2846

Efficacy and Safety of Apremilast Monotherapy in moderate-to-severe Plaque Psoriasis: A Systematic Review and Meta-analysis

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Introduction & Objectives: Psoriasis is a chronic, inflammatory, immune-mediated disease of the skin. Plaque psoriasis is the most common clinical phenotype of psoriasis. Apremilast is an oral phosphodiesterase type 4 inhibitor, recently approved by the US Food and Drug Administration (FDA) for the management of plaque psoriasis. The aim of the present study was to assess the efficacy and safety of Apremilast monotherapy in the treatment of moderate to severe plaque psoriasis.

Materials & Methods: This systematic review included randomized conrolled trials (RCTs) evaluating Apremilast 20 mg twice daily (BID) and 30 mg BID in comparison to placebo for the management of plaque psoriasis. We searched Embase, Medline, and CENTRAL. We sought to evaluate the following outcomes: Psoriasis Area and Severity Index score (PASI)-75, PASI-50, PASI-90, static Physician Global Assessment (sPGA), and adverse event. Risk ratio (RR) was used to represent dichotomous outcomes and adverse events, and the data was pooled using the inverse variance weighting method.

Results: A total of 8 RCTs that enrolled 2,635 participants deemed eligible. Apremilast 30 mg BID and 20 mg BID were significantly more efficacious than placebo in achiving PASI-75 over 16 weeks (RR=4.60, 95% CI 3.29-6.41and RR=3.15, 95% CI 1.96-5.07, respectively). Apremilast 30 mg BID showed significantly higher rate of adverse event compared to placebo (RR=1.24, 95% CI 1.16-1.33), whereas Apremilast 20 mg BID did not exhibit any significant difference (RR=1.13, 95% CI 0.91-1.42).

Conclusion: This meta-analysis demonstrated that Apremilast monotherapy provides a novel therapeutic option for plaque psoriasis with acceptable tolerability and safety profile.

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Abstract N°: 2884

Patient characteristics and treatment pattern among patients with moderate-to-severe plaque psoriasis using systemic treatment in China: Real-World evidence from a retrospective observational study

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TITLE: Patient characteristics and treatment pattern among patients with moderate-to-severe plaque psoriasis using systemic treatment in China: Real-World evidence from a retrospective observational study

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Introduction & Objectives:

Real-world evidence on patients with moderate-to-severe Psoriasis (PsO) receiving systemic therapies is limited in China. The study aims to depict the patients' characteristics and treatment pattern among patients with moderate-to-severe PsO using systemic treatment in China.

Materials & Methods:

This retrospective observational study used electronic medical records data from 2 hospitals in China between January 2018 and December 2021.The study included adult patients with moderate-to-severe plaque PsO and having at least one clinical visit. Patients' index systemic treatment was defined as the 1st treatment of oral systemic medications or biologics within the observation period. Analyses were conducted on patients with follow-up period ≥ 6 months after index systemic treatment prescription in the observation period. Treatment pattern of discontinuation, switching, and add-on of index systemic treatments, as well as treatment duration was analyzed.

Results:

Overall, 1,102 patients with moderate-to-severe plaque PsO were included in the analysis (mean age: 44.9±14.6; male: 77.2%). For index systemic treatment, most patients in the study used conventional oral systemic medication (83.94%) with median duration of 92 (2-1459) days, while biologics were received as the index systemic treatment by 16.06% of patients with median duration of 199 (15-485) days. Acitretin (71.69%) was the primary choice with median duration of 84 (2-1459) days. Secukinumab (5.54%) and adalimumab (5.35%) were found as the two most common used biologics, with the median duration of 235 (29-329) days and 224 (15-441) days, respectively. No patients used targeted oral systemic medications due to the fact that no targeted oral systemic medications were approved in China during the observation period.

During the 6-month follow-up period, 87.84% of the patients discontinued the index systemic treatments while 5.81% of the patients switched to a new systemic medication. Among patients using index conventional oral medications and biologics, 94.59% and 52.54% discontinued index systemic treatment and 4.86% and 10.73%

switched treatment, respectively. Adding a different systemic treatment to the ongoing index systemic treatment was rare and with similar frequency for patients with conventional oral treatment (2.27%) or biologics (2.26%).

Conclusion:

Conventional oral systemic medications were still the primary choice of systemic treatment, but with short treatment duration. The discontinuation rate in the patients receiving systemic treatment was generally high, while discontinuation rate among patients receiving biologics as index systemic treatment appears to be lower than patients with conventional oral systemic treatment. These results are limited by the relatively small number of patients with index biologics treatment in the analysis given late approval timeline in China. Future studies with larger population are needed to elucidate these findings.

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Abstract N°: 2916

Use of guselkumab in the treatment of severe psoriatic arthritis in real world practice

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Introduction & Objectives: Guselkumab is an IL-23 inhibitor that has recently been approved for the treatment of active psoriatic arthritis (PsA) that does not respond to treatment with conventional synthetic disease-modifying anti-rheumatic drugs(csDMARDs). However, the prescription habits are unknown and the experience in real life is still limited and often comes from multidisciplinary consultations between dermatology and rheumatology.

Materials & Methods: Observational, retrospective, non-interventional study conducted in a single hospital. Demographic data, body mass index, cardiovascular risk factors, number and type of previous treatments, presence of cancer, concomitant infection with hepatitis B and C viruses, and human immunodeficiency were collected from patients diagnosed with PsA. The characteristics of the PsA were collected, such as the type and number of affected domains and comorbidities. Disease activity was quantified using joint counts, C-reactive protein, assessment scales (RAPID-3, BASDAI, DAPSA and/or MDA) according to treatment by objectives. Combined use of guselkumab with DMARDs including targeted therapies, degree of response, discontinuation with reason for withdrawal, and adverse effects were collected. Patients included in a clinical trial were excluded.

Results: Twenty-six patients were included, 17 women (65.4%), with a mean disease duration of 7.8 years. Twenty-four patients (92.3%) had joint involvement (14 oligoarticular, 9 polyarticular and 1 distal joint involvement). Thirteen patients had enthesitis and 5 patients had dactylitis. Six patients had axial involvement. All had cutaneous involvement, 7 of whom had pustular or palmoplantar involvement. Three patients had hepatitis B or C infection, 1 had human immunodeficiency and 3 had a history (1) or concomitant presence (2) of cancer. All patients had received between 1 and up to 8 previous biologics or non-biologics (3 at least 1, 4 two and 19 between 3 and 8). Twenty-one patients (80.7%) had received previous non-biologic DMARDs including apremilast. Twenty-four patients (92.3%) received up to a total of 48 prior biologics (31 anti-TNF, 10 anti-IL-17 and 7 anti-IL-12/23). Twelve patients (46.1%) received combination therapy with non-biologic DMARDs including 3 with apremilast and 1 with upadacitinib. In 2 patients (7.6%) treatment was discontinued: in 1 due to the patient's wish and in 1 due to infection after prosthetic implantation. No other treatment-related adverse events were observed.

Conclusion: In our clinical practice, two guselkumab prescription profiles stand out. One is indicated in a severe PsA population, with a high failure rate to biologics, with long disease duration, in which blockade of other therapeutic targets has been exhausted. Another in which guselkumab is used in PsA in which the safety profile predominates in patients with chronic viral infections or concomitant tumors, which denotes confidence in its safety in these circumstances. This confidence is reaffirmed by the frequent use of guselkumab in combination therapy, even with targeted therapies. All patients had cutaneous involvement, especially the palmoplantar forms, suggesting a prescriber preference for its use in patients with predominantly cutaneous involvement. Treatment discontinuations were infrequent, highlighting the safety of guselkumab in these patients.

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Abstract N°: 2920

Two cases of Generalized Pustular Psoriasis (von Zumbusch) flares successfully treated with Spesolimab.

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Introduction & Objectives: Generalized pustular psoriasis (GPP) is a severe and rare form of psoriasis, characterized by erythematous-edematous plaques with widespread pustules and systemic symptoms. Recently, a novel molecule, an anti-IL-36R, named Spesolimab, has shown promising efficacy for the GPP flare treatment. This poster presents two cases of the first GPP patients treated with Spesolimab in Brazil. The objective of this report is to share the experience of patients with a GPP flare treated with Spesolimab, as well as to provide valuable insights into the authors' experience with the use of this new medication.

Materials & Methods: Data from the medical records of two patients diagnosed with Generalized Pustular Psoriasis and treated with Spesolimab were collected. The study participants have provided consent.

Results: Case 1: A 66-year-old retired female patient presented to the dermatology service complaining about erythematous lesions with pustules, associated with local pain and itching that had started one week before. Subsenquently, the lesions have disseminated and were accompanied by fever. Previous flares with similar characteristics, which were treated with systemic corticosteroids and antibiotics were reported by the patient. A skin biopsy and other tests were performed and Generalized Pustular Psoriasis was diagnosed based on European diagnostic criteria. Acitretin, cyclosporine and corticosteroids were initiated but adequate clinical control wasn't achieved. Consequently, it was decided to indicate 900mg of Spesolimab IV. One week after the infusion, only partial response was reached (GPPASI=10.2) and a second dose of Spesolimab 900mg was administered. The patient exhibited a rapid response to the medication the following week (GPPASI=3), and currently maintains complete clearance of the lesions without using any other medication for GPP. **Case 2:** A 27-year-old female patient reports a history of flares of erythematous lesions associated with pustules since the age of 11. The patient describes worsening intensity and frequency of the flares. At the age of 21, the patient progressed to a generalized condition associated with systemic symptoms requiring hospitalization. A diagnosis of GPP was made, and treatment with cyclosporine was initiated, resulting in clinical improvement. During follow-up in the outpatient setting, cyclosporine was discontinued, and Risankizumab was initiated. However, a new flare occurred with the induction dose of Risankizumab, leading to its discontinuation and the reintroduction of cyclosporine. After a year, the patient returned with another flare. On this occasion, an infusion of 900mg of Spesolimab was administered, resulting in a rapid response of cutaneous and systemic symptoms, with a decrease in pustules and erythema observed during the one-week follow-up visit. Maintenance treatment with Ustekinumab was initiated, and no new flares have been reported.

Conclusion: GPP is a dermatosis associated with systemic symptoms and elevated inflammatory markers. It is a potentially life-threatening condition, and traditional treatments can lead to side effects such as hepatotoxicity, renal insufficiency, and immunosuppression. Spesolimab offers the advantage of being a safer and more efficient alternative by specifically targeting IL-36 pathway.

BI was given the opportunity to review the manuscript for medical and scientific accuracy as well as intellectual property considerations.

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Abstract N°: 2934

Increased dental comorbidities in patients with psoriasis: a nationwide population-based cohort study in Korea

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Introduction & Objectives:

Despite the growing recognition of periodontitis as a dental comorbidity of psoriasis, relatively little is known about the relationship between other common dental diseases and psoriasis. We hypothesized that patients with psoriasis have an increased risk of overall dental comorbidities and investigated the risk of potential dental comorbidities in patients with psoriasis.

Materials & Methods:

We conducted a nationwide population-based cohort study using a database obtained from the National Health Insurance Service (NHIS). The psoriasis cohort consisted of individuals aged 20 years or older and who had at least two documented visits to a dermatologist with a diagnosis of psoriasis (ICD-10 code L40) between 2010 and 2017. Age- and sex-matched control subjects were randomly selected at a 1:5 ratio. We identified the incidence of the following potential dental comorbidities from the index year until the end of the study: (i) dental caries, (ii) pulp and periapical disease, (iii) periodontal disease, (iv) gingival changes, and (v) tooth loss.

Results:

In the final study population, the psoriasis cohort consisted of 15,165 patients, and the control cohort consisted of 75,825 subjects. After adjusting for potential cofactors, the adjusted hazard ratio (HR) of dental caries (1.105; 95% confidence interval [CI] 1.078–1.132), pulp and periapical disease (1.07; 95% CI, 1.044–1.096), and periodontal disease (1.108; 95% CI, 1.088-1.129) were significantly higher compared to the control cohort ($p < 0.001$). In the psoriasis cohort, there were 4,275 patients who had received systemic anti-psoriatic agents such as cyclosporine, methotrexate, acitretin, and biologics. For these patients, the adjusted HR risk of all potential dental comorbidities was not significantly different from that of the control cohort.

Conclusion:

Patients with psoriasis have an increased risk of dental comorbidities such as dental caries, pulp and periapical disease, and periodontal disease. This increased risk is more significant in those patients who had not received systemic agents.

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Abstract N°: 3086

Arthritis Hit Rate in Patients with Psoriasis Referred for Rheumatology Evaluation

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Introduction & Objectives:

Psoriatic arthritis (PsA) is a chronic inflammatory arthritis that afflicts many patients with psoriasis, causing pain and impairing their quality of life. Early detection and treatment are crucial as PsA can lead to structural joint damage and reduced physical function. The objective of this study was twofold: to determine the proportion of patients with psoriasis referred from a dermatology department due to suspicion of PsA who were diagnosed with PsA or other rheumatologic conditions, and to identify clinical and patient-reported variables that can help identify patients with psoriasis in whom joint discomfort is indicative of PsA.

Materials & Methods:

This single-center retrospective study included all patients with psoriasis who had been referred for rheumatological evaluation between 2014 and 2018 based on suspicion of PsA.

Results:

A total of 364 patient records were examined, revealing 106 patients with psoriasis who had been referred for rheumatologic evaluation due to suspicion of PsA. Patients with a prior PsA diagnosis were excluded from the analysis. Among the referred patients, 23.6% were diagnosed with either peripheral or axial PsA, or both. Furthermore, 23.6% were diagnosed with osteoarthritis, and an additional 14.2% were diagnosed with inactive PsA. The positive predictive values/negative predictive values for a PsA diagnosis based on patient-reported swollen joints and dermatologist-assessed swollen joints at referral were 40%/100% and 50%/92%, respectively.

Conclusion:

In this study, it was found that 23.6% of patients with psoriasis with symptoms suggestive of PsA were diagnosed with peripheral and/or axial arthritis following rheumatologic evaluation. The presence of patient-reported swollen joints and dermatologist-assessed swollen joints indicated a high likelihood of peripheral PsA. Additionally, the absence of patient-reported swollen joints indicated a very low probability of diagnosing peripheral PsA.

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Abstract N°: 3104

Psoriasis, anti-TNF therapy and an unexpected guest.

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Introduction & Objectives:

Anti-TNF therapy is valuable for moderate-severe psoriasis control but poses an increased infection risk.

Materials & Methods:

We present a case of a 45-year-old male alcohol consumer with severe psoriasis controlled with infliximab, who developed evening fever (40ºC) for 5 weeks, weight loss, arthromyalgia, and general malaise; following a dental infection. Initial investigations, including blood tests, chest x-ray, urine culture and sediment, revealed mild leukopenia. Empirical treatment with amoxicillin-clavulanate was ineffective.

Consequently, the patient was admitted and the antiTNF suspended. Further studies revealed progressive pancytopenia (590 neutrophils/mm3, 8g/dL hemoglobin, 84000 platelets/mm3), elevated CRP (229mg/L), marked hepatosplenomegaly and retroperitoneal lymphadenopathy. The echocardiogram, mantoux, serologies (HIV, HBV, HCV) and blood cultures were all negative.

Due to prolonged fever, hepatosplenomegaly, and pancytopenia, Leishmania serology and bone marrow biopsy were performed, confirming Visceral Leishmaniasis (VL). Treatment with intravenous liposomal amphotericin B led to an excellent response.

Results:

Studying patients on anti-TNF therapy with fever of unknown origin is challenging, requiring consideration of a broader range of infectious diseases.

Regarding the patient's psoriasis, initial treatment with acitretin and PUVA had a partial response. A year after the VL, biologic therapy was resumed with Ustekinumab 45mg with a good initial response that lost efficacy over time. Methotrexate association was not tolerated due to elevated VCM and transaminitis. Increasing ustekinumab to 90mg resulted in a partial response. Switching to antiIL17 treatment was not considered due to IL17's role in leishmania control. Once risankizumab became available, it was prescribed with a good response, achieving a PASI score of 3.6 without new incidents.

Conclusion:

Leishmania eradication cannot be confirmed through available tests. Delaying immunosuppressive treatment for 1-2 years after VL is recommended, and careful selection of the therapeutic target is advised to prevent disease reactivation.

AntiTNF increases tuberculosis infection risk due to its role in TH1 response and granuloma formation, crucial for eliminating intracellular pathogens like leishmania and mycobacteria. IL17 promotes the recruitment and

activation of neutrophils and macrophages in the site of infection and it limits the growth of pathogens by working with IFN-gamma to boost nitric oxide and reactive oxygen species production in infected macrophages. Therefore, IL17 could be a critical component of the immune response against leishmania infection. Exhaustive knowledge of both the infection control pathways and the mechanism of action of biological treatments are essential.

In this case, an antiIL23 was chosen for its favourable safety profile, leading to successful disease control without any infectious complications.

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Abstract N°: 3106

Tildrakizumab improves signs and symptoms in patients with moderate to severe plaque psoriasis in a real-world setting: a holistic approach.

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Introduction:

Plaque psoriasis is a chronic inflammatory skin disease with the main signs and symptoms being plaques on the body and scalp, infestation of the nails, itching and an associated reduction in quality of life.

Many patients suffer from more than one sign or symptom at the same time. The objective of this interim analysis is to assess the impact of treatment with tildrakizumab on these signs and symptoms in routine clinical practice over 100 weeks (W100). The 5 relevant scores for the assessment of the disease severity were set as a combined response criterium, to reflect a holistic approach in all relevant areas.

Materials & Methods:

TILOT is an ongoing 3-year non-interventional study in adult patients with moderate-to-severe chronic plaque psoriasis who are eligible for systemic biologic treatment and receive TIL 100 mg (s.c.) as part of routine clinical practice in accordance with the Summary of Product Characteristics. The study evaluates, amongst others, effectiveness and safety based on Psoriasis Area and Severity Index (PASI), Physician Global Assessment on a 5-point scale in scalp and nails, itch-VAS and Dermatology Life Quality Index (DLQI). In this interim analysis at W100 these relevant scores for the assessment of the disease severity were set as a combined endpoint. Patients who are responders in the context of the combined response criterium must achieve all 5 criteria, PASI <3 and Nail-PGA 0/1 and Scalp-PGA 0/1 and Itch-NRS <3 and DLQI ≤5. Data are presented as observed cases (OC) and using last observation carried forward (LOCF).

Results:

This analysis was performed on the full analysis set of 503 patients. For the interim analysis at W100 data from 350 patients are available. 81.6 % of patients had scalp involvement and 45.3% suffered from nail infestations at baseline. At study start, the mean [Standard deviation] age was 47.5 years [15.2], 63.4% of patients are male. The PASI was 15.9 [9.1], DLQI 13.0 [7.3] and Itch-VAS 56-0 [28.7]. Patients with scalp or nail involvement at baseline achieved response rates of 64.4% (OC), 50.3% (LOCF) and 58,2% (OC), 45.2% (LOCF) for the combined endpoint. For the overall population, improvement in all 5 categories, PASI <3, Scalp-PGA 0/1, Nail-PGA 0/1, Itch-NRS <3 and DLQI ≤5 in W100 was achieved by 67.9% (OC), 50.9% (LOCF) resp. Over the entire study duration a constant increase in responders was observed. No new or unexpected safety signals were detected.

Conclusion:

A high proportion of patients treated with tildrakizumab met the combined response criterion, meaning most patients being free or almost free from skin, scalp, nail involvement and itching and they experience an improvement in quality of life independently from baseline expression of the disease. The application of a combined response criterium, comprised of the most common signs and symptoms of moderate to severe plaque psoriasis, reflects a more holistic assessment of the treatment outcome in routine practice.

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Abstract N°: 3108

Treatment effects of ixekizumab and adalimumab at the individual digit level with nail and distal interphalangeal joint involvement in patients with psoriatic arthritis

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Introduction & Objectives: Psoriatic nail disease is intimately linked to adjacent distal interphalangeal joint (DIP) disease, and it is important to ascertain whether DIP-nail complex behaves differently under different biological therapies. The aim of this analysis was to assess the effect of ixekizumab (IXE) and adalimumab (ADA) at the individual digit level in improving nail and joint disease, in patients with psoriatic arthritis and concomitant nail involvement.

Materials & Methods: This post hoc analysis included patients from SPIRIT-H2H (NCT03151551) treated with either IXE or ADA who had baseline nail disease (NAPSI total score >0) and DIP involvement in at least one simultaneous digit, with either tenderness, swelling or both, at the individual digit level for each hand. Proportions of patients having a NAPSI total score >0 and proportions of patients having DIP involvement (tenderness or swelling) were evaluated at baseline and Week 24; post-baseline assessments were compared between treatment arms using Fisher's exact test.

Results: Of the intent-to-treat population of SPIRIT-H2H (N=566), 354 patients had a NAPSI total score >0 and DIP involvement (swelling or tenderness) in at least 1 joint simultaneously at baseline (IXE, N=186 and ADA, N=168). Of these patients, significantly fewer IXE-treated patients had a NAPSI total score of > 0 at Week 24 ($p<0.05$ for 9/10 digits; Table) and numerically fewer IXE-treated patients had DIP involvement at Week 24 across all ten digits ($p<0.05$ for 4/10 digits; Table). Numerically fewer IXE-treated patients had joint tenderness at Week 24. A similar pattern of improvement was seen out to Week 52 (Table).**

Conclusion: In this analysis, in patients from SPIRIT-H2H with psoriatic arthritis who had nail involvement and DIP involvement at baseline, patients treated with IXE had less nail involvement, less DIP involvement and less tenderness compared to those treated with ADA at Week 24.

Previously presented at European Alliance of Associations for Rheumatology - EULAR 2023; 31stMay-3rd June, 2023; Milan, Italy.

Figures and tables.

Table. The proportion (%) of patients with (A) NAPSI >0 and (B) DIP involvement (tenderness or swelling) at Week 24 at the individual digit level among patients treated with either IXE (N=188) or ADA (N=168) who had NAPSI >0 and distal interphalangeal joint involvement at baseline. *p<0.05, †p<0.1, ‡p<0.001 vs ADA, Fisher's Exact test p-value.

	Left Hand					Right Hand				
	Little	**Ring**	**Middle**	**Fore**	**Thumb**	**Thumb**	**Fore**	**Middle**	**Ring**	**Little**
NAPSI >0 (%) Week 24										
IXE Q4W	17.0*	17.6*	14.2†	15.3†	11.4†	15.3†	13.6†	15.3*	15.9†	13.1
ADA Q2W	27.9	27.9	25.5	27.3	23.6	27.3	25.5	26.7	26.7	21.2
p-value	**0.0191**	**0.0276**	**0.0097**	**0.0079**	**0.0039**	**0.0079**	**0.0062**	**0.0113**	**0.0169**	0.0602
Week 52										
IXE Q4W	10.9*	10.3	10.9	10.3	9.1	12.1	9.7	10.9	7.3	10.9
ADA Q2W	21.4	16.6	15.9	17.2	14.5	19.3	17.2	19.3	12.4	14.5
p-value	**0.0128**	0.1304	0.2400	0.0958	0.1547	0.0659	0.0641	0.0538	0.1770	0.3924
DIP involvement (%) Week 24										
IXE Q4W	10.7	11.3*	15.8*	19.8	17.5	15.8	20.9	21.5*	11.9	10.7*
ADA Q2W	15.2	20.0	25.5	27.3	24.8	22.4	28.5	30.9	17.0	18.8
p-value*	0.2590	**0.0357**	**0.0319**	0.1249	0.1115	0.1307	0.1312	**0.0495**	0.2168	**0.0459**
Week 52										
IXE Q4W	9.0	10.2	16.9	16.9	11.4	11.4	13.9	15.7	13.3	10.8
ADA Q2W	13.1	15.2	22.8	20.0	15.2	13.1	21.4	24.1	13.1	10.3
p-value*	0.2779	0.2301	0.2008	0.5571	0.4014	0.7295	0.0987	0.0643	1.0000	1.0000

Data are presented as proportion of patients (%). Abbreviations: ADA, adalimumab; IXE, ixekizumab.

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Abstract N°: 3110

Sustained efficacy and safety of tildrakizumab over 2 years in patients with moderate to severe plaque psoriasis in routine clinical practice: interim results in week 100 from the non-interventional, prospective, multicenter study TILOT

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Introduction:

The anti–IL-23 p19 monoclonal antibody Tildrakizumab (TIL) is approved for treatment of moderate to severe plaque psoriasis and has demonstrated good efficacy and safety. The objective of this analysis is to assess the maintained effectiveness and safety of tildrakizumab in routine clinical practice over 100 weeks (W100).

Materials & Methods:

TILOT is an ongoing 3-year non-interventional study in adult patients with moderate-to-severe chronic plaque psoriasis who are eligible for systemic biologic treatment and receive TIL 100 mg (s.c.) as part of routine clinical practice in accordance with the Summary of Product Characteristics. The study evaluates effectiveness and safety based on Psoriasis Area and Severity Index (PASI), body surface area (BSA), Physician Global Assessment on a 5-point scale (global, scalp, nail-PGA), itch and pain (visual analog scale; VAS), Dermatology Life Quality Index (DLQI) as well as patient's and physician's satisfaction. Data are presented as observed cases (OC) and using last observation carried forward (LOCF).

Results:

This interim analysis at W100 assessed data from 350 patients. From Baseline to W100 the absolute PASI improved by 86.5% (OC) and 67.8% (LOCF) and 84.1% (OC) and 68.1% (LOCF) of patients reported a PASI <3. A PGA of clear or almost clear (0 or 1) was reported in 74.9%/61.9% (OC/LOCF) of patients. Scalp-PGA of clear or almost clear (0-1) was achieved in 80.8% (OC) and 73.4% (LOCF) of patients with scalp involvement at study start. Nail-PGA decreased by 71.4%/61.2% (OC/LOCF) in patients with nail involvement at baseline. A reduction in itch of 77.4% (OC), 62.2% (LOCF) respectively is detected. Proportions of patients with mean itch-NRS <3 are 87.5% (OC) and 74.0 (LOCF). Detailed results are presented in the table below. The full analysis set comprised of 503 patients. 153 (30.4%) patients discontinued treatment before W100, mainly due to lack of efficacy (N= 95 [18.9%]) or lost to follow-up. The safety profile was in line with data from phase III clinical trials. No new or unexpected safety signals were reported.

	Baseline	W100
		OC
PASI, mean (SD)	15.9 (9.1)	1.6 (2.3)
PGA, mean (SD)	3.1 (0.6)	0.9 (0.9)
DLQI, mean (SD)	13.0 (7.3)	2.2 (3.7)
Scalp-PGA, mean	2.6 (0.9)	0.6 (1.0)
Nail-PGA, mean	1.8 (0.9)	0.4 (0.8)
Itch-VAS, mean	56.0 (28.7)	12.7 (19.3)

Conclusion:

This interim analysis demonstrates the sustained efficacy and safety of tildrakizumab in a real-world setting. Patients with plaque psoriasis in sensitive areas or suffering from itch showed good response, reflected in significant improvements of all measured parameters including treatment satisfaction.

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Abstract N°: 3116

Effectiveness of secukinumab and guselkumab in patients with moderate-to-severe psoriasis after ustekinumab failure in real world clinical practice.

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Introduction & Objectives: The ARROW study, a phase II clinical trial, showed greater clinical efficacy of secukinumab (SEK) versus guselkumab (GUS) in patients with moderate-to-severe plaque psoriasis, who presented recalcitrant plaques that were resistant to ustekinumab (UTK) after 16 weeks of treatment. The objective of this study was to compare the effectiveness and survival of SEK and GUS in patients with moderate-to-severe psoriasis and insufficient response to UTK at week 12-16 and 48 weeks in real world clinical practice.

Materials & Methods: Two psoriasis cohorts complied by Spanish psoriasis group were analyzed: the SEK cohort (November 2015-December 2017) and GUS cohort (March 2019- September 2019). All patients who had received UTK as the last treatment prior to GUS or SEK, irrespective of basal PASI or reason for UTK discontinuation, were included for comparison. Clinical and disease activity data were collected, including PASI at weeks 12-16 and 48. A propensity score and a matched analysis were performed to minimize the historical cohort comparison bias. Statistical analysis was performed using SPSS (version 22.0 for Windows). Values of $p < 0.05$ were considered statistically significant.

Results: 277 patients were included, 171 (61.7%) treated with SEK and 106 (38.3%) treated with GUS. Demographic statistically relevant differences were found between the SEK and GUS cohorts regarding the proportion of men (37.8% vs 56.6%; p=0.01), mean weight (86.4kg SD 17.3 vs 80kg SD 5, 6; p=0.04), mean number of previous biological treatments (BT) (2.55 vs 2.13; p=0.001) and baseline PASI (13.7 SD 8.8 vs 8.4 SD 5.03; p<0.001).** The proportion of patients who achieved an absolute PASI response ≤ 3 was higher in the group treated with GUS compared to the group treated with SEK at week 12-16 (81.7% vs 68.2; p=0.01) and at week 48 (93.6% vs. 71.1%; p<0.01). Survival rate was higher in the SEK group (8.28 months, SD 0.42) versus GUS (6.8 months, SD 0.69) without reaching statistical significance (p=0.18). In the subgroup of patients who had only received UTK as BT in the SEK (n=24) or GUS (n=36) cohorts, no differences were found in the PASI ≤ 3 response at weeks 12-16 (p=0.580) or at week 48 (p=0.272). After applying propensity score testing and matched analysis using the demographic variables showing baseline differences, no differences were found regarding PASI ≤ 3 response either at week 12-16 or week 48.

Conclusion:

GUS showed higher effectiveness in the short and medium-long term, although interpretation is complex as the cohorts were asynchronous and had major demographic differences. No significant differences were found regarding drug survival. When statistical methods were applied to balance both cohorts and in the group of patients who had only used UTK as BT (analyzed to minimize the previously mentioned biases) both drugs showed similar effectiveness and persistence. Therefore, according to our data both drugs seem suitable in

psoriasis patients with insufficient response to UTK in clinical practice.

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Abstract N°: 3120

Tildrakizumab demonstrates high efficacy regardless of baseline characteristics in patients with moderate-to-severe chronic plaque psoriasis in conditions close to real clinical practice

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Introduction & Objectives

Tildrakizumab (TIL) is a high-affinity anti-interleukin-23p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.1,2 The objective of this analysis was to examine the response to TIL in different subgroups of patients from the TRIBUTE study defined by baseline characteristics.

Materials & Methods

TRIBUTE is a 24-week open-label phase IV study to assess TIL 100 mg efficacy and safety in adult patients with moderate-to-severe chronic plaque psoriasis eligible for systemic biologic treatment. Patients were either naïve to systemic biologic treatment or had had a primary/secondary failure to treatment with ≥1 anti-tumour necrosis factor agents. Efficacy assessments were proportions of patients who had an absolute Psoriasis Area and Severity Index (PASI) ≤3, PASI ≤1, and a Dermatology Life Quality Index (DLQI) score of 0 or 1 (DLQI 0/1) at week 24. Subgroups were defined based on baseline patient characteristics: current smoking status (yes/no/ex-smoker), weight (<90/≥90 kg), body mass index (<25/≥25 kg/m2), disease duration (<5/5-<10/≥10 years), baseline PASI (<20/≥20), and previous biologic exposure (bio-naïve/bio-experienced). Analyses were performed for the intention-to-treat population (N=177) and were based on observed cases.

Results

The proportions of TIL-treated patients who achieved absolute PASI scores ≤3 and ≤1 and DLQI 0/1 at week 24 by subgroups of baseline characteristics are shown in **Table 1**. Overall, TIL showed high levels of efficacy and improvements in quality of life regardless of patients' baseline characteristics. However, PASI ≤1 and DLQI 0/1 response rates were significantly higher among bio-naïve versus bio-experienced patients, and PASI ≤3 and PASI ≤1 responders had significantly lower PASI scores at baseline and lower body mass index, respectively. Up to week 24, 29.4% of patients had at least one treatment emergent adverse event (TEAE). The most frequent TEAE was headache (6.2%). Only one serious TEAE was reported (coronavirus infection not related to TIL that led to death).

Table 1. Percentage of PASI≤3, PASI≤1 and DLQI 0/1 responders at week 24 by subgroups of baseline characteristics

	PASI ≤3	p-value*	PASI ≤1	p-value*	DLQI 0/1	p-value*
Smoking status						
Yes	96.0	0.0667	68.9	0.6110	72.9	0.6336
No	83.0		67.9		72.3	
Ex-smoker	82.9		58.5		62.2	
Weight (kg)						
<90	90.0	0.3963	67.3	0.7687	70.3	0.9583
≥90	85.7		65.1		70.7	
Body mass index (kg/m2)						
<25	93.4	0.1288	77.1	0.0297	66.7	0.4357
≥25	85.7		60.7		72.6	
Disease duration (years)						
<5	90.9	0.5890	75.0	0.3022	71.8	0.5336
5-<10	92.3		69.2		79.2	
≥10	86.4		62.1		67.7	
PASI						
<20	91.0	0.0470	66.4	0.9769	69.7	0.6999
≥20	79.5		66.7		73.0	
Previous biologic exposure						
Bio-naïve	89.9	0.3067	69.6	0.0402	75.2	0.0123
Bio-experienced	83.3		50.0		51.7	

* Chi-square (versus non-responders). DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index.

Conclusion

Tildrakizumab demonstrates high efficacy, improvements in quality of life and a favorable safety profile regardless of baseline characteristics in conditions close to real clinical practice in patients with moderate-to-severe chronic plaque psoriasis.

References

1Thaçi D, et al. BJD 2021;185:323–34; 2Drerup KA, et al. Dermatology 2022;238:615–19.

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Abstract N°: 3121

Super responders to tildrakizumab treatment in moderate-to-severe chronic plaque psoriasis in conditions close to real clinical practice

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Introduction & Objectives

Tildrakizumab (TIL) is a high-affinity anti-interleukin-23p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.1,2 The objective of this analysis was to evaluate and characterize the proportion of super-responder patients to TIL from the TRIBUTE study.

Materials & Methods

TRIBUTE is a 24-week open-label phase IV study to assess TIL 100 mg efficacy and safety in adult patients with moderate-to-severe chronic plaque psoriasis eligible for systemic biologic treatment. Patients were either naïve to systemic biologic treatment or had had a primary/secondary failure to treatment with ≥1 anti-tumour necrosis factor agents. Super-responders were defined as those patients who achieved Psoriasis Area and Severity Index (PASI) equal to 0 at week 16 and week 24. Non-super-responders were those patients who presented a PASI>0 at week 16 and week 24 or achieved PASI=0 only in one of the two time points (16 or 24 weeks). Analyses were performed for the intention-to-treat population (N=177) and were based on observed cases.

Results

A total of 20.4% of patients were super-responders, as they presented a PASI=0 at week 16 and week 24. Baseline characteristics of super-responder and non-super-responder patients are shown in **Table 1**. With the exception of age, there were no significant differences between the two groups in baseline characteristics, although a trend for differences by sex and Body Surface Area (BSA) affected was observed.

Table 1. Baseline characteristics of super-responder and non-super-responder patients

	Super-responders N=35	Non-super-responders N=137	p-value
Age	40.6 (11.4)	45.5 (12.5)	0.0364
Sex			
Female	15 (42.9)	37 (27.0)	0.0684
Male	20 (57.1)	100 (73.0)	
Smoking status			
No	12 (34.3)	41 (29.9)	0.0880
Yes	15 (42.9)	59 (43.1)	
Ex-smoker	5 (14.3)	35 (25.6)	
Weight (kg)	81.3 (24.7)	81.7 (17.4)	0.9280
<90	24 (68.6)	86 (62.8)	0.0967
90-<120	8 (22.9)	48 (35.0)	
≥120	3 (8.6)	3 (2.2)	
Disease duration (years)	14.0 (11.4)	16.0 (12.3)	0.3922
<5	10 (28.6)	33 (24.1)	0.7507
5-<10	6 (17.1)	20 (14.6)	
≥10	19 (54.3)	84 (61.3)	
PASI	16.1 (7.6)	16.2 (8.6)	0.9234
<20	27 (77.1)	106 (77.4)	0.9769
≥20	8 (22.9)	31 (22.6)	
BSA (% affected)	25.7 (14.3)	20.9 (13.7)	0.0698
DLQI	12.9 (7.4)	14.3 (7.4)	0.3378
Previous biologic exposure			
Bio-naïve	25 (71.4)	111 (81.6)	0.1827
Bio-experienced*	10 (28.6)	25 (18.4)	

Data are mean (SD) or n (%). BSA, Body Surface Area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; SD, standard deviation.*≥1 anti-tumour necrosis factor agents

Conclusion

Our study revealed, in conditions close to real clinical practice, the presence of one in five patients who super respond to TIL at week 16 and 24. Both groups were similar in baseline characteristics, however, super-responder patients were significantly younger than non-super-responders. In super-responders, a trend towards a higher frequency of females and a greater BSA affected at baseline could be argued.

References

1Thaçi D, et al. BJD 2021;185:323–34.

2Drerup KA, et al. Dermatology 2022;238:615–19.

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Abstract N°: 3122

Tildrakizumab improves sleep quality and psoriasis-related pruritus and pain in patients with moderate-to-severe plaque psoriasis in conditions close to real clinical practice

Antonio Costanzo*[1], Aldo Cuccia[2], Esteban Daudén[3], Gabriella Fabbrocini[4], Raquel Rivera-Diaz[5], Kristian Gaarn Du Jardin[6], Ismail Kasujee[6], Lluís Puig[7], José Manuel Carrascosa[8]

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Introduction & Objectives

Tildrakizumab (TIL) is a high-affinity anti-interleukin-23p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety. Itch and skin pain can be two of the most burdensome symptoms associated with psoriasis affecting patients' quality of life,1 with an effect on sleep.2 The objective of this analysis from the TRIBUTE study was to assess the efficacy of TIL 100 mg on sleep improvement after 24 weeks through its correlation with Psoriasis Area and Severity Index (PASI) and psoriasis-related pruritus, pain, and scaling.

Materials & Methods

TRIBUTE is a 24-week (W) open-label phase IV study to assess TIL 100 mg efficacy in adult patients with moderate-to-severe chronic plaque psoriasis in conditions similar to routine clinical practice. The Medical Outcomes Study (MOS)-Sleep scale evaluates sleep impairment on 6 domains (disturbance, adequacy, somnolence, snoring, awakened by shortness of breath/headache, and quantity of sleep), ranging from 0 to 100 (except for sleep quantity), with higher scores reflecting more of the attribute indicated by the subscale name. The MOS-Sleep Index II is a four-domain (disturbance, adequacy, somnolence, awakened by shortness of breath/headache) aggregate measure. The score ranges from 0 to 100 (100=worse sleep problems). Pruritus, pain, and scaling were evaluated by a Numerical Rating Scales (NRS) ranging from 0 to 10 (10=worse symptoms). Analyses were based on observed cases.

Results

A total of 177 patients were included (mean [SD] age of 44.6 [12.4] years; 69.5% male). At W24, 88.4%, 76.5%, and 84.9% of patients achieved PASI ≤3, pruritus-NRS <3, and pain-NRS <3, respectively. Median scaling-NRS decreased from 8.0 to 1.0 at W24 (median change from baseline: -6.0). At baseline, mean (SD) Sleep Index II was 39.8 (20.3) decreasing to 28.5 (15.6) at W24 (close to the population norm of 25.83), with a mean change from baseline of 10.4, which is larger than the minimal clinically important difference of 5.1.4 Pearson's correlation coefficients (r) between MOS-Sleep domains and PASI, pruritus, pain, and scaling measures at W24 are shown in **Table 1**. At W24, sleep disturbance, adequacy, and shortness of breath/headache dimensions, as well as MOS-Sleep Index II showed significant correlations with pruritus and pain. There was no significant correlation between PASI or scaling changes and sleep improvement.

Table 1. Pearson's correlation coefficients (r) between MOS-Sleep domains and PASI, pruritus, pain, and scaling measures at week 24

	Disturbance	Quantity	Adequacy	Shortness of breath/headache	Snoring	Somnolence	Slee Inde II
PASI	0.039	-0.115	-0.076	-0.021	0.138	0.038	0.04
Pruritus	0.142	0.017	-0.135	0.162*	0.091	0.116	0.19
Pain	0.268**	-0.040	-0.202*	0.186*	0.109	0.109	0.287
Scaling	0.147	0.090	-0.138	0.072	0.108	0.012	0.15

*p<0.05; **p<0.01; MOS, Medical Outcomes Study; PASI, Psoriasis Area and Severity Index

Conclusion

In conditions close to real clinical practice, tildrakizumab improved sleep quality in patients with psoriasis through improving itching and pain, which are highly correlated. These correlations highlight the importance of evaluating other endpoints beyond PASI to assure improvements in overall well-being of patients.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3123

Tildrakizumab improves sleep quality, quality of life and work productivity in patients with moderate-to-severe plaque psoriasis in conditions close to real clinical practice

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Introduction & Objectives

Tildrakizumab (TIL) is an interleukin-23p19 inhibitor approved for the treatment of moderate-to-severe plaque psoriasis. The objective was to assess the efficacy of TIL 100 mg on sleep improvement after 24 weeks and its correlation with quality of life (QoL), patient-relevant treatment benefits and impairments in work and activities.

Materials & Methods

TRIBUTE is a 24-week (W) open-label 100 mg TIL phase IV study in adult patients with moderate-to-severe plaque psoriasis in conditions close to real clinical practice. The Medical Outcomes Study (MOS)-Sleep scale evaluates sleep problems on 6 domains (disturbance, adequacy, somnolence, snoring, awakened by shortness of breath/headache, sleep quantity; range 0-100 [except for sleep quantity], with higher scores reflecting more of the indicated attribute). The Sleep Index II is a four-domain aggregate measure (range 0-100; 100=worse sleep problems). QoL assessments included Dermatology Life Quality Index (DLQI; range 0-30; 30=worst QoL) and Skindex-16 (overall score range 0-100; 100=worst QoL). The Patient Benefit Index (PBI) evaluates patient-relevant treatment benefits (range 0-4; 4=maximal benefit; PBI ≥1=relevant benefit). The Work Productivity and Activity Impairment (WPAI) questionnaire gives 4 scores (%): work time missed, impairment while working, overall work impairment, and activity impairment. Analyses were based on observed cases.

Results

177 patients were included (mean [SD] age 44.6 [12.4] years; 69.5% male). Mean (SD) DLQI score decreased from 14.1 (7.4) at baseline (BL) to 2.0 (3.6) at W24. At W24, 70.4% of patients had a DLQI 0-1. At BL, mean (SD) overall Skindex-16 score was 68.5 (25.0) vs 14.9 (21.8) at W24. At W24, mean (SD) PBI score was 3.4 (0.6) and 98.7% of patients achieved a PBI score ≥1. All WPAI scores improved after 24 weeks (e.g., mean [SD] overall work impairment decreased from 40.2 [32.5] at BL to 8.1 [19.7] at W24). At BL, mean (SD) Sleep Index II was 39.8 (20.3) vs 28.5 (15.6) at W24. Pearson's correlation coefficients between MOS-Sleep domains at W24 and DLQI, Skindex-16, PBI, and WPAI measures are shown in **Table 1**. Sleep disturbance, adequacy, and Sleep Index II showed significant correlations with QoL and work and activities measurements. There was no significant correlation between patient-relevant treatment benefits and sleep improvement.

Table 1. Pearson's correlation coefficients (r) between MOS-Sleep domains at week 24 and DLQI, Skindex-16, PBI,

and WPAI measures

	Disturbance	Quantity	Adequacy	Shortness of breath/headache	Snoring	Somnolence	S I
DLQI (W24)	0.368**	-0.112	-0.339**	0.106	0.008	0.143	0.
Skindex-16 (CfB in the overall score)	0.264**	-0.051	-0.285**	0.136	0.107	0.093	0.
PBI (W24)	-0.063	-0.016	0.143	-0.005	-0.111	0.027	-(
WPAI (CfB)**:**							
Overall work impairment	0.313**	-0.207	-0.287*	0.203	-0.116	0.127	0.
Activity impairment	0.186*	-0.041	-0.201*	0.140	-0.015	0.139	0.

*p<0.05; **p<0.01. CfB, change from baseline; DLQI, Dermatology Life Quality Index; MOS, Medical Outcomes Study; PBI, Patient Benefit Index; W, week; WPAI, Work Productivity and Activity Impairment

Conclusion

In conditions close to real clinical practice, TIL improved sleep quality, which were highly correlated with improvements in QoL and work productivity and activity measurements. This highlights the importance of looking beyond the skin symptoms to improve the overall well-being of patients with moderate-to-severe psoriasis.

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Abstract N°: 3131

Depression and its associated factors among psoriasis patients at the Regional Dermatology Training Center (RDTC) in Moshi, Tanzania.

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Introduction & Objectives: The chronic nature and the aesthetic changes related to psoriasis can lead to social stigmatization and psychological distress, which can cause depression. In addition, due to the shared pro-inflammatory cytokines in both conditions, they can easily coexist. Furthermore, there are multiple psoriasis-related factors contributing to depression. However, with the current lack of awareness of mental health, the relationship between depression and psoriasis is not just a problem for Tanzania but is also a global problem.

This study aimed to determine the proportion of psoriasis patients with depression and the disease factors associated with depression among patients attending the RDTC.

Materials & Methods: This cross-sectional study recruited all adult patients with psoriasis who consulted the Regional Training Center (RDTC) outpatient clinic in Moshi, Tanzania, from December 2019 to April 2020. The permission to conduct the study was sought and obtained from the Kilimanjaro Christian Medical University College Research and Ethics Committee and the Principal of the RDTC before starting the study. Data was collected through a questionnaire that was subdivided into two parts. The first part asked about the socio-demographic characteristics, the medical history, the current treatment, and the physical examination. The second part was the PHQ-9, a multilinguistic validated questionnaire for diagnosing symptoms of depression.

The patients enrolled in the study were either newly diagnosed or already on psoriasis treatment. Psoriasis was mainly diagnosed clinically. Only one patient had a biopsy to confirm pustular psoriasis. All psoriasis patients were thoroughly examined after reading and signing a consent form. In all patients, the Body Surface Area (BSA) was calculated using the patient's palm for reference, representing 1% of the body surface. A score of less than 5% BSA affected corresponded to mild psoriasis; moderate psoriasis meant 5%–10% BSA affected, and severe psoriasis more than 10% BSA. After the physical examination, the PHQ-9 was used to assess the presence and severity of depression amongst the psoriasis patients. Each of the 9 items on the PHQ-9 is scored from 0 to 3, and the total score ranges from 0 to 27. A PHQ-9 score of 0-4 meant none to minimal symptoms; 5-9 meant mild depression; 10-14 meant moderate depression; 15-19 meant moderately severe depression; and 20-27 meant severe depression. We used SPSS version 24 to analyze our data. The median and IQR were calculated for continuous data, and percentages were used for categorical data. We did a univariate and multivariate regression analysis to determine the factors associated with depression, and the odds ratio was used to measure the strength of the association. A p-value of less than 0.05 was considered a statistically signifiant association.

Results: We found that 38.2% had none to minimal depressive symptoms, 29.4% had moderate depression, 20.6% had mild depression, and 11.8% had moderately severe depression. We also found that having psoriasis for more than 5 years and severe psoriasis are associated with depression among psoriasis patients attending RDTC (P-value=0.02 and P-value=0.04).

Conclusion: These data showed that most of our psoriasis patients suffer from mild to moderately severe depression. The longer duration and severity of psoriasis may be associated with depression among psoriatic patients.

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Abstract N°: 3138

Effectiveness, safety and survival of guselkumab for the treatment of difficult-to-treat Areas: Scalp, Nail, Palmoplantar and Genital Psoriasis accompanied with moderate-to-severe plaque PsO in real clinical practice

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Introduction & Objectives: . Guselkumab is a human IgG1λ monoclonal antibody that binds selectively to the p19 subunit of IL-23. Few series of real clinical practice reflecting the use of GUS in difficult to treat locations: scalp, facial, genital, palmoplantar and nail psoriasis (PsO) have been published. **Objective.** To evaluate the effectiveness, safety and survival of Guselkumab in patients with difficult to treat locations as well as moderate-to-severe PsO.

Materials & Methods: This is an observational, retrospective multicenter study of real clinical practice. Patients were treated with guselkumab 100mg subcutaneous every 8 weeks (w). A total of 183 patients with moderate-to-severe PsO were included in this study and 42 of them had been affected with difficult to treat locations. Treatment response was assessed by PASI, BSA, VAS pruritus and DLQI over 156 w, and sIGA over 52w. Data are presented as mean ± standard deviation for continuous variables, and number and percentage for categorical variables. Wilcoxon tests were performed to analyze possible differences between periods of time. Survival was calculated using Kaplan–Meier survival analysis. All analyses were performed by GraphPad Prism 8.0.0 (California USA, www.graphpad.com").

Results: Our population composed by 183 patients with moderate-to-severe PsO presented a mean age of 50.53 years, 60.65 % were male, had a mean PsO evolution of 21.74 years, a mean BMI of 29 and 38.79% of them were obese. They also presented other comorbidities: dyslipidemia (34.4%), arterial hypertension (28.96%); diabetes (15.84%); psoriatic arthritis (26.22%); Non-alcoholic fatty liver disease (NAFLD) (10.92%) and depression (14.2%). Last comorbidity was increased in patients with difficult to treat location (16%). At baseline, disease parameters were: PASI=13, BSA=17.9, VAS pruritus=5.6, DLQI=13.7. Moreover, 42 patients had difficult to treat locations with a baseline sIGA: 3.68 (Table 1). After two administrations all disease parameters decreased significantly versus baseline: PASI=1.66 (2.64) ($p<0.0001$); BSA=1.68 (2.95) ($p<0.0001$); VAS pruritus=0.66 (1.1) ($p<0.0001$) and DLQI=1.2 (2.1) ($p<0.0001$). Statistically significant differences were found after just one administration of Guselkumab in all parameters, improving until 156 w. Similarly, patients with difficult to treat locations improved significantly sIGA = 0.6 (0.7) . Besides, if we classify the different locations (scalp, facial, genital, palmoplantar and nail PsO), we found in all of them significant differences in sIGA versus baseline at 4w . This population also improve their PASI, VAS pruritus and DLQI in short and long term. In fact, 93.8% and 91.3% of patients maintain sIGA 0/1 and PASI 0/1 at 52w, respectively. After 156 weeks of treatment, global survival was 83% (included discontinuation by any cause) and 95.65% due to lack of effectiveness or safety issues. In difficult to treat locations population the survival scores were even better; 92% and 93.7 respectively.

Conclusion: Guselkumab showed excellent effectiveness, safety and survival results in the control of PsO in a real clinical practice. Population who had difficult to treat locations improved since the first administration maintaining

sIGA and other parameters near the remission until 52w. More than 90% of patients that initiated Guselkumab , remained on treatment after 156w.

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Abstract N°: 3140

Calcipotriol/Betamethasone Dipropionate Aerosol Foam for Plaque Psoriasis: A Prospective, Observational, Non-Interventional, Single-Center Study on Patient Adherence and Satisfaction in real clinical practice

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Introduction & Objectives: Psoriasis is a chronic inflammatory disease characterized by erythematous and scaly skin lesions, with a negative impact on patients' quality of life. Patients with mild–moderate psoriasis can be treated with topical medications, such as the combination drug calcipotriol/betamethasone dipropionate (Cal/BD), available in different formulations, including the foam.

The main objective was to assess the adherence to Cal/DB foam in patients with mild to moderate plaque psoriasis 4 weeks after initiating treatment, using the validated Morisky Green scale.

The secondary objective was to determine the degree of patient satisfaction both during treatment and at the end of treatment, by means of the Treatment Satisfaction Questionnaire for Medication (TSQM 9).

Materials & Methods: Patients included were aged ≥18 years, had a diagnosis of mild to moderate plaque psoriasis located in trunk and extremities for at least 6 months.Treatment was applied only to psoriasis plaques on the trunk and/or extremities, avoiding use in areas such as the scalp, face, genitals and/or skin folds.

Data were collected at baseline and at weeks 4 and 12. Adherence and satisfaction were assessed by Morisky Green and TSQM-9 questionnaires, respectively. Psoriasis severity was assessed by PASI and BSA. Quality of life (QoL) was measured by the Dermatology Life Quality Index (DLQI).

Results: A total of 100 patients (51 men and 49 women, mean age 40 years) with mild to moderate plaque psoriasis in treatment with Cal/BD foam were included.

At week 12, 70 patients showed high adherence, 20 patients had moderate adherence and 9 patients had poor adherence.

Patient-reported satisfaction assessed by TSQM-9 scale at 4 weeks (visit 1): 64% of the patients were completely satisfied with the treatment, 29% of the patients (were moderately satisfied,. At week 12-(visit 2), 72% of the patients were completely satisfied with the treatment.

No side effects related to the application of Cal/ BD aerosol foam were reported.

The evolution of psoriasis severity (assessed by PASI and BSA) and quality of life were also measured

Regarding its cosmetic properties, 17% rated as the most significant fact that the product did not leave residues or stains on the skin; 4% valued the absence of odor, and 81% highlighted as most relevant the easy application of the foam.

In terms of general satisfaction with Cal/BD aerosol foam, 65% of the patients were very satisfied, 25% was satisfied, 7% was not very satisfied, and 3 % was not at all satisfied.

Conclusion: This 12-week study in patients with plaque psoriasis located on the trunk and extremities showed that Cal/DB foam provides significant improvement in the treatment of this dermatosis, while maintaining very

good adherence to treatment, with a favorable safety profile. The high level of adherence, related to the fast onset of action, and the adequate cosmeticity of the vehicle, make Cal/DB spray foam a first-line topical treatment in this pathology.

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Abstract N°: 3151

big hope on small molecule !! a comparative study for safety and efficacy of oral apremilast as monotherapy versus in combination with narrow band uvb for chronic plaque psoriasis

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Introduction & Objectives: :

Psoriasis is a chronic, inflammatory disease characterized by erythematous, scaly plaques over the skin which occurs due to hyper-proliferation of keratinocytes**.** Psoriasis being a serious global problem with a reported prevalence of psoriasis in countries ranging between 0.09% and 11.4%. Approximately 1.3% to 34.7% of individuals with psoriasis develop psoriatic arthritis that leads to joint deformations and disability. Individuals with psoriasis are at increased risk of developing other serious clinical conditions such as cardiovascular and other non-communicable diseases (NCDs). Psoriasis affects mental health and people suffering from the disease experience significant social stigma.

Treatment modalities for psoriasis include immunosuppressants and biologicals which are associated with side effects**.** With limited research on the use of combined therapy, this comparative study was done for the safety and efficacy of oral apremilast and its combination with NBUVB in chronic plaque** psoriasis patients

OBJECTIVES :

1.To assess the safety and efficacy of Oral Apremilast versus Oral Apremilast and Narrow Band UVB in patients with moderate to severe chronic plaque psoriasis.

\2. To assess clinical improvements based on Psoriasis Area and Severity Index (PASI) score.

Materials & Methods: This was a longitudinal comparative study for 18 months, 30 patients each in groups A and B treated with oral Apremilast and oral Apremilast and NBUVB respectively. PASI scores done at baseline and at every 4 weeks up to 24th week until PASI 75 was attained.

Results: 100.0% of those in group A and 96.7 % in group B had achieved 75% reduction in the PASI scores. The response time was significantly lesser in Group B compared to group A. Only minor side effects noted. Though all 100.0% of them had relapse in both, average duration in group B was significantly prolonged compared to group A.

Conclusion: : Patients with psoriasis have higher incidence of comorbidities including arthritis, metabolic syndrome, cardiovascular diseases and depression. It reduces the quality of life and associated with higher healthcare utilization and increase cost.

Methotrexate, acitretin, cyclosporine is the commonly used systemic agents and are associated with cumulative and end organ toxicities, treatment related adverse effects and requires proper monitoring during treatment. Whereas, biological agents have limitations of added costs to health care and possibility of iatrogenic immunosuppression. In this background, an agent that is orally administered, less toxic, cost-effective having optimal efficacy is APREMILAST. There is no associated organ toxicity and doesn’t require blood investigations for monitoring, hence decreases the cost burden on the patients.

Combined therapy with narrow band ultra violet B was found to be significantly better in terms of average

response and relapse time compared to monotherapy. Synergistic effect might lead to faster clearance of the disease with lesser cumulative toxicity when compared to other immunosuppressants. Hence this comparative study is worthwhile to know its safety and shows that there is big hope on small molecule indeed.

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Abstract N°: 3220

Incidence of psoriatic arthritis among psoriasis patients newly initiated with secukinumab in a US claims database and a UK registry

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Introduction & Objectives:

Approximately 20%–30% of patients with psoriasis (PsO) have a concurrent diagnosis of psoriatic arthritis (PsA)1,2 with an annual incidence rate (IR) of 2.7 cases per 100 PsO patients.3 A retrospective US cohort study based on an electronic health record database using IL-12/23 or IL-23 inhibitors suggests a reduction in progression of PsO to inflammatory arthritis versus (vs) TNF inhibitors.4 There are limited data on IR of PsA in patients with PsO treated with secukinumab. The purpose of this retrospective, real-world cohort study was to assess the IR of PsA among patients with PsO treated with secukinumab or other biologics and assess the time from the treatment initiation to first diagnosis of PsA.

Materials & Methods:

The current analysis was performed on two databases, a United States administrative claims database, IBM® MarketScan® database5: Commercial Claims and Encounters and Medicare Supplemental Beneficiaries from 01-Jan-2010 to 30-Sep-2020, and an Ireland/United Kingdom registry, BADBIR,6 from 01-Jan-2016 to 01-Sep-2021. This study included patients with PsO who had received secukinumab or any other biologic (excludes secukinumab). From the BADBIR registry, only secukinumab data were available. The primary objective was to assess the IR of PsA among PsO patients with newly initiated secukinumab. In MarketScan, PsA was identified using the ICD-10-CM code; in BADBIR, PsA was recorded as a binary variable. The secondary objective was to assess time from secukinumab initiation to the first diagnosis of PsA.

Results:

From the MarketScan® database, 3.6% (N=695) and 4.7% (N=14,429) of adult patients were included in the secukinumab or other biologics cohorts, respectively; from the BADBIR registry, 37.9% (N=476) adult secukinumab-treated patients were included. The IRs (per 100 patient years) of PsA in patients with PsO were slightly lower for patients treated with secukinumab vs those treated with other biologics over 3 years (MarketScan® database: 3.32 vs 4.01, respectively; BADBIR registry: 1.80; **Table 1**). Patients treated with secukinumab had a lower IR of PsA in the first year of treatment vs those treated with other biologics (MarketScan® database: 3.75 vs 5.98, respectively; BADBIR registry: 2.78; **Table 1**). **Figure 1** shows that over 3 years (1095 days), patients treated with secukinumab had a lower probability of developing PsA vs those treated with other biologics. In patients who developed PsA treated with secukinumab in the post-index period (7.6%, N=53/695) vs other biologics (9.4%, N=1350/14,429), there was a longer median time from treatment initiation to first diagnosis of PsA (MarketScan® database: 336 days vs 238 days, respectively). In patients who developed PsA treated with secukinumab in the BADBIR registry (4.2%, N=20/476), median time from treatment initiation to first diagnosis of PsA was 271 days. Time for 3% and 5% of patients to develop PsA in the MarketScan® database was longest in patients treated with secukinumab (264 days and 601 days, respectively) vs those treated with other biologics (128 days and 286 days, respectively).

Conclusion:

IR of PsA was lower and time to develop PsA was longer for patients treated with secukinumab vs other biologics. IRs of PsA were highest in the first year and decreased over 3 years with secukinumab treatment. Study limitations were absence of group adjustment for potential confounding factors, and that data after 3 years should be interpreted with caution due to low sample size.

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Table 1. Three-year incidence rates of PsA among patients with PsO treated with secukinumab or other biologics

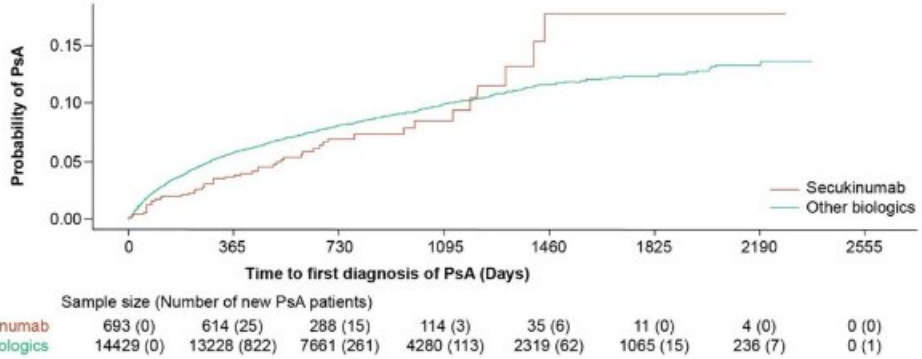
PsA Onset	Total	0 – 1 year(s)	> 1 – 2 years	> 2 – 3 years
MarketScan® database				
Secukinumab	N = 695	N = 695	N = 616	N = 286
Number of new PsA patients (N)	43	25	15	3
Exposure in person - years	1295.56	666.75	440.17	188.65
Incidence Rate*	**3.32**	**3.75**	**3.41**	**1.59**
Lower (95% CI)	2.40	2.43	1.91	0.33
Upper (95% CI)	4.47	5.54	5.62	4.65
Other biologic±	N = 14,429	N = 14,429	N = 13,210	N = 7649
Number of new PsA patients (N)	1196	822	261	113
Exposure in person - years	29,830.91	13,751.78	10,312.07	5767.06
Incidence Rate*	**4.01**	**5.98**	**2.53**	**1.96**
Lower (95% CI)	3.79	5.58	2.23	1.61
Upper (95% CI)	4.24	6.40	2.86	2.36
BADBIR registry				
Secukinumab	N = 476	N = 476	N = 462	N = 332
Number of new PsA patients (N)	20	13	5	2
Exposure in person - years	1114	468.28	402.11	243.21
Incidence Rate*	**1.80**	**2.78**	**1.24**	**0.82**
Lower (95% CI)	1.10	1.48	0.40	0.10
Upper (95% CI)	2.77	4.75	2.90	2.97

*Per 100-patient year

±Excluding secukinumab

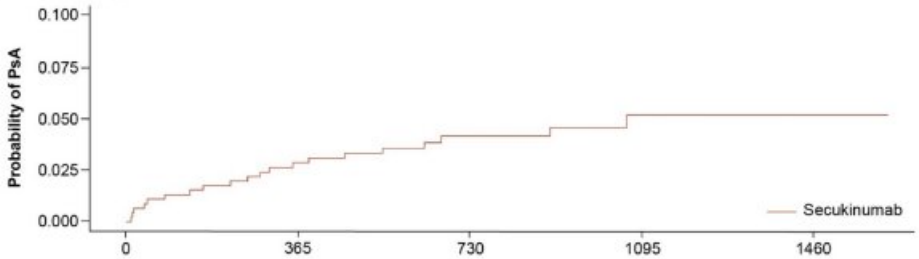
CI, confidence interval; N, total number of patients; PsA, psoriatic arthritis; PsO, psoriasis

A. MarketScan® database



Sample size (Number of new PsA patients)								
Secukinumab	693 (0)	614 (25)	288 (15)	114 (3)	35 (6)	11 (0)	4 (0)	0 (0)
Other biologics	14429 (0)	13228 (822)	7661 (261)	4280 (113)	2319 (62)	1065 (15)	236 (7)	0 (1)

B. BADBIR registry



Sample size (Number of new PsA patients)					
	462 (0)	449 (13)	322 (5)	140 (2)	26 (0)

Figure 1. Time from initiation of secukinumab and other biologics to the first diagnosis of PsA up to 3 years. **(A)** Cumulative incidence curve showing the time to first PsA diagnosis (days) among patients with PsO from the MarketScan® database treated with secukinumab or other biologics. **(B)** Cumulative incidence curve showing the time to first PsA diagnosis (days) among patients with PsO from the BADBIR registry treated with secukinumab. PsA, psoriatic arthritis; PsO, psoriasis.

EA DV CONGRESS
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3247

Exploring the inflammatory nexus between Psoriasis and Multiple Sclerosis

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Introduction & Objectives:

Psoriasis and multiple sclerosis (MS) are both complex immune-mediated, inflammatory conditions. T-helper 1 (Th1),Th17, and Th17.1 T-cells are implicated and pathogenetically integral to both diseases. This study evaluated novel cellular biomarkers linking psoriasis and MS.

Materials & Methods:

Twenty-six patients with MS and 12 patients with both MS and psoriasis (PsoMS) were identified and compared to 10 age and sex matched healthy controls (HC). All MS patients bar one, were treated with immune modulating medication. Mass cytometry (CyTOF) was used to comprehensively analyse T-helper CD4+ cell subsets derived from the peripheral blood mononuclear cells of patients and controls.

Results:

The frequency of Th17 CD4+ T-cells (CCR4+CCR6+CXCR3-) was not different among MS, PsoMS and HC but there was significant depletion of the CD4+Th1 (CXCR3+ CCR4- CCR6-) and Th17.1 (CXCR3+ CCR4- CCR6+) T-cell subsets in MS and PsoMS compared to HC. The frequency of Th17.1 T-cells was no different between PsoMS and MS, and was neither influenced by the type of immune-modulating treatment nor disease progression.

Conclusion:

A T-cell immunotype is not distinguishable between people with MS and PsoMS, treated with immune modulating medications. Surprisingly, suppression of Th17.1 T-cells occur universally independent of the type of treatment used for these patients including B-cell suppression and may represent the treatable nexus of these two immune conditions.

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Abstract N°: 3289

Risk of Developing Inflammatory Arthritis in Psoriasis Patients Initiating Treatment with Biologics: A Population Based Analysis

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Introduction & Objectives: Patients with psoriasis (PsO) are at risk of developing inflammatory arthritis, including psoriatic arthritis (PsA). Recent research has shown a relationship between biologic use among psoriasis patients and incidence of inflammatory arthritis1. Using a similar research design, we assessed the impact of initiation of different classes of biologics among PsO patients on the risk of developing inflammatory arthritis and/or PsA using real world data.

Materials & Methods: Patients included in this analysis were enrolled in the Optum database between Jan 2014 and Dec 2022 and required 2 ICD-9/ICD-10 diagnoses codes of PsO. The initial PsO diagnosis is considered the index date, and the first treatment with a biologic after the index diagnosis is considered the index treatment. Continuous enrollment was required for at least 6 months prior to index diagnosis and 2 weeks after the index treatment. Patients with a history of rheumatologist visits, use of methotrexate, or prior biologics were excluded from this analysis. Patients were assigned to 4 cohorts based on the biologic mechanism of action (IL-23, IL-17, IL12/23, and TNF inhibitors), depending on which biologic they received first. Patients were followed for up to 3 years, until inflammatory arthritis developed (identified by ICD-9/ICD-10 codes), until patients switched or discontinued their biologics, or were lost to follow-up (end of insurance continuous enrollment), whichever occurred first. Risk of developing inflammatory arthritis and/or PsA was assessed using an adjusted Cox proportional hazards model using IL-23 inhibitors (newest class of biologic) as the reference group while controlling for differences in baseline patient characteristics (main analysis). Sensitivity analyses modifying the confirmation of outcome occurrence to require at least 2 instances of ICD-9/ICD-10 codes and expanding the required continuous enrolment post index treatment initiation to 3 and 6 months were conducted to test the robustness of the main analysis findings.

Results: A total of 7144 biologic naïve PsO patients were included with 2330 in the IL-23 cohort, 1100 in the IL-12/23 cohort, 819 in the IL-17 cohort, and 2895 in the TNF cohort. Baseline characteristics are presented in **Table 1**. Patients receiving IL-23 and IL-17 inhibitors had numerically longer times from diagnosis to first treatment and were numerically more likely to have reported joint pain prior to the index treatment. Apremilast usage at the index treatment ranged from 8.23% of patients receiving TNF inhibitors to 17.04% in patients receiving IL-23 inhibitors. Patients receiving IL-23 for PsO were significantly less likely to develop inflammatory arthritis or PsA relative to other classes of biologics in the main analysis. **(Table 2)**. Results from the sensitivity analyses were generally consistent with the main analysis findings.

Conclusion: Biologic-naïve** psoriasis** patients treated with IL-23 inhibitors were significantly less likely to develop inflammatory arthritis or PsA compared to patients treated with IL-17, IL-12/23, or TNF inhibitors. A potential limitation of this study is channeling bias as providers may preferentially prescribe specific biologics to patients with early markers of PsA. These results support recent research findings about the differential impact of biologics class on future risk of inflammatory arthritis.

1Singla et al. The Lancet Rheumatology. April 2023.

Table 1. Baseline Demographics

	IL23 N=2330	IL17 N=819	IL12/23 N=1100	TNF N=2895
Age, mean (SD)	47.31 (15.17)	50.92 (15.37)	44.78 (15.37)	47.70 (15.31)
Female, N (%)	1,089 (46.74%)	414 (50.55%)	524 (47.64%)	1,429 (49.36%)
Time from diagnosis to first treatment in days, mean (SD)	594.88 (618.91)	530.05 (559.63)	341.83 (435.36)	326.71 (438.91)
Baseline comorbid obesity event, N (%)	539 (23.13%)	219 (26.74%)	192 (17.45%)	669 (23.11%)
Joint pain prior to index treatment, N (%)	977 (41.93%)	345 (42.12%)	362 (32.91%)	1,101 (38.03%)
Baseline Apremilast use, N (%)	397 (17.04%)	100 (12.21%)	110 (10.0%)	241 (8.32%)

Table 2. Adjusted Cox Models for Development of Inflammatory Arthritis or PsA (Main Analysis)

	Any Inflammatory Arthritis			
	Hazard Ratio	Lower CI	Upper CI	Pr(>|z|)
Cohort: IL 17	2.06	1.36	3.11	0.0006
Cohort: IL 12/23	1.78	1.18	2.69	0.0064
Cohort: TNF	1.91	1.36	2.67	0.0002
Reference group: IL-23				
	PsA			
Cohort: IL 17	1.98	1.15	3.41	0.0132
Cohort: IL 12/23	1.83	1.09	3.08	0.0228
Cohort: TNF	2.28	1.5	3.48	0.0001
Reference group: IL-23				

Adjusted covariates: age, sex, race, region, duration of PsO to index biologic treatments less than or equal to 2 years, number of baseline hospitalizations, baseline Charlson comorbidity score, baseline comorbidities including cardiovascular diseases, hypertension, COPD, diabetes, obesity, liver disease, renal disease, baseline apremilast use, joint pain any time prior to index biologic treatment

EA DV CONGRESS
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3303

Association of patient-reported disease burden and treatment switching among patients with plaque psoriasis on nonbiologic systemic therapy

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Introduction & Objectives: Better understanding of the relationship between quality of life and treatment patterns in psoriasis may help guide therapeutic algorithms. This study evaluated the association between patient-reported disease burden and treatment switching from nonbiologic to biologic therapy in patients with plaque psoriasis enrolled in the CorEvitas Psoriasis Registry.

Materials & Methods: This cross-sectional study included biologic-naive patients aged ≥18 years who had used nonbiologic systemic therapy 28–365 days prior to their Registry enrollment between April 2015 and August 2022. A switch to biologic therapy was defined as the introduction of biologic treatment up to 45 days post-enrollment, in addition to or in place of the initial nonbiologic systemic therapy. Measures of patient-reported disease burden collected at enrollment were: the Dermatology Life Quality Index (DLQI); Work Productivity and Activity Impairment Index (WPAI); itch, skin pain, fatigue, and Patient Global Assessment (PGA), measured on visual analog scales (VAS); and the EuroQoL 5-Dimension, 3-Level (EQ-5D-3L) questionnaire. The association between each patient-reported disease burden measure and switching to biologic therapy was evaluated using multivariable logistic regression models, adjusting for age, sex, race, ethnicity, work status, body mass index, psoriasis duration, psoriatic arthritis status, disease severity, number of prior nonbiologic therapies used, and history of difficult-to-treat areas. A secondary analysis stratified each model by patients with PASI scores ≤2 or >2.

Results: Of 848 patients included in the analysis, 323 (38.1%) switched to biologic treatment at enrollment. Significantly higher odds of switching were observed for patients reporting greater vs lesser burden on the DLQI (adjusted odds ratio [aOR] = 1.55; 95% CI, 1.08–2.23); VAS measures of itch (aOR = 2.14; 95% CI, 1.49–3.08), skin pain (aOR = 2.18; 95% CI, 1.45–3.29), fatigue (aOR = 1.66; 95% CI, 1.15–2.40), or PGA (aOR = 3.09; 95% CI, 1.94–4.91); or WPAI activities impairment (aOR = 2.51; 95% CI, 1.72–3.65). Numerically higher odds of switching were observed for greater vs lesser burden measured by EQ-5D-3L. In the secondary analysis, 52 of 330 patients with PASI scores ≤2 (15.8%) switched to biologic treatment. Among patients with PASI scores ≤2, those with greater vs lesser burden for VAS itch, skin pain, or PGA, or with impairment of their usual activities as measured by EQ-5D-3L had significantly higher odds of switching to biologic treatments.

Conclusion: Data collected from real-world patients with plaque psoriasis suggest that, in addition to disease severity, patient-reported disease burden, such as itch and skin pain, may be an important driver of switching from a nonbiologic to biologic therapy, even among patients with a low degree of skin involvement.

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Abstract N°: 3319

Ixekizumab significantly improved quality of life and joint pain in patients with psoriatic arthritis, nail disease and DIP Involvement from SPIRIT-H2H

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Introduction & Objectives:

In the SPIRIT-H2H study in adults with Psoriatic Arthritis (PsA), 65% of patients had nail nail psoriasis (PsO) at baseline and of these, 96.2% had simultaneous distal interphalangeal joint (DIP) disease in ≥1 digit at baseline. Significantly more patients experienced improvements in nail PsO with ixekizumab (IXE) treatment vs adalimumab (ADA). The analysis describes the impact of IXE and ADA in patients with PsA and concomitant nail and DIP involvement on quality of life (QoL), function and joint pain.

Materials & Methods:

This analysis included patients from SPIRIT-H2H treated with IXE or ADA who had simultaneous nail and DIP involvement (swelling or tenderness) in ≥1 digit at baseline. Nail PsO was measured using Nail Psoriasis Severity Index (NAPSI), joint involvement by tender/swollen joint count scores and joint pain by patient's assessment of pain Visual Analogue Scale. QoL measures were Dermatology Life Quality Index (DLQI), Health Assessment Questionnaire-Disability Index (HAQ-DI) and Short Form-36 Mental and Physical Component Summary Scores (SF-36 MCS/PCS). Patients were evaluated at baseline and Week 4, 8, 12, 16, 24, 32, 40, and 52. Joint pain and SF-36 MCS/PCS changes from baseline were analyzed using mixed effects model of repeated measures while patients achieving DLQI ≤1 or HAQ-DI change ≥0.35 (minimal clinically important difference) were analyzed using logistic regressions.

Results:

354 patients had a NAPSI total score >0 and DIP involvement in ≥1 digit simultaneously at baseline (IXE, N=186; ADA, N=168) (Table 1). IXE-treated patients had a significant improvement in joint pain at Week 4 and a larger improvement in joint pain over 52 weeks vs ADA-treated patients (Figure 1). Also, most of IXE-treated patients achieved a DLQI score of 0 or 1, and these statistically significant differences were observed at Week 4 and sustained at each visit over 52 weeks (Figure 2). IXE-treated patients also showed statistically significant improvements in SF-36 MCS at Week 4, 12 and 32 vs ADA-treated patients; numerically greater improvements in favor of IXE were sustained at all other visits (Figure 3). IXE-treated patients showed a larger improvement in SF-36 PCS over 52 weeks vs ADA-treated ones, and these differences reached statistical significance at Week 24 and 32 (Figure 3). Similar proportions of patients treated with IXE or ADA showed a clinically important improvement in HAQ-DI (Table 2).

Conclusion:

In patients with simultaneous nail and DIP involvement in ≥1 digit at baseline, IXE treatment resulted in significant improvements across multiple QoL measures, and greater improvements in joint pain vs ADA treatment. This data may help health care providers make clinical decisions concerning the care of PsA in patients with nail and DIP involvement.

Presented at CCR East-39th Annual, 2023.

Figures and Tables.

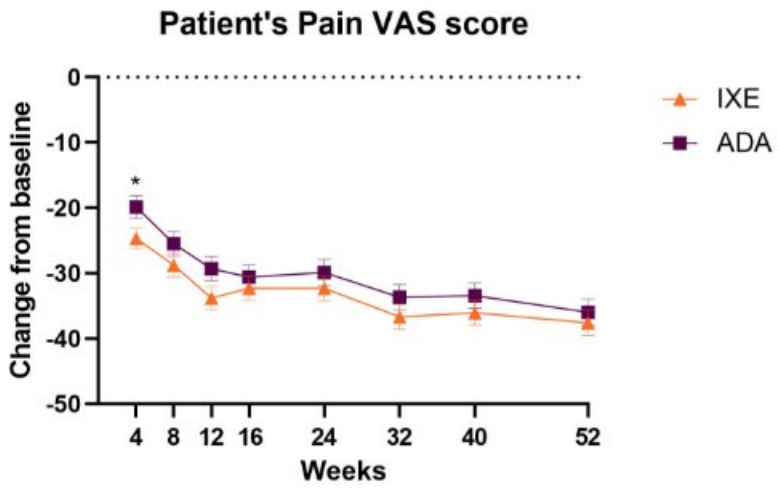

Figure 1. Change from baseline in patient reported joint pain over 52 weeks in patients treated with either IXE or ADA who had simultaneous NAPSI >0 and DIP joint involvement at baseline. Data are presented as least squares mean ± standard error. *Significant difference in joint pain improvement between IXE vs ADA treatment denoted by *(p<0.05). Abbreviations: ADA=adalimumab; IXE=ixekizumab; NAPSI=Nail Psoriasis Severity Index; VAS=Visual Analog Scale.*

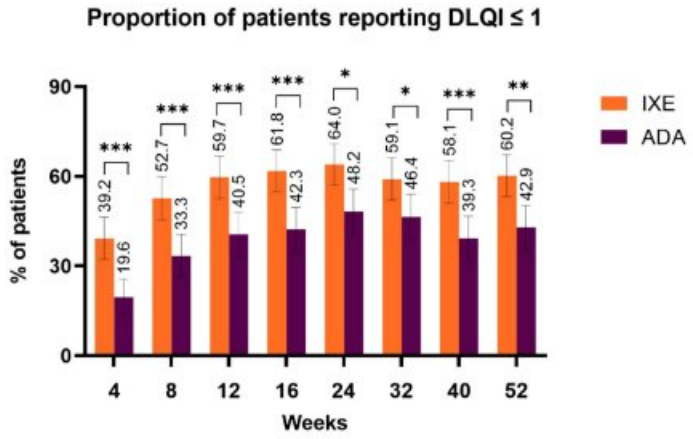

Figure 2. Proportion (%) of patients reporting DLQI scores of 0 or 1 over 52 weeks, among those treated with IXE or ADA who had simultaneous NAPSI >0 and DIP joint involvement at baseline. DLQI scores 0-1 are considered to have no effect on patient's life. Data are NRI mean ± 95% confidence intervals. *Significant difference in DLQI response between IXE vs ADA treatment denoted by *(p<0.05), **(p< 0.01), and ***(p <0.001). Abbreviations: ADA=adalimumab; DIP=Distal Interphalangeal Joint; DLQI=Dermatology Life Quality Index; IXE=ixekizumab; NAPSI=Nail Psoriasis*

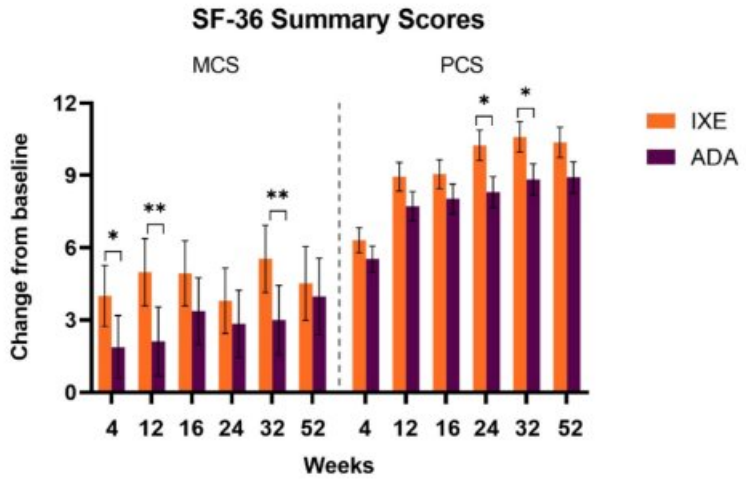

Figure 3. Change from baseline in 36-item Short Form Health Survey Mental and Physical Component Scores over 52 weeks in patients treated with either IXE or ADA who had simultaneous NAPSI >0 and DIP joint involvement at baseline. Data are least squares mean ± standard error. *Significant difference in component scores between IXE vs ADA treatment denoted by *(p<0.05) and **(p< 0.01). Abbreviations: ADA=adalimumab; DIP=Distal Interphalangeal Joint; IXE=ixekizumab; MCS=Mental Component Score; NAPSI=Nail Psoriasis Severity Index; PCS=Physical Component Score; SF-36=Medical Outcomes Study 36-Item Short Form Health Survey*

Table 1. Baseline demographics and disease characteristics of patients treated with either ixekizumab or adalimumab who had simultaneous NAPSI >0 and DIP joint involvement at baseline.

Data are mean ± standard deviation unless stated otherwise.

	IXE (N=186)	ADA (N=168)
Age, years	47.4 ± 11.76	48.7 ± 12.51
Male, n (%)	115 (61.8)	96 (57.1)
Duration of PsA, years	7.4 ± 7.80	6.4 ± 6.70
NAPSI fingernails	19.5 ± 18.18	19.3 ± 16.50
Tender Joint Count	20.5 ± 13.19	22.6 ± 15.47
Swollen Joint Count	10.9 ± 7.58	11.3 ± 8.86
Joint Pain VAS, mm	60.2 ± 22.55	61.5 ± 21.86
HAQ-DI	1.2 ± 0.60	1.3 ± 0.72
DLQI	10.5 ± 7.85	10.5 ± 7.58
SF-36 MCS	45.3 ± 11.43	44.6 ± 11.02
SF-36 PCS	37.2 ± 7.98	36.2 ± 9.13

Abbreviations: ADA=adalimumab; DIP=Distal Interphalangeal Joint; HAQ-DI=Health Assessment Questionnaire-Disability Index; IXE=ixekizumab; MCS=Mental Component Score; NAPSI=Nail Psoriasis Severity Index; PCS=Physical Component Score; PsA=psoriatic arthritis; SF-36=Medical Outcomes Study 36-Item Short Form Health Survey; VAS=Visual Analog Scale.

Table 2. The proportion (%) of patients with a clinically important improvement in HAQ-DI (minimal clinically important difference ≥0.35) among patients treated with either ixekizumab or adalimumab who had simultaneous NAPSI >0 and DIP joint involvement at baseline.

Assessed for patients with HAQ-DI score ≥0.35 at baseline. Data are NRI mean.

	IXE	ADA	p-value
Week 4	44.6	42.9	0.691
Week 8	58.6	51.8	0.168
Week 12	60.2	58.9	0.691
Week 16	60.8	60.1	0.826
Week 24	60.2	62.5	0.742
Week 32	64.0	61.3	0.517
Week 40	62.4	61.3	0.793
Week 52	60.2	58.9	0.716

Abbreviations: ADA=adalimumab; DIP=Distal Interphalangeal Joint; HAQ-DI=Health Assessment Questionnaire-Disability Index; IXE=ixekizumab; NAPSI=Nail Psoriasis Severity Index; NRI=non - responder imputation.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3327

An integrated safety analysis of treatment-emergent fungal infections in patients with psoriasis, psoriatic arthritis, or axial spondyloarthritis treated with ixekizumab from 26 clinical studies

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Introduction & Objectives: Interleukin (IL)-17 plays a role in host defense against common extracellular pathogens, including fungi. Treatment with IL-17 inhibitors has been associated with fungal infections. Ixekizumab (IXE) is an anti-IL-17A monoclonal antibody approved for the treatment of psoriasis (PsO) in adults and children, psoriatic arthritis (PsA) in adults, and axial spondyloarthritis (axSpA) in adults. This integrated *post hoc* analysis investigates treatment-emergent fungal infections in IXE-treated patients across the approved indications.

Materials & Methods: Safety data on fungal infections were pooled from the IXE pediatric and adult clinical trial programs, comprising 26 clinical studies. Here we describe the types of fungal infections, number of infections, recurrence (defined by at least two separate events irrespective of location), severity (defined at the investigator's discretion), events that lead to discontinuation, and anti-fungal medications. Data are presented as frequency or incidence rate per 100 person-years (IR).

Results: Fungal infections were reported in patients with PsO (IR=4.0), PsA (IR=4.1), and axSpA (IR=2.7; Table 1). Across indications, most fungal infections were not recurrent and were classified as mild or moderate in severity (Table 1). There were few severe fungal infections in patients with PsO (IR=0.1), PsA (IR=0.0), and axSpA (IR=0.0; Table 1). Most fungal infections in patients with PsO, PsA, and axSpA were candidiasis (IR=1.9, IR=2.5, IR=1.4, respectively) and superficial dermatophytosis (IR=1.5, IR=1.0, IR=1.0, respectively). No cases of subcutaneous and systemic mycosis infections were reported. The proportions of patients with PsO, PsA, and axSpA who received a topical *vs* systemic anti-fungal medication were 53.6% *vs* 1.1%, 47.8% *vs* 0.0%, and 45.6% *vs* 3.5%, respectively (Table 2). Most fungal infections did not lead to discontinuation of IXE (Table 2).

Conclusion: Consistent with previously disclosed IXE data, the majority of treatment-emergent fungal infections observed in patients with PsO, PsA, or axSpA treated with IXE were: (*i*) not recurrent; (*ii*) mild or moderate in severity, (*iii*) associated with candidiasis and superficial dermatophytosis, (*iv*) managed with topical anti-fungal medications or no treatment reported, and (*v*) not leading to drug discontinuation.

Previously presented at Congress of Clinical Rheumatology East - 39th Annual.

Table 1. Incidence rates (95% confidence intervals) of fungal infections based on recurrence and severity.

	PsO (N = 7088) Total Patient-Years = 18369.71	PsA (N = 1401) Total Patient-Years = 2247.652	axSpA (N = 932) Total Patient-Years 2097.711
Patients with			
≥1 Fungal Infections[a]	4.0 (3.7-4.3)	4.1 (3.3-5.0)	2.7 (2.1-3.5)
1 Fungal Infection[b]	2.9 (2.7-3.2)	3.2 (2.6-4.1)	2.1 (1.6-2.9)
2 Fungal Infections[c]	0.7 (0.6-0.8)	0.7 (0.4-1.1)	0.4 (0.2-0.8)
≥3 Fungal Infections[d]	0.4 (0.3-0.5)	0.2 (0.1-0.5)	0.2(0.1-0.50
Severity[e]			
Mild	2.4 (2.2-2.6)	3.2 (2.5-4.0)	2.0 (1.4-2.7)
Moderate	1.5 (1.4-1.7)	0.8 (0.5-1.3)	0.7 (0.4-1.2)
Severe	0.1 (0.0-0.1)	0.0 (0.0-0.3)	0.0 (0.0-0.3)

Numbers are rounded.
[a]Patients with at least 1 fungal infection; [b]Patients with only 1 fungal infection; [c]Patients with 2 fungal infections (not inclusive of patients with only 1 fungal infection); [d]Patients with 3 or more fungal infections (not inclusive of patients with only 1or 2 fungal infections); [e]Patients with multiple occurrences of the same event are counted under the highest severity. Abbreviations: AxSpa, axial spondyloarthritis; N, number of patients in the analysis population; PsA, psoriatic arthritis; PsO, psoriasis.

Table 2. Anti-fungal medications used in patients treated with ixekizumab experiencing at least one treatment-emergent fungal infection, and events that lead to discontinuation.

	PsO (N=731) n (%)	PsA (N=92) n (%)	axSpA (N=57) n (%)
Systemic therapy	8 (1.1%)	0 (0.0%)	2 (3.5%)
Topical therapy	392 (53.6%)	44 (47.8%)	26 (45.6%)
Non-specified	5 (0.7%)	0 (0.0%)	0 (0.0%)
No treatment reported	326 (44.6%)	48 (52.2%)	29 (50.9%)
Events leading to discontinuation	1 (0.0%)	1 (0.1%)	1 (0.1%)

Patients treated with multiple different medications were counted in more than one medication category.
Abbreviations: axSpA, axial spondyloarthritis; N, number of patients in the analysis population; n, number of patients in the specified category; PsA, psoriatic arthritis; PsO, psoriasis.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3345

Use of anti Il-23 p19 inhibitors in cancer patients with severe psoriasis, a multicentric Italian experience

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Introduction & Objectives:

Psoriasis is a systemic immune-mediated disease associated with an increased risk of comorbidities, such as psoriatic arthritis, cardiovascular disease, metabolic syndrome, inflammatory bowel disease, psychiatric disorders, and malignancy. There is a lack of experience in the use of biologic therapies in patients with psoriasis and a history of malignancy. The latest biologics drugs are thought to be safe in this population but scientific literature is limited.

Materials & Methods:

In this retrospective multicentric study, we assessed the safety and the efficacy of IL-23 p19 inhibitors (risankizumab, guselkumab, tildrakizumab) in psoriatic patients with a previous diagnosis of neoplasia. The efficacy of biologic treatments was evaluated by assessing the Psoriasis Area and Severity Index (PASI) score at every visit and during the follow-up. All patients were evaluated by an oncologist before starting the treatment and periodically during follow-up.

Results:

20 patients with a diagnosis of neoplasia and concomitant use of biologic agents were followed in our study. These psoriatic patients had several comorbidities and were strictly monitored during the study. Out of 20 patients, 9 patients were treated with risankizumab, 8 patients were treated with guselkumab and 3 patients were treated with tildrakizumab. No patients had evidence of neoplasia worsening during the study period. Study limitations include the retrospective nature and the different type of neoplasia in patients receiving biologic drugs.

Conclusion:

Based on our experience, IL-23p19 inhibitors appear to be safe and effective in psoriatic patients with a previous diagnosis of neoplasia.

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Abstract N°: 3357

Assessing humanistic burden among patients with moderate to severe psoriasis in the United States

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Introduction & Objectives: Various treatments for psoriasis are available, yet evidence reveals substantial humanistic burden remains. This study assessed the humanistic burden among patients with moderate to severe psoriasis.

Materials & Methods: This non-interventional, cross-sectional survey study in adult patients with moderate to severe psoriasis in the USA grouped patients based on treatment at time of survey. The survey collected demographics, clinical characteristics, and outcomes associated with humanistic burden via the Dermatology Life Quality Index (DLQI), the Work Productivity and Activity Impairment Questionnaire–Psoriasis (WPAI-PSO), and questions on disease-related anxiety and depression.

Results: Within this study population of 882 patients, 92.8% were currently receiving treatment (mean duration=2.9 [±4.8] years). Over the past 30 days, 76.8% experienced anxiety and 57.4% experienced depression due to psoriasis. Of the 677 patients with anxiety due to psoriasis, 58.6%, 20.5%, and 12.6% experienced it for several days, more than half the days, and nearly every day, respectively. Of 506 patients who experienced depression due to psoriasis, 67.2%, 16.4%, and 8.5% experienced it for several days, more than half the days, and nearly every day, respectively. Compared with other treatment groups, patients in the untreated/nonprescription group experienced more depression (78.0%) and anxiety (94.0%). Topical/phototherapy and untreated/nonprescription groups had the smallest percentage of patients who believed their anxiety had decreased (yes definitely, probably yes) since initiating their current treatment (26.5% and 27.8%, respectively). Similar results were seen for depression, with 23.4% of topical/phototherapy users and 27.7% of the exploratory group reporting that their depression decreased since starting treatment. Compared with TNFi and ustekinumab users, apremilast users reported lower reduction in depression (50.4%. 52.1%, 43.6% respectively) (all P <0.001). Mean DLQI global score overall was 8.9. Ustekinumab users had the lowest DLQI score (7.6), indicating better quality of life (QoL), compared with 8.1 for apremilast users, 8.8 for TNFi users, 10.3 for topical/phototherapy users, and 11.3 for the untreated/nonprescription group (P<0.001). DLQI scores increased with psoriasis severity (P<0.001). Of 528 employed patients, the mean absenteeism score was 6.0, presenteeism score was 25.4, total work productivity impairment score was 27.9, and activity impairment score was 29.3. Topical/phototherapy and exploratory group patients and those receiving TNFis had greater presenteeism and activity impairment scores, indicating worse productivity, than those receiving apremilast or ustekinumab.

Conclusion: Patients' current treatment, or lack thereof, influences how psoriasis impacts QoL, anxiety and depression, and productivity. We recommend physicians consider QoL in addition to symptom management when making treatment decisions.

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Abstract N°: 3361

Deucravacitinib improves Dermatology Life Quality Index in patients with moderate to severe psoriasis: Results from the phase 3 POETYK PSO-1 and PSO-2 trials

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Introduction & Objectives: We assessed improvements in Dermatology Life Quality Index (DLQI) from the phase 3, double-blind, POETYK PSO-1 and PSO-2 trials to determine the impact of deucravacitinib on quality of life. Deucravacitinib is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy.

Materials & Methods: The POETYK trials randomized patients with moderate to severe plaque psoriasis to placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily (1:2:1). DLQI meaningful change thresholds (MCTs) were derived using anchor- and distribution-based methods using data from POETYK PSO-1. Improvements in DLQI scores and individual items were evaluated using change from baseline and an MCT-based responder analysis through Week 52.

Results: Mean changes from baseline in DLQI were greater for deucravacitinib as early as Week 1 vs placebo in POETYK PSO-1 (−3.67 vs −2.18) and PSO-2 (−3.49 vs −2.82) and Week 4 vs apremilast in PSO-1 (−5.63 vs −4.83) and Week 8 in PSO-2 (−7.35 vs −6.31). Improvements were consistent across all individual items. More patients treated with deucravacitinib achieved ≥4-point improvement on the DLQI (MCT ≥4) at Week 16 vs placebo-treated and apremilast-treated patients in POETYK PSO-1 (77.6% vs 43.4% and 68.8%, respectively) and PSO-2 (78.6% vs 44.9% and 69.3%). Higher responses vs apremilast were maintained through Week 24 in POETYK PSO-1 (79.5% vs 67.9%) and PSO-2 (79.2% vs 67.5%). In PSO-1, 81.6% achieved MCT ≥4 at Week 52 with continuous deucravacitinib treatment. Results were similar when applying an MCT ≥5.

Conclusion: Deucravacitinib improved DLQI as early as Week 1 vs placebo and Week 4 vs apremilast. Higher proportions of patients reached MCT ≥4 and MCT ≥5 with deucravacitinib vs placebo and apremilast, with sustained responses through Week 52.

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Abstract N°: 3370

Evaluating prevalence and consequence of residual disease among patients with moderate to severe psoriasis in the United States

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Introduction & Objectives: To assess unmet needs in psoriasis (PsO), this study assessed the prevalence of and factors associated with residual disease in patients (pts) with moderate to severe PsO receiving apremilast, and compared clinical and humanistic burden in apremilast users with vs without residual disease.

Materials & Methods: This non-interventional, cross-sectional, online survey study of adults with PsO in the US collected information on demographics and clinical characteristics, current treatment, prevalence of residual disease, flare-ups, humanistic burden (via Dermatology Life Quality Index [DLQI], Work Productivity and Activity Impairment Questionnaire–Psoriasis [WPAI-PSO], and questions on disease-related anxiety and depression), and healthcare resource use (HCRU). Pts were defined as having residual disease if they had ≥3 on the Body Surface Area scale or reported moderate, severe, or very severe PsO on a 6-point PsO severity scale. Respondents viewed a profile of a hypothetical once-daily oral treatment and asked about their anxiety associated with it.

Results: Among 344 apremilast users, 50.6% had ≥3% BSA or at least moderate severity over the past week. Pts were significantly more likely to experience residual disease if they were Black (OR=4.5, 95% CI=1.6-12.2) vs White; if their treatment duration was ≥1 y (OR=16.5, 95% CI=7.9-34.4) vs <1 year; if they had ≥2 flare-ups (OR=10.0, 95% CI=4.9-20.1) vs 0-1 flare-ups in the past 3 mo; and if they had ≥4 body regions affected (OR= 8.6, 95% CI=3.8-19.8) vs 1-3. The mean (SD) number of flare-ups in the past 3 mo was greater in apremilast users with residual disease (4.7 [±7.6]) vs those without (0.9 [±1.1]) (P<0.001). A higher percentage of apremilast users with residual disease experienced anxiety (89.7% vs 50.0%) and depression (69.0% vs 23.6%) over the past 30 days vs those without (P<0.001). A higher percentage of apremilast users with residual disease had anxiety for several days or more (94.9% vs 78.8%) over the past 30 days than those without (P=0.001). Pts with residual disease also had greater depression severity (very depressed, depressed) vs those without (23.0% versus 4.2%; P<0.001). When shown a hypothetical once-daily oral PsO treatment, 71.8% of apremilast users with residual disease said it would cause less anxiety than treatment given as an injection/infusion. Apremilast users with residual disease had significantly higher mean DLQI and WPAI scores vs those without, indicating lower QoL and productivity (P<0.001). These pts also had higher all-cause and PsO-related HCRU than those without residual disease.

Conclusion: Among apremilast users, those with residual disease had more flare-ups, worse QoL, anxiety, depression, and work productivity, and greater HCRU than those without residual disease. We recommend that physicians evaluate residual disease in pts treated for PsO to identify alternative treatment options that may mitigate clinical and humanistic burden.

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Abstract N°: 3372

Ixekizumab reduces key IL-17 and IL-23 pathway genes more rapidly than guselkumab: 4-week results from IXORA-R

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Introduction & Objectives: Blockade of interleukin (IL)-17 and IL-23 inflammatory pathways by ixekizumab (IXE) and guselkumab (GUS) are highly effective treatments for plaque psoriasis. We compared the early effects of IXE and GUS on psoriasis pathway genes in lesions between baseline and weeks 1, 2, and 4.

Materials & Methods: In IXORA-R (NCT03573323), adults with moderate-to-severe psoriasis received approved dosing of IXE or GUS. A total of 54 patients (32 IXE, 22 GUS) were included in the RNA sequencing (RNAseq) analysis. Gene expression was analyzed for patients treated with IXE versus GUS and a separate cohort of healthy controls (N=26).

Results: Treatment effect, from baseline transcriptome genes, was observed for IXE at weeks 1 (14%), 2 (31%), and 4 (48%), but was only observed for GUS at week 4 (8%). Expression of several highly up-regulated genes were modulated with both treatments at week 4 (S100A7, S100A8, S100A9, S100A12, IL36A, IL36G, IL19, PI3, and KRT16), with a fold-change decrease with IXE at least 5-times greater than with GUS. Average percent improvement for transcriptome genes was ~50% with IXE versus ~25% with GUS at week 4, which was also reflected in the IL-17-centric pathway analyses. GUS results at week 4 were similar to IXE week 1 outcomes.

Conclusion: When measured with RNAseq, transcriptomic changes were earlier and more robustly dampened with IXE compared with GUS, primarily in psoriasis-centric pathways including the IL-17/IL-23 signaling pathway. These results within the first 4 weeks support the clinical observation of faster psoriasis resolution in IXE-treated patients compared to GUS.

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Abstract N°: 3381

Registry of psoriasis health outcomes: A longitudinal real-world collaboration (RePhlect)—Global registry design and approach

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Introduction & Objectives: Deucravacitinib, an oral, allosteric tyrosine kinase 2 (TYK2) inhibitor, is approved in the US, EU, and other countries for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Two global, phase 3 clinical trials, POETYK PSO-1 and PSO-2, demonstrated the superior efficacy of deucravacitinib vs placebo and apremilast. Real-world patient registries generate data on the long-term effectiveness of therapies in clinical practice. The Registry of Psoriasis Health Outcomes: A Longitudinal Real-World Collaboration (RePhlect) study aims to assess the real-world, long-term use of deucravacitinib in a diverse, global population of patients with psoriasis.

Materials & Methods: RePhlect is a prospective, observational, real-world study of adult patients with diagnosis of moderate to severe plaque psoriasis who are treated with deucravacitinib or other conventional systemic psoriasis therapy. The registry will be established in 6 countries, and the data will be collected in partnership with existing registries (in the US, Canada, Germany, and UK) or by setting up de novo registries (in Japan and France). Patients may be enrolled if they are aged ≥18 years, newly initiating systemic treatment, and not enrolled in an interventional clinical trial. Patients will be enrolled at treatment initiation (baseline visit) and followed up every 6 months for up to 5 years. Primary outcomes include skin clearance as measured by body surface area involved, Psoriasis Area and Severity Index (PASI) score, and Physician or Investigator Global Assessment score; health-related quality of life as measured by the Dermatology Life Quality Index (DLQI) score; and drug survival. Secondary and exploratory outcomes will examine the demographics and clinical characteristics of patients initiating treatments of interest, evaluate disease activity with additional measures including patient-reported outcomes using visual analog scales, assess the impact of therapies on healthcare resource utilization and work productivity, and describe treatment safety profiles. Once data are available from all countries, pooled analyses are planned to generate long-term, global comparative effectiveness data for deucravacitinib that demonstrate its real-world impact on clinical practice and treatment outcomes.

Results: Patient enrollment in RePhlect began in North America in 2022. As of April 2023, patients enrolled in the study included 148 receiving deucravacitinib and 84 receiving apremilast.

Conclusion: RePhlect is a multicountry, intercontinental, collaborative effort to generate evidence on the real-world comparative effectiveness of deucravacitinib that will help to establish its long-term effectiveness and further complement the clinical trial data of deucravacitinib. This abstract describes the design and approach for setting up the Global RePhlect registry.

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Abstract N°: 3384

Dimethyl Fumarate in Psoriasis

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Introduction & Objectives:

Analysis of patients receiving dimethyl fumarate (DMF) therapy to determine differential gene regulation in response to treatment.

Materials & Methods:

As part of a phase 3b clinical study assessing the efficacy and safety of DMF a sub-cohort of participants had additional blood (n=48) and skin (lesional, n=28 and non-lesional, n=15) biopsies (3mm) from photo-protected back or buttock skin taken for a multiomic analysis. Here we present the blood RNA gene expression from baseline, week 4 and 24 week correlating with the clinical outcomes of PASI (Psoriasis Area and Severity Index) and physicians global assessment. Whole blood RNA was extracted using PAXgene blood RNA System and gene regulation was assessed using RNA-seq GEN27012 by Novogene.

Results:

In the full 48 samples blood RNA sequence analysis demonstrated statistically significant differences in gene regulation when baseline samples were compared with samples both at 4 weeks and at 24 weeks post treatment irrespective of response (fig.1). Expression of IDO1 and TFF3 increased over time whilst CD2 and KIF5C decreased. CD2 is reported to stimulate Naïve T cells via keratinocytes (Orlik et al., 2020) and is a target for a biologic (Alefacept), which reduces infiltrating T cells while activating dendritic cells and inflammatory genes (Chamian et al., 2005). TFF3 is associated with cell migration by activating STAT3, MAPK and PI3K. CLC, STAC, and CCL23 gene expression significantly increased at week 4 compared to that of baseline. CLC is reported to be involved in imune surveillance for inflammatiuon and tumours and has recently been reported to play vital role in immune sipression function of the regulatoiry T cells (Swaminathan et al., 1999; Liu et al., 2005; and Kubach 2007). In the preliminary analysis 33 patients were assessed for PASI and response was categorised into PASI75, PASI50-75, PASI<50 or a final absolute PASI (<3). In this cohort KIF5C, CXCR3, and GZMK all decreased in expression over time (fig.2), with CXCR3 showing evidence of a more prominent effect in responders (blue dots) at week24. CXCR3 is present in infiltrating T cells in psoriasis lesion. GZMK gene expression was significantly reduced at week 24.

Figure 1

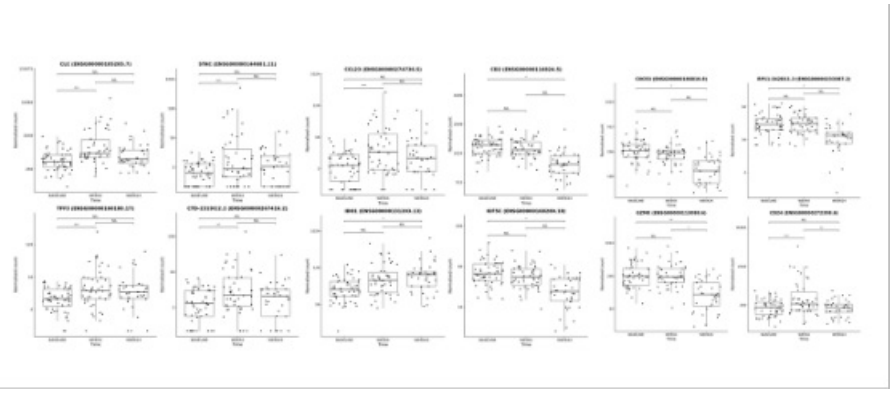
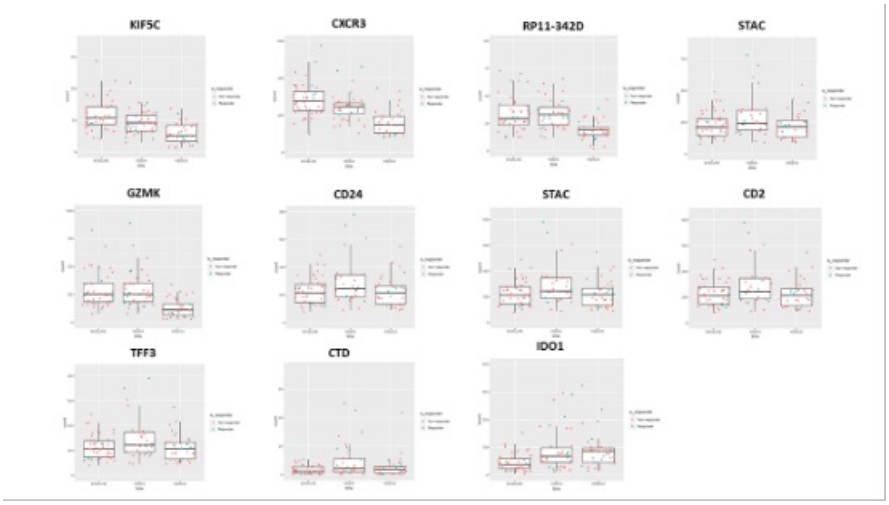


Figure 2



Conclusion:

Gene expression changes significantly from baseline by week 4 in patients taking DMF, with pathways relevant to the pathogenesis of psoriasis being dis-regulated. Preliminary data also indicate patients who achieve a higher level of response may have reduced CXCR3 at week 24 although this will require validation. Future analysis will be able to compare these signals in skin and blood and perform a multiomic assessment of response layering in analyses of DNA and the proteome.

Grant reference: Almirall

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Abstract N°: 3392

A literature review of real-world evidence from psoriasis patient registries and its role in decision-making

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Introduction & Objectives: Psoriasis is a chronic, inflammatory skin disease mediated by the immune system and affecting approximately 2% of the global population. As a chronic condition, the treatment of moderate to severe psoriasis typically requires the use of multiple systemic therapies over a patient's lifetime. The efficacy and safety of conventional systemic and biologic treatments are first examined in clinical trials. Today, patient registries are increasingly used to monitor the long-term outcomes of systemic therapies for psoriasis in real-world settings.

Materials & Methods: We conducted a systematic review to assess how psoriasis patient registries utilize real-world evidence on the health outcomes of psoriasis treatments. We searched PubMed and Embase for observational studies using psoriasis patient registry data published between January 2018 and March 2023 in English. We included studies that examined the outcomes of psoriasis treatment in adult patients in real-world settings. We excluded studies that (1) used non-observational methods, (2) did not evaluate treatment outcomes, and (3) did not use registry data. Screening and data extraction were performed by two independent reviewers and followed PRISMA reporting guidelines. To assess how these studies have informed practice, treatment, and reimbursement guidelines, we will conduct a narrative review of recommendations based on psoriasis patient registry studies found in clinical guidelines and coverage and reimbursement reports published from 2018 to 2023.

Results: A total of 1178 titles and abstracts were identified and 79 full-text articles using data from 32 registries were included for analysis based on our criteria. Real-world studies were categorized by the primary type of outcome reported. Thirty studies examined effectiveness, 22 studies evaluated drug survival, 14 studies reported safety outcomes, and 13 studies described the baseline characteristics of psoriasis patients using specific treatments. PASI was the most frequently reported measure in 26 studies evaluating effectiveness (87%). DLQI measurements were the second-most common effectiveness measure reported in 19 studies (63%). BSA, IGA, and PGA measurements were reported in fewer than 50% of studies measuring effectiveness. Safety studies covered a wide variety of outcomes from mortality to risks of cardiovascular events, serious infections, and skin cancer. Only three studies evaluated the impact of psoriasis treatment on healthcare resource utilization.

Conclusion: These findings demonstrate that data from psoriasis patient registries are used to assess a variety of health outcomes, including effectiveness, drug survival, safety, and utilization. Patient registries play a critical role in evaluating the long-term outcomes of psoriasis treatments in terms of real-world treatment effectiveness, drug survival, health-related quality of life, safety, and healthcare resource utilization.

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Abstract N°: 3397

Characterisation of the sociodemographics of patients with psoriasis in Romania compared to Germany

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Introduction & Objectives:

Psoriasis is a chronic inflammatory disorder with polygenic predisposition and triggering environmental factors. Individual patient experiences can vary greatly depending on access to dermatology care, effective treatment and social support. It is important to understand disease demographics, environmental risk factors and associated comorbidities, which may be affected by background population rates, on an individual country-by-country basis. Romania has the highest prevalence of psoriasis in Europe, almost double that of Germany. Our aim was to compare sociodemographics between a cohort of psoriasis patients in Romania and Germany to identify any features which could explain the increased prevalence of disease.

Materials & Methods:

This was a cross sectional study involving two different psoriasis patient groups: one from a Romanian public hospital (n=22) and one comprised of online survey participants in Germany with a diagnosis of psoriasis (n=44). Data was collected from May to August 2022 with information on age, sex, alcohol, smoking, co-morbidities and body mass index (BMI). Statistical analysis was completed using Jamovi v2.0 (Sydney, Australia). Chi-square test was used to compare categorical variables, student's t-test to compare parametric data and Mann-Whitney U to compare non-parametric data.

Results:

Patients in Romania were older ($p<0.001$) and more likely to be male ($p=0.042$). Significant differences were noted between the two cohorts with regards to smoking and alcohol. Active smoking was significantly more common in Romanian patients (63.6% vs 36.4%, $p=0.012$) while alcohol consumption was more likely in German patients (70.5% vs 36.4%, $p=0.008$). In the German patient group, 30% reported a diagnosis of depression while not a single Romanian patient did ($p=0.004$). BMI was similar between the two groups and there were no differences in the prevalence of hypertension, diabetes, psoriatic arthritis, inflammatory bowel disease, hepatic steatosis or anxiety.

Conclusion:

Romania has the highest prevalence of psoriasis in Europe. Little research has been conducted into the reasons for this burden. We have identified an increased frequency of active smoking in patients in Romania compared to Germany. The younger age and female predominance in the German cohort is probably explained by their recruitment via an online survey. Depression was common in the German cohort potentially reflecting cultural differences and increased alcohol use. This study has not identified any significant discrepancies in sociodemographics which may explain the increased prevalence. Further research is needed with larger studies assessing the epidemiology of psoriasis in Romania and underlying genetic differences which could explain the high burden of disease.

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Abstract N°: 3418

Comparative Effectiveness of Biologics Across Clinically Relevant Comorbidity Subgroups with Moderate-to-Severe Plaque Psoriasis: Results at Week 12 from the PSoHO Study in a Real-World Setting

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Introduction & Objectives: Patients with moderate-to-severe plaque psoriasis (PsO) value rapid treatment effects. However, with the wide range of biologic treatments available it can be challenging to determine the most suitable option for achieving that outcome. Particularly little is known about the comparative effectiveness of approved biologics in special patient subpopulations, including those who smoke or have comorbid metabolic or psychiatric illnesses. To address this gap, we aimed to evaluate the real-world effectiveness of approved biologics at week 12 across twelve clinically relevant subgroups.

Materials & Methods: The Psoriasis Study of Health Outcomes (PSoHO) is an ongoing, international, prospective, observational study comparing the effectiveness of anti-IL-17A biologics (ixekizumab, secukinumab) to other approved biologics in a heterogeneous population receiving treatment for moderate-to-severe PsO. In this analysis, 1981 patients were stratified at baseline according to the presence or absence of six comorbidities: smoking, diabetes, hypertension, dyslipidemia, depression, and anxiety. This analysis compared the proportion of patients who achieved pre-specified outcomes at week 12 within each subgroup between the anti-IL-17A and the other biologics cohorts. These included the primary endpoint, ≥90% improvement in Psoriasis Area and Severity Index scores (PASI90) and/or static Physician Global Assessment (sPGA) 0/1, as well as the secondary outcome of 100% improvement (PASI100), at week 12. Missing data were imputed using non-responder imputation. Unadjusted response rates are reported with 95% confidence intervals (CI).

Results: In this analysis of 1981 patients, 39.0% were in the anti-IL-17A cohort (received ixekizumab [n=532] or secukinumab [n=241]), while 61.0% (n=1208) received other biologics. As previously reported (Pinter et al., 2022), by week 12, higher proportions of patients had achieved both the primary endpoint as well as the more stringent PASI100 when treated with anti-IL-17A than other biologics. Our new analysis shows that, in achievement of the primary endpoint, this difference between biologic types was greatest in those with comorbid hypertension (anti-IL-17A response rate: 71.6% [95% CI: 65.4% - 77.8%]; other biologics: 51.1% [45.2% - 57.0%]) (**Fig.1**). Similarly, in achievement of PASI100, the difference between anti-IL-17A and other biologics was greatest in those with comorbid dyslipidemia (anti-IL-17A: 35.9% [28.1% - 43.7%]; other biologics: 17.0% [11.8% - 22.2%]) or hypertension (anti-IL-17A: 34.3% [27.8% - 40.8%]; other biologics: 15.4% [11.1% - 19.7%]) (**Fig.2**).

Conclusion: Across these clinically relevant subpopulations, a greater proportion of participants attained a high-level treatment response (primary endpoint) or total skin clearance (PASI100) by week 12 when being treated with anti-IL-17A biologics than other approved biologics in a real-world setting. Our data indicate that anti-IL-17A biologics are particularly more effective than other biologics for PsO patients with comorbid hypertension or dyslipidemia.

Reference:** Pinter A, Puig L, Schäkel K, Reich A, Zaheri S, Costanzo A,*et al.* Comparative effectiveness of

biologics in clinical practice: Week 12 primary outcomes from an international observational Psoriasis Study of Health Outcomes (PSoHO). *J Eur Acad Dermatol* 2022;36:2087-100.

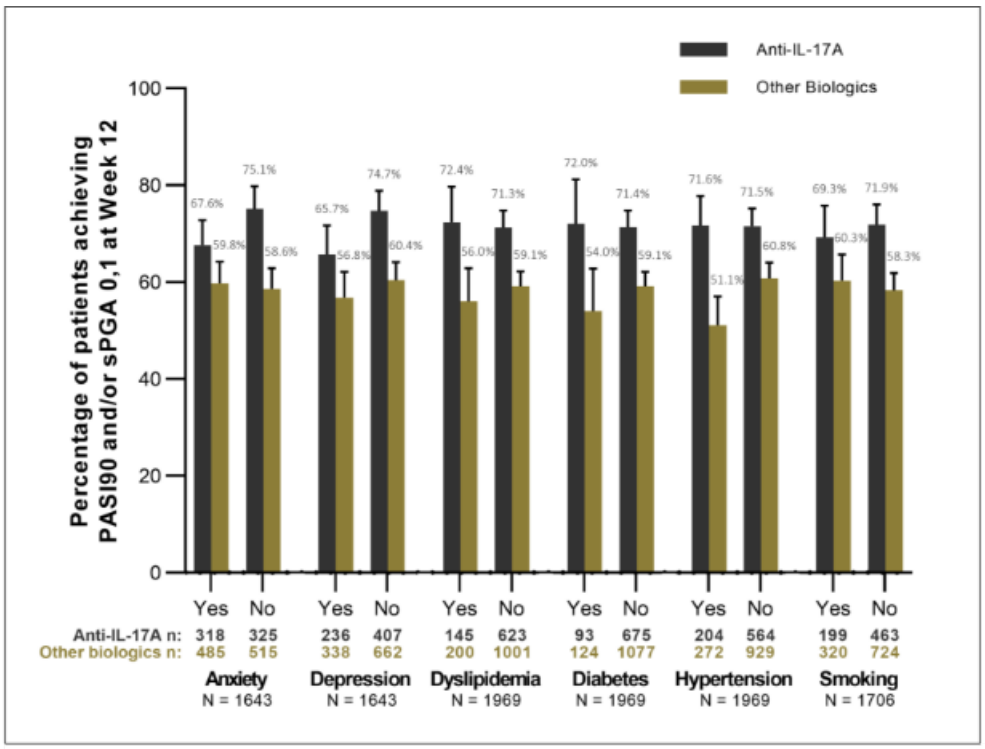

Figure 1: Percentage of patients in clinically relevant subgroups who achieved the primary endpoint of either PASI90 and/or sPGA 0/1, indicating a high-level response, after 12 weeks of real-world clinical treatment with either anti-IL-17A biologics (ixekizumab or secukinumab) or other biologics approved for the treatment of moderate-to-severe PsO. Regarding smoking status, 'Yes' indicates current smoker while 'No' indicates never or former smoker.

IL, interleukin; PASI90, ≥90% improvement in Psoriasis Area and Severity Index score from baseline; PsO, psoriasis; sPGA 0/1, static Physician Global Assessment score of 0 or 1.

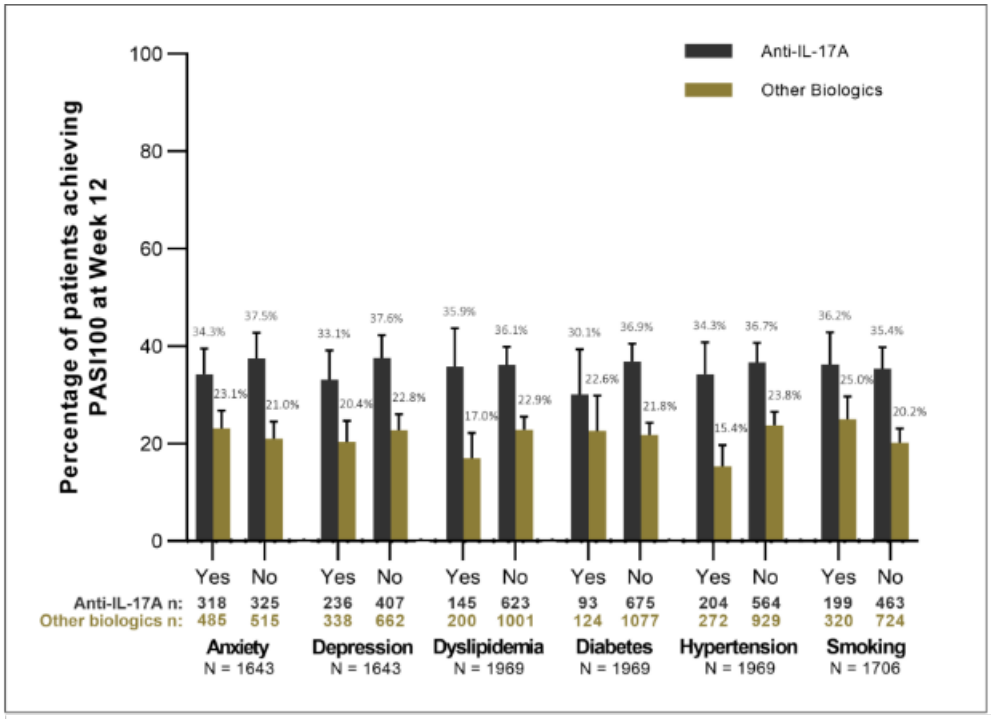

Figure 2: Percentage of patients in clinically relevant subgroups who achieved PASI100, indicating total skin clearance, after 12 weeks of real-world clinical treatment with either anti-IL-17A biologics (ixekizumab or secukinumab) or other biologics approved for the treatment of moderate-to-severe PsO. Regarding smoking status, 'Yes' indicates current smoker while 'No' indicates never or former smoker.

IL, interleukin; PASI100, 100% improvement in Psoriasis Area and Severity Index score from baseline; PsO, psoriasis.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3432

Efficacy and Safety of Secukinumab in the Treatment of Chronic Plaque Psoriasis

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[1]Fatima Jinnah Medical University, Dermatology Department, Lahore, Pakistan,[2]Lahore General Hospital, Dermatology Department, Lahore, Pakistan

Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease and is associated with significant comorbidities including depression, cardio-metabolic disorders and diminished quality of life. Interleukin (IL)-17A plays an integral part in the pathogenesis of psoriasis. Secukinumab is a fully human, monoclonal anti-IL-17A antibody indicated for the treatment of moderate to severe plaque psoriasis.

The objective of this study was to determine the efficacy and safety of secukinumab in the treatment of chronic plaque psoriasis. The scarcity of research data related to this topic warrants the need to evaluate long-term efficacy and safety of this drug in our setting.

Materials & Methods:

Twelve patients of chronic plaque psoriasis, fulfilling the inclusion & exclusion criteria, were enrolled in the study. Patients were given 300 mg of secukinumab subcutaneously at weekly intervals for two consecutive weeks (week 0-1) followed by a dose of 150 mg at weekly intervals for three weeks (week 2-4) and then a dose of 150 mg at monthly intervals until week 24. Each patient was followed up for further 28 weeks. In case of relapse, patients were given 150 mg secukinumab subcutaneously on monthly intervals for further 3 months.

Primary end points for establishing the efficacy of the treatment included, at least 75% reduction from baseline in psoriasis area & severity index score (PASI 75) at week 12 and achievement of dermatology life quality index (DLQI) score of 0-1 at week 12. Secondary end points of study were at least 90% reduction in PASI score (PASI 90) till week 24 and maintenance of PASI 90 from week 24 through week 52. Safety of secukinumab was assessed by observing any side effects in the patients on each follow up visit.

Results:

Both primary efficacy end points were achieved in our study. PASI 75 was attained in 11 (91.7%) patients at week 12 (**Figure 1**). DLQI score of 0-1 (no effect at all on quality of life) was observed in 11 (91.7%) patients at week 12 (**Table 1**).

Secondary end point of PASI 90 was also achieved in 11 (91.7%) patients before week 24. PASI 100 was achieved in 4 (33.3%) patients at week 24. Maintenance of PASI 90 from week 24 through week 52 was seen in 4 (33.3%) patients (**Figure 2**). Relapse was observed in 7 (58.3%) patients. PASI 90 was again achieved in these patients with the monthly maintenance dose of secukinumab.

Safety of secukinumab was established as no significant adverse effects were observed in any patient during and post treatment (**Table 2**).

Conclusion:

Secukinumab showed excellent efficacy in the treatment of moderate to severe chronic plaque psoriasis with a

very good safety profile. It is highly effective in achieving early and rapid reduction of PASI score.

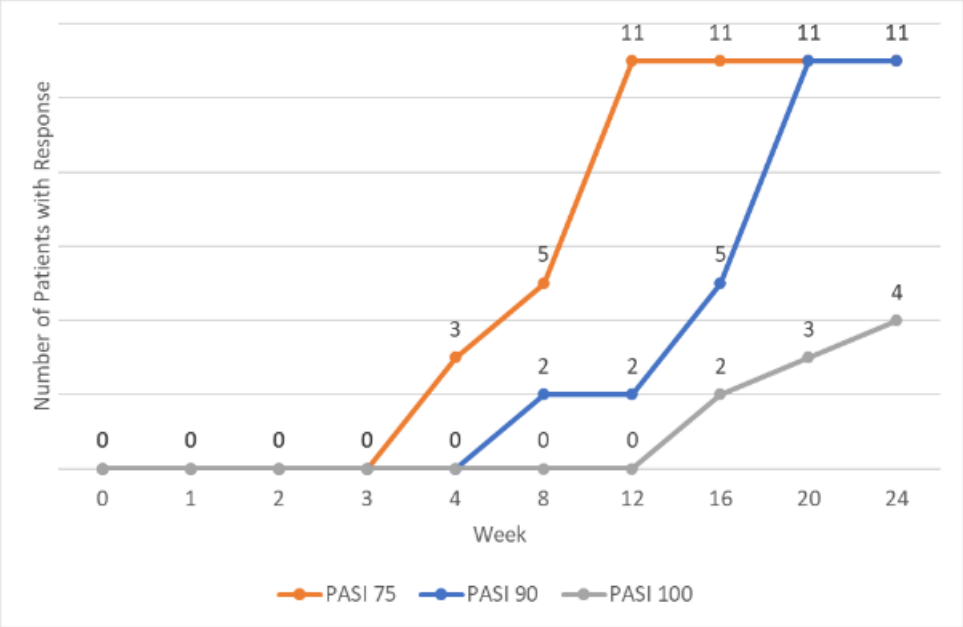

Figure 1: Efficacy of Secukinumab – PASI Response

DLQI Score	Interpretation	At Baseline	At Week 12
		n	%
0-1	No effect at all	0	0 %
2-5	Minimum effect	0	0 %
6-10	Moderate effect	0	0 %
11-20	Very large effect	8	66.7 %
21-30	Extremely large effect	4	33.3 %

Table 1: Efficacy of Secukinumab – DLQI Scores

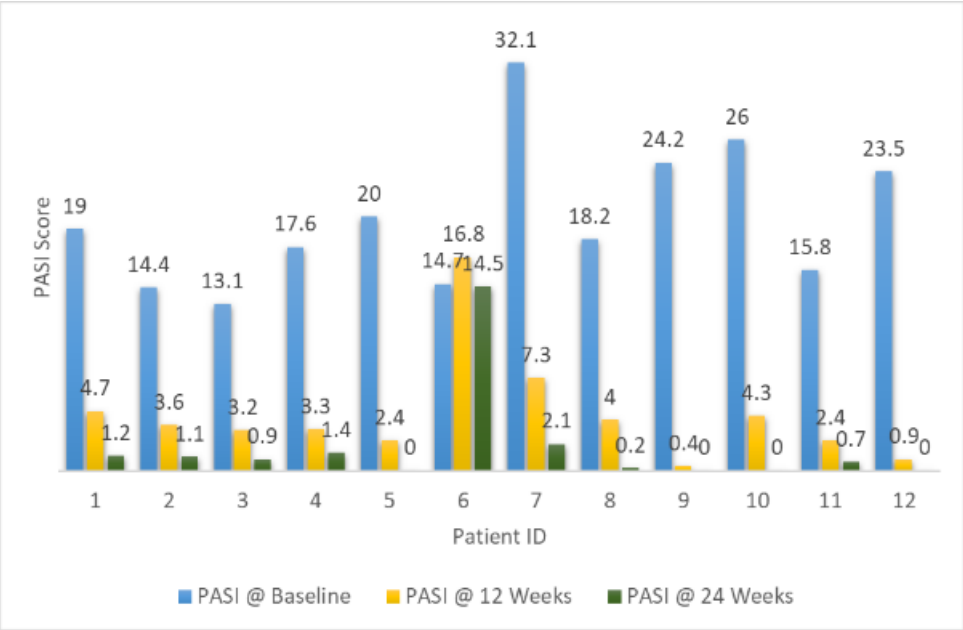

Figure 2: PASI scores of patients at baseline, week 12 and week 24

Side Effects	2 Weeks	4 Weeks	8 Weeks	12 Weeks	24 Weeks	52 Weeks
NASOPHARYNGITIS	-	-	-	-	-	-
URTI	-	-	-	-	-	-
RHINORRHOEA	+ (2)	-	-	-	-	-
ORAL HERPES	-	-	-	-	-	-
ORAL CANDIDIASIS	-	-	-	-	-	-
URTICARIA	-	-	-	-	-	-
OTHER (SPECIFY)	-	-	-	-	-	-
GIT COMPLAINTS (Diarrhea, Constipation, Mucus or Blood in stool)	+ (1)	-	-	-	-	-
SOB, PRODUCTIVE COUGH, WEIGHT LOSS	-	-	-	-	-	-

Table 2: Adverse effects of secukinumab in the treatment of chronic plaque psoriasis (n)

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Abstract N°: 3438

Real-world long-term skin clearance and patient-reported outcomes among patients with moderate to severe psoriasis treated with risankizumab – an interim analysis from an international medical chart review (RAPID) study

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Introduction & Objectives: Biologic agents are indicated for the treatment of moderate to severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy. Risankizumab (RZB), an interleukin 12/23 inhibitor, has shown efficacy in PsO clinical trials; however, real-world data, especially outside of the United States, is limited. This study sought to describe characteristics and clinical outcomes of patients with PsO using data collected from an established panel of participating dermatologists in Canada, Czech Republic, Germany, Japan, and Poland.

Materials & Methods: This ongoing, retrospective, multi-country medical chart review study collected data, starting in 09/2022, from licensed dermatologists who have actively treated adult patients with moderate to severe PsO for ≥3 years and have direct access to patient medical charts. Patients initiating treatment with RZB on or after 01/2019 (index date: date of RZB treatment initiation), had moderate to severe PsO (ie, Investigator Global Assessment [IGA] or static Physician's Global Assessment [sPGA] score ≥3), and medical records available for ≥12 months post-index date. Records had to include recorded Psoriasis Area and Severity Index (PASI), IGA, or sPGA scores ≤3 months prior to index date, ≤6 months after the index date, and between 7-18 months post-index date. Patient characteristics were descriptively reported for patients with moderate to severe PsO at baseline. Outcomes were the proportion of patients achieving clear or almost clear PsO (IGA/sPGA = 0 or 1); PASI = 0, ≤1; 90%, or 100% improvement from baseline in PASI; mean change in Dermatology Life Quality Index (DLQI) scores; proportion of patients achieving DLQI=0/1; and mean change in itch and skin pain (range: 0-10) at 12- and 18-months post-index date. Only patients with outcomes available at all timepoints (ie, 12- and 18-months post-index date) were included in this analysis.

Results: For this interim analysis, a total of 271 patients with moderate to severe PsO were included. Most patients (66.4%) were male and the mean time from diagnosis was 9.9 ± 9.9 years (Table 1). The majority (76.4%) of patients were biologic-naïve and had scalp PsO (73.4%); almost half of patients had PsO on skin folds (41.3%) or nails (46.1%). The mean IGA/sPGA at baseline was 3.7 ± 0.5, with a mean body surface area affected of 27.4% ± 15.8% and a mean PASI of 23.1 ± 12.1. On a scale of 1 to 10, the mean itch and skin pain severity scores were 7.3 ± 6.0 and 5.2 ± 5.6, respectively. Over time, the proportion of patients achieving IGA/sPGA = 0 or 1 increased, with up to 92.4% of patients reporting clear or almost clear skin after 18 months of treatment (Figure 1A). Similarly, by 18 months, 88.3% of patients achieved a PASI ≤1 (Figure 1B) and 90.4% achieved PASI 90 (Figure 1C). Patients also reported a marked decrease in DLQI, itch, and skin pain scores at 12 and 18 months (Figure 2).

Conclusion: This study assessed a population of patients with severe disease similar to that was assessed in clinical trials. This interim analysis demonstrates the long-term durable real-world effectiveness of RZB in patients with moderate to severe PsO. Patients receiving RZB demonstrated continued improvement in disease and symptom severity over 18 months, with >90% of patients reporting clear or almost clear skin. As this study is

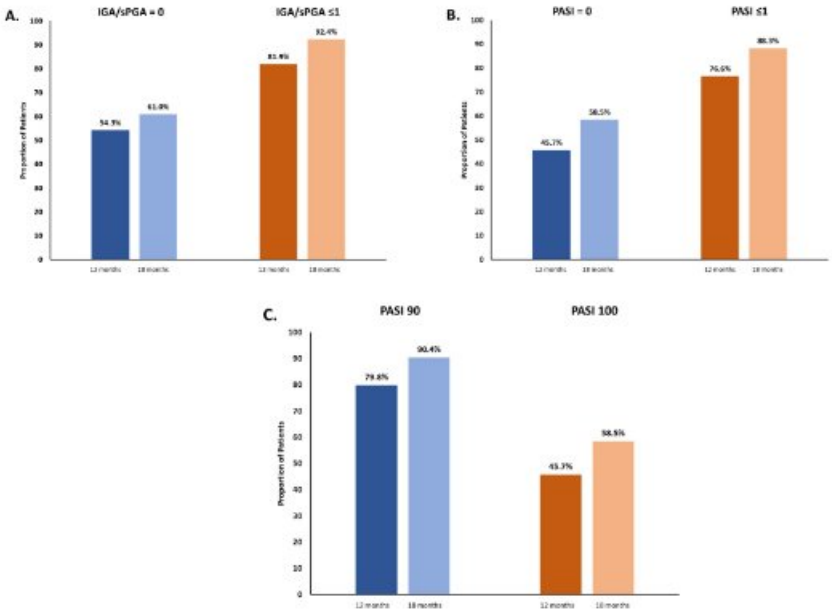
ongoing, future analyses will assess outcomes in a larger population.

Table 1: Baseline Demographic and Clinical Characteristics Among Patients with Moderate to Severe PsO Receiving Risankizumab

Characteristic	Patients with Moderate to Severe PsO (IGA/sPGA ≥3) N=271
Age [years], mean ± SD	48.6 ± 11.9
Male, n (%)	180 (66.4)
Years since PsO diagnosis to index date, mean ± SD	9.9 ± 9.9
IGA/sPGA, mean ± SD	3.7 ± 0.5
Disease Severity, n (%)	
Moderate (IGA/sPGA=3)	85 (31.4)
Severe (IGA/sPGA=4)	186 (68.6)
BSA, mean ± SD	N=133 27.4 ± 15.8
PASI, mean ± SD	N=266 23.1 ± 12.1
DLQI, mean ± SD	N=265 15.2 ± 7.2
Itch VAS, mean ± SD	N=40 7.3 ± 6.0
Pain VAS, mean ± SD	N=14 5.2 ± 5.6
BMI, mean ± SD	N=234 25.4 ± 4.1
Country, n (%)	
Japan	102 (37.6)
Germany	69 (25.5)
Poland	53 (19.6)
Canada	45 (16.6)
Czech Republic	2 (0.7)
Biologic-naïve, n (%)	207 (76.4)
Smoking status, n (%)	
Never	110 (40.6)
Past, but not current	81 (29.9)
Current	69 (25.5)
Family history of PsO, n (%)	124 (45.8)
Family history of autoimmune disease excluding PsO, n (%)	38 (14.0)
Comorbidities, n (%)	
Cardiovascular diseases	74 (27.3)
Depression	49 (18.1)
Diabetes	3838 (14.0)
Psoratic arthritis	33 (12.2)
Anxiety	31 (11.4)
PsO locations, n (%)	
Scalp	199 (73.4)
Nail	125 (46.1)
Skin folds	112 (41.3)
Facial	104 (38.4)
Palmoplantar	76 (28.0)
Genital	75 (27.7)
None of the above	19 (7.0)

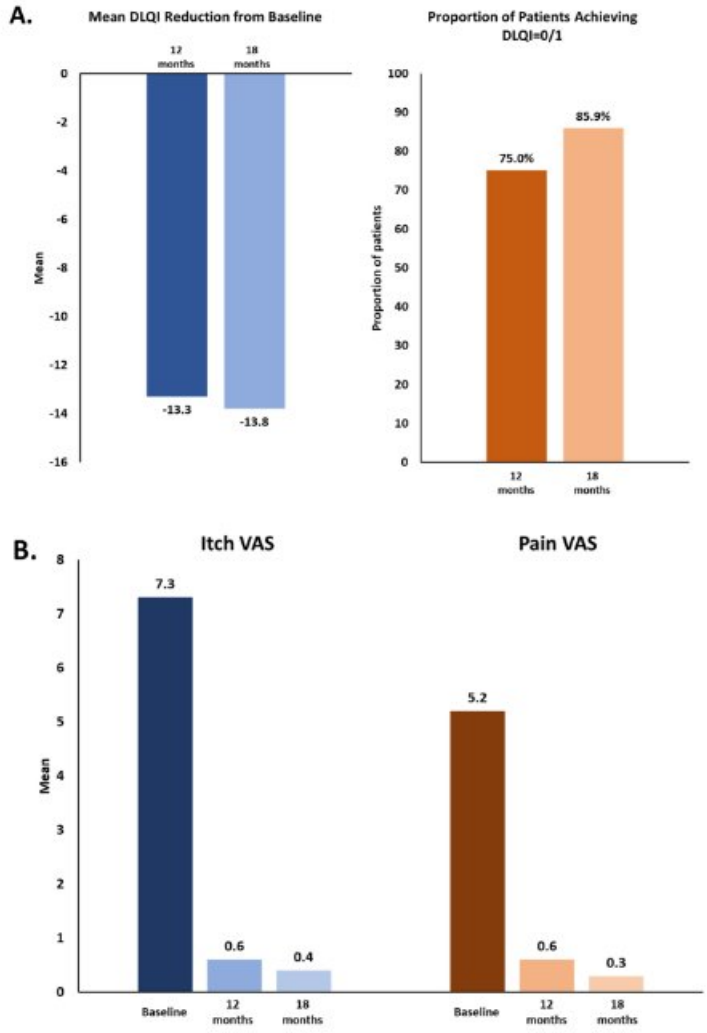
BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality index; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; SD, standard deviation, sPGA, static Physician's Global Assessment.

Figure 1: Proportion of patients achieving clear or almost clear skin through 18 months of treatment with risankizumab



IGA, Investigator Global Assessment, PASI, Psoriasis Area and Severity Index, sPGA, static Physician's Global Assessment.

Figure 2: Patient-reported itch and skin pain scores over time



DLQI, Dermatology Life Quality Index; VAS, visual analog scale.

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Abstract N°: 3448

Switching and discontinuation rates of biologics among psoriasis patients in Germany: A retrospective analysis of InGef claims database

Andreas Pinter[1], Ahmed M Soliman[2], Karina Manz[3], Valeria Weber[3], Paul Ludwig[4], Anja Mocek[3], Ariane Hoer[3], Mark Lebwohl[5]

[1]University Hospital Frankfurt am Main, Germany, [2]AbbVie Inc., United States, [3]IGES Institut GmbH, Berlin, Germany, [4]InGef - Institute for Applied Health Research Berlin GmbH, Berlin, Germany,[5]Ichan School of Medicine at Mt. Sinai, United States

Introduction & Objectives:

Anti-interleukin and anti-tumor necrosis factor agents can be used in the treatment of moderate-severe psoriasis (PsO). To achieve disease control, patients treated with these biologics may require therapy modification. This study aimed at evaluating treatment switching and discontinuation in patients with PsO treated with biologics in Germany.

Materials & Methods:

We conducted a retrospective, non-interventional cohort study based on German claims data covering the years 2016 to 2021. Data source was the Institute for Applied Health Research Berlin (InGef) sample database, which comprises anonymized, longitudinal, and nationwide claims from about 4 million individuals.

Adult patients were included into 11 drug-specific cohorts if they initiated a biologic therapy (index date) and were diagnosed with PsO prior to or in the same quarter of the year as the index date. Risankizumab (RIS), guselkumab (GUS), tildrakizumab (TIL), ustekinumab (UST), brodalumab (BRO), ixekizumab (IXE), secukinumab (SEC), adalimumab (ADA), certolizumab (CER), etanercept (ETA), and infliximab (INF) were considered. Also, patients had to have continuous insurance coverage for at least 182 days prior to and 365 days after the index date to be included. Patients with comorbidities, for which the respective drug was also approved, were excluded. Patients were included in each drug-specific cohort they met the inclusion criteria for.

We evaluated treatment switching and discontinuation 365 days after the index date using Kaplan-Meier analyses. Treatment switching was defined as a switch to a different biologic or a different drug was added to the treatment within 150% of the days' supply (number of days the dispensed package was assumed to last) of the last dispensation. Treatment discontinuation was defined as a gap in treatment equal to 150% of the days' supply of the last dispensation.

We used multivariate Cox regression to estimate drug-specific adjusted hazard ratios for treatment discontinuation and switching.

Results:

We included 2,565 patients with PsO treated with RIS (n=145), GUS (n=354), TIL (n=205), UST (n=241), BRO (n=166), IXE (n=259), SEC (n=612), ADA (n=454), CER (n=29), ETA (n=91), or INF (n=9). At 365 days, patients treated with RIS had a 98.6% probability to not change the treatment compared with 96.1% for GUS, 95.1% for SEC, 90.7% for IXE, 88.4% for UST, 86.3% for ADA, 86.2% for CER, 85.9% for TIL, 83.5% for ETA, 84.9% for BRO, and 55.6% for INF. Compared to patients treated with RIS, the risk for having a switch was statistically significantly ($p<0.05$) higher in patients treated with all other agents except GUS (Table 1).

At 365 days, patients treated with RIS had a 69.7% probability to not discontinue the treatment compared with 61.0% for UST, 58.1% for TIL, 57.5% for IXE, 55.6% for INF, 52.1% for SEC, 50.6% for GUS, 42.8% for BRO, 37.9% for CER, 32.2% for ADA, and 30.8% for ETA. Compared to patients treated with RIS, the risk for a discontinuation was statistically significantly ($p<0.05$) higher in patients treated with all other agents except UST (Table 2). 45.0% of patients with a treatment discontinuation restarted the same therapy during the observation period (range: 0.0% (INF) to 60.0% (GUS)).

Conclusion:

During the considered one-year period, treatment discontinuation occurred more often than treatment switching in patients with PsO initiating a biologic therapy. Rates of discontinuation and switching varied across agents and were lowest for RIS.

Table 1: Hazard ratio estimates for treatment switching.

Effect		Crude (unadjusted) hazard ratio estimates			Adjusted hazard ratio estimates		
		Point estimate	95% CI	p-value	Point estimate	95% CI	p-value
Index agent (reference: RIS)							
Anti-IL 23	GUS	2.89	[0.66 - 12.71]	0.16	3.03	[0.69 - 13.35]	0.14
	TIL	10.82	[2.58 - 45.35]	< 0.05	13.18	[3.14 - 55.34]	< 0.05
Anti-IL 12/23	UST	8.82	[2.10 - 37.01]	< 0.05	12.69	[3.01 - 53.43]	< 0.05
Anti-IL 17	BRO	11.78	[2.79 - 49.72]	< 0.05	13.66	[3.23 – 57.71]	< 0.05
	IXE	6.89	[1.65 - 29.58]	< 0.05	8.17	[1.93 - 34.59]	< 0.05
	SEC	3.59	[0.86 - 15.03]	0.08	5.32	[1.27 - 22.37]	< 0.05
Anti-TNF-alpha	ADA	10.56	[2.58 - 43.18]	< 0.05	18.59	[4.51 - 76.68]	< 0.05
	ETA	12.96	[2.96 - 56.69]	< 0.05	21.59	[4.89 - 95.31]	< 0.05
Age		1.00	[1.00 - 1.01]	0.36	1.00	[0.99 - 1.01]	0.56
Sex (reference: female)							
male		0.65	[0.50 - 0.84]	< 0.05	0.66	[0.51 - 0.86]	< 0.05
CCI		1.08	[1.00 - 1.17]	0.05	1.10	[1.01 - 1.19]	0.04
Systemic treatment during the 182-day baseline period (reference: no)							
yes		0.96	[0.72 – 1.28]	0.78	1.16	[0.86 - 1.56]	0.34
Treatment with biologics during the 182-day baseline period (reference: no)							
yes		2.45	[1.88 - 3.20]	< 0.05	3.49	[2.59 - 4.71]	< 0.05

Note: Certolizumab and Infliximab were excluded from the regression analysis due to low patient numbers.

Table 2: Hazard Ratio estimates for treatment discontinuation.

Effect		Crude (unadjusted) hazard ratio estimates			Adjusted hazard ratio estimates		
		Point estimate	95% CI	p-value	Point estimate	95% CI	p-value
Index agent (reference: RIS)							
Anti-IL 23	GUS	1.94	[1.39 - 2.69]	< 0.05	1.89	[1.36 - 2.63]	< 0.05
	TIL	1.48	[1.08 - 2.12]	< 0.05	1.55	[1.08 - 2.23]	< 0.05
Anti-IL 12/23	UST	1.36	[0.95 - 1.94]	0.09	1.33	[0.93 - 1.91]	0.12
Anti-IL 17	BRO	2.59	[1.81 - 3.71]	< 0.05	2.69	[1.88 - 3.85]	< 0.05
	IXE	1.51	[1.06 - 2.14]	< 0.05	1.57	[1.11 - 2.23]	< 0.05
	SEC	1.85	[1.34 - 2.53]	< 0.05	1.89	[1.38 - 2.61]	< 0.05
Anti-TNF-alpha	ADA	3.38	[2.46 - 4.63]	< 0.05	3.60	[2.61 - 4.96]	< 0.05
	ETA	3.67	[2.50 - 5.40]	< 0.05	3.86	[2.62 - 5.70]	< 0.05
Age		1.00	[0.99 - 1.00]	0.39	1.00	[0.99 - 1.00]	0.28
Sex (reference: female)							
male		0.84	[0.75 - 0.94]	< 0.05	0.84	[0.75 - 0.94]	< 0.05
CCI		1.03	[0.99 - 1.07]	0.12	1.05	[1.01 - 1.10]	< 0.05
Systemic treatment during the 182-day baseline period (reference: no)							
yes		0.67	[0.59 - 0.76]	< 0.05	0.61	[0.54 - 0.70]	< 0.05
Treatment with biologics during the 182-day baseline period (reference: no)							
yes		0.91	[0.79 - 1.04]	0.17	0.94	[0.81 - 1.08]	0.36

Note: Certolizumab and Infliximab were excluded from the regression analysis due to low patient numbers.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3471

Molecular profile of interleukin-17RA blockade by brodalumab in Japanese patients with psoriasis

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[1]The Rockefeller University, Laboratory for Investigative Dermatology, New York, United States,[2]Nagoya City University, Department of Geriatric and Environmental Dermatology, Nagoya, Japan, [3]Osaka Metropolitan University, Department of Dermatology, Osaka, Japan, [4]Shinshu University, Department of Dermatology, Matsumoto, Japan, [5]Kyoto Prefectural University of Medicine, Department of Dermatology, Kyoto, Japan, [6]Yokohama City University, Department of Environmental Immuno-Dermatology, Yokohama, Japan, [7]Kyowa Kirin Co., Ltd., Medical Affairs, Tokyo, Japan

Introduction & Objectives:

Psoriasis is a chronic, systemic, inflammatory disease and presents with well-demarcated, dry, raised, red skin lesions covered with silvery scale. The importance of the IL-17 axis in psoriasis is high, as biological agents that inhibit the IL-17 signal at various targets have shown efficacy in psoriasis. Brodalumab, a human anti-IL-17 receptor A (IL-17RA) monoclonal antibody, is globally approved for psoriasis and shows the efficacy. We aim to characterize the molecular feature of IL-17RA blockade by brodalumab in psoriatic skin and serum.

Materials & Methods:

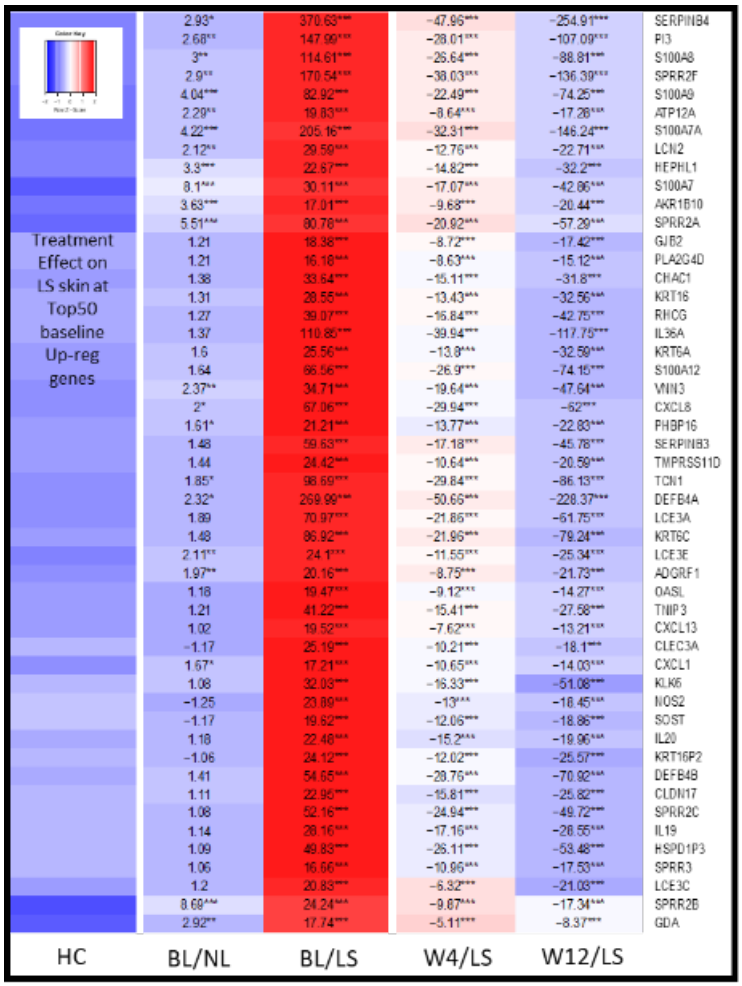
The ESPRIT study was conducted at 5 facilities across Japan from March 2020 to December 2021 and included patients aged ≥18 years who had plaque psoriasis with PASI score >10 or BSA >10% (Trial identifier of Japan Registry of Clinical Trials: jRCTs041190114). Patients received brodalumab 210 mg subcutaneously in daily clinical practice on day 1 and at weeks 1 and 2, followed by subcutaneous doses every 2 weeks thereafter until week 12. Healthy volunteers were enrolled based on the patient's age group and sex. Skin samples were collected at baseline, week 4, and 12, and serum samples were collected at baseline, week2, 4, and 12 from psoriasis patients. Normal skin specimens from healthy volunteers and nonlesional psoriatic skin from psoriatic patients were also collected. The skin specimens and serum samples were utilized for RNA sequencing and Olink high-throughput proteomics, respectively. Differentially expressed genes (DEGs) were defined as fold change of ≥ |1.5| and false discovery rate ≤ 0.05. In addition, IL-17 family cytokines were evaluated by quantitative reverse transcription polymerase chain reaction (qRT-PCR).

Results:

Forty patients were enrolled, 39 until week 4, and 37 at week 12 were used for molecular profiling. The median PASI score at baseline was 19.0, and the score significantly reduced to 0.4 at week 12 ($P < 0.0001$). The rate of PASI score 0 was 35.0% at week 12. Principal component analysis showed overlap between nonlesional skin at week 4 and week 12. The psoriasis disease transcriptome had 6303 genes at baseline, and it decreased to 788 (13%) and 303 (5%) at week 4 and week 12 respectively. Overall top 50 DEGs upregulated in BL. LS. began to be suppressed from week 4 and decreased to the same level as nonlesional at week 12 by brodalumab treatment. Heat maps of both top 50 genes and proteins showed that the expression profiles between at baseline and at week 4 or 12 were different. Interestingly, various genes, such as IL1A, IL36B, IL1B, TGFA, REN and IL17C in skin biopsy samples showed large improvement by brodalumab treatment even at 4 weeks. Messenger RNA levels of IL17A, IL17F, IL17C, IL23A(p19) and IL12B(p40) at both week 4 and 12 were significantly decreased from baseline but not that of IL12A(p35) by qRT-PCR. In particular, IL17C was decreased by 85% as early as week 4.

Conclusion:

These data suggested that IL-17RA blockade by brodalumab treatment induced rapid changes of the molecular profiling, such as IL17C, compared to baseline. Changes in the molecular profile of the lesions and their maintenance of a suppressed state may have led to the rapid clinical efficacy and high achievement rate of PASI score of 0 at 12 weeks.



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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3472

Two cases of generalized pustular psoriasis successfully treated with spesolimab

Masahiro Kamata*[1], Shoya Suzuki[1], Hideyuki Nakajima[1], Ayu Watanabe[1], Hideaki Uchida[1], Makoto Ito[1], Saori Azuma[1], Kotaro Hayashi[1], Yayoi Tada[1]

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Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare, recurrent, and sometimes life-threatening skin disease with systemic inflammation characterized by erythema and sterile pustules spreading over the entire body accompanied by acute fever and vascular hyperpermeability. Treatment options are limited. Spesolimab, an anti-interleukin-36 receptor antibody, showed significant efficacy with tolerable safety for GPP in a clinical trial, Effisayil-1. Recently, it was approved for the treatment of GPP. However, real-world data are limited. We experienced two cases of GPP successfully treated with spesolimab.

Results:

A 37-year-old female took carbocisteine and clofedanol hydrochloride for persistent cough after COVID-19 infection six days before her referral to our department. Three days later, she noticed erythema on her limbs and trunk, then she withdrew these medicines immediately. However, the eruption did not improve and got exacerbated, which resulted in the referral to our department. At her first visit to our department, she presented with erythema and pustules on the limbs and trunk, especially intertriginous areas, accompanied by fever and edema. Laboratory tests showed elevated white blood cell count, neutrophil count, and eosinophil count, elevated serum levels of C-reactive protein, and decreased serum levels of albumin. Skin biopsy revealed spongiform pustule of Kogoj. Considering the persistent eruption after withdrawal of the drugs and clinical and pathological findings, she was diagnosed with GPP, and received 900mg of spesolimab. Four hours later after initiation of sepsolimab, her temperature increased from 37.8 to 39.9 degrees Celsius with the eruption of erythema multiforme, which was considered infusion reaction. She was treated with antipyretics and topical high potency corticosteroid. Four days later, the eruption of GPP and erythema multiforme improved and she reached remission.

A 57-year-old female noticed erythema and pustules on palms and soles 13 years before. Three years later, they spread over her entire body, and she presented with erythroderma. She was diagnosed with GPP and received etretinate, oral corticosteroid, and diaphenylsulfone, which did not induce sufficient improvement. Three years later, she initiated infliximab. After four courses of administration, eruption was exacerbated. She switched to adalimumab. Two years later, due to aggravation of eruption, she switched to secukinumab. Four months later, however, its insufficient improvement resulted in switching to brodalumab. One year later, she switched to ixekizumab for more improvement. However, she still experienced flares with pustules on palms and soles. Therefore, she initiated spesolimab. Two courses of spesolimab cleared pustules on palms and soles, and good conditions were maintained with bimekizumab. Six months later, she presented with pustules on palms and soles again. She received two courses of spesolimab, which resulted in improvement in pustules.

Conclusion:

Spesolimab was effective for GPP at an acute phase and GPP which was refractory to other biologics. Infusion reaction should also be noted as one of adverse events.

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Abstract N°: 3489

Impact of patient psoriasis on partner well-being in a real-world setting: 28-week interim data of the phase IV POSITIVE study

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Introduction & Objectives

Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition as well as their families'. However, information on the impact of psoriasis on patients' families, particularly partners, is scarce. Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.1,2 The objective of this analysis was to investigate the impact of psoriasis on the well-being of partners of patients included in the POSITIVE study.

Materials & Methods

POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.3 Partner's well-being was assessed through the FamilyPso questionnaire, which is a self-administrated questionnaire to assess the burden on partners of patients with psoriasis.4 The questionnaire has 15 items divided into five domains: (1) perceived strain by social reactions to the partner's psoriasis; (2) strain caused by cleaning; (3) acute emotional strain attributed directly to the psoriasis; (4) restrictions of social life; and (5) general emotional strain. The items are scaled in a 5-point Likert format: 0=not true, 1=somewhat true, 2=moderately true, 3=quite true, 4=very true, with the supplementary option "does not apply to me". Here, we report 28-week interim data using an observed cases approach.

Results

The cohort comprised 263 patients, of whom 162 (61.6%) were married or living in marital union. The FamilyPso was completed by 113 and 64 partners at baseline and week 28, respectively. Mean (SD) age of patients was 46.3 (14.6) years (19.8% of patients aged ≥60 years), and 65.8% of them were male. Mean (SD) time since psoriasis

diagnosis was 15.3 (13.2) years. Mean (SD) total FamilyPso score decreased from 1.3 (0.9) at baseline to 0.8 (0.9) at week 28 ($p<0.001$), with a mean (SD) change from baseline of -0.4 (0.7). The mean (SD) FamilyPsO scores by domain at baseline and week 28 were 1.1 (1.1) and 0.7 (0.9) for "perceived strain by social reactions to the partner's psoriasis", 1.4 (1.2) and 1.0 (1.2) for "strain caused by cleaning", 1.2 (1.1) and 0.7 (1.0) for "acute emotional strain attributed directly to the psoriasis", 0.9 (1.2) and 0.4 (0.9) for "restrictions of social life", and 1.9 (1.2) and 1.3 (1.3) for "general emotional strain".

Conclusion

There is an impact of patient's psoriasis on social and emotional well-being of their partners, which highlights the unmet needs not only in the management of psoriatic patients but also their families. Tildrakizumab significantly improved partners' well-being after 28 weeks.

References

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Abstract N°: 3490

Patient-reported well-being using tildrakizumab in a real-world setting: 28-week interim data of the phase IV POSITIVE study

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Introduction & Objectives

Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition as well as their families', impacting on their overall well-being.1 Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.2,3 The objective of this analysis was to assess the effectiveness of tildrakizumab on the overall well-being of patients with moderate-to-severe psoriasis treated with tildrakizumab in routine care.

Materials & Methods

POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab.4 Participant countries are Austria, Belgium, France, Germany, Italy, Spain, Switzerland, The Netherlands, and United Kingdom. Well-being was assessed through the 5-item WHO Well-being Index (WHO-5). The score ranges from 0 to 100, where 0=absence of well-being and 100=maximal well-being.5 As a reference, the mean WHO-5 score in the general population of the countries participating in the POSITIVE study was calculated to be 63.9,5 and was 52.2 among women with breast cancer or 56 among patients with type 2 diabetes.6,7 The threshold for a clinically relevant change is considered to be 10 points.5 When WHO-5 is used for the screening of depressive symptoms, a cut-off score of ≤50 is used, with a score of ≤28 indicating possible presence of moderate-to-severe depressive symptoms.5 Here, we report 28-week interim data using an observed cases approach.

Results

A total of 263 patients were included (65.8% male, mean [SD] age of 46.3 [14.6] years, mean body mass index of 28.2 [5.8] kg/m2, 34.2% current smokers). Mean (SD) time since psoriasis diagnosis was 15.3 (13.2) years. Mean (SD) WHO-5 score significantly increased from 53.9 (22.1) at baseline to 67.1 (20.1) at week 16 ($p<0.001$; mean

change from baseline of 12.4) and to 67.3 (20.2) at week 28 ($p<0.001$; mean change from baseline of 12.7). At baseline, 41.2% of patients had a WHO-5 score ≤50 (17.6% of patients ≤28). The percentages decreased to 20.2% (5.2% of patients ≤28) and 20.6% (5.7% of patients ≤28) at week 16 and week 28, respectively.

Conclusion

The well-being level at baseline of this cohort of patients with moderate-to-severe plaque psoriasis was comparable to the well-being level found in other diseases, which highlights the unmet needs in the management of psoriatic patients, with around 40% of them showing depressive symptoms at baseline. For the first time, we demonstrated that tildrakizumab significantly improved patients' well-being in patients with moderate-to-severe plaque psoriasis, achieving a well-being status similar to the general population after 16 weeks, which was maintained up to week 28.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3491

Real-world safety of tildrakizumab in patients with moderate-to-severe psoriasis: 28-week interim data of the phase IV POSITIVE study

Ulrich Mrowietz*[1], Rachel Sommer[2], Ziad Reguiai[3], Sascha Gerdes[4], Esteban Daudén[5], Wolfgang Weger[6], Julia-Tatjana Maul[7], Philip Laws[8], Luigi Naldi[9], Pierre-Dominique Ghislain[10], Elke De Jong[11], Sicily Mburu[12], Volker Koscielny[13], Eric Massana[13], Ismail Kasujee[13], Matthias Augustin[2]

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Introduction & Objectives

Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition as well as their families', impacting on their overall well-being. Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.1 The objective of this analysis was to further assess the safety of tildrakizumab in patients with moderate-to-severe psoriasis in routine care.

Materials & Methods

POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.2 Here, we report 28-week interim safety data.

Results

A total of 263 patients were included (65.8% male, mean [SD] age of 46.3 [14.6] years). The percentage of patients that withdrew from the study for any reason was 4.2% (n=11). At the point of this interim analysis, 8.7% of patients (n=23) had ≥1 adverse event (AE) and 2.3% of patients (n=6) had ≥1 treatment-related AE. The total number of AEs was 36 (72.2% of mild severity). One patient (0.4%) discontinued from the study due to an AE (urinary tract infection). The most frequent AE (1.9% of patients) was COVID-19, followed by nasopharyngitis (1.5%). There was only one patient (0.4%) who had a serious AE (atrophic rhinitis). No deaths or serious AEs related to tildrakizumab were reported.

Conclusion

The safety data provided here was consistent with previous studies1,3 and there were no new safety signals. This prospective study demonstrates a reassuring safety profile of tildrakizumab in a real-world setting over 28 weeks.

References

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Abstract N°: 3492

Real-world effectiveness, quality of life, and treatment satisfaction with tildrakizumab in patients with moderate-to-severe psoriasis: 28-week interim data of the phase IV POSITIVE study

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Introduction & Objectives

Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition as well as their families', impacting on their overall well-being.1 Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.2,3 The objective of this analysis was to assess the effectiveness, impact on health-related quality of life (HRQoL), and treatment satisfaction in patients with moderate-to-severe psoriasis treated with tildrakizumab in routine care.

Materials & Methods

POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.4 Effectiveness outcomes included proportions of patients achieving absolute Psoriasis Area and Severity Index (PASI) scores ≤5, ≤3 and ≤1. The HRQoL instrument was Dermatology Life Quality Index-Relevant (DLQI-R). Treatment satisfaction was assessed through the Treatment Satisfaction Questionnaire for Medication (TSQM-9). Here, we report 28-week interim data using an observed cases approach.

Results

A total of 263 patients were included (65.8% male, mean [SD] age of 46.3 [14.6] years). Mean (SD) PASI decreased from 13.4 (7.7) at baseline to 1.6 (2.5) at week 28 ($p<0.001$), with a mean (SD) change from baseline of -11.6 (7.5). At week 28, 92.6%, 85.1%, and 55.3% of patients achieved PASI ≤5, PASI ≤3 and PASI ≤1 responses, respectively. Mean (SD) DLQI-R score decreased from 12.3 (7.7) at baseline to 3.1 (4.7) at week 28 ($p<0.001$), with a mean (SD) change from baseline of -9.0 (7.8). At week 28, 37.8% of patients with DLQI-R >1 at baseline had a DLQI-R score of 0 or 1. At week 28, the mean (SD) scores on TSQM-9 domains were 77.2 (22.2) for

effectiveness, 81.8 (16.7) for convenience, and 78.3 (20.3) for global satisfaction.

Conclusion

Tildrakizumab significantly improved skin symptoms and patients' HRQoL, with high rates of treatment satisfaction in patients with moderate-to-severe plaque psoriasis after 28 weeks in a real-world setting.

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Abstract N°: 3508

Comparison of Biologics vs. Methotrexate Treatment on Disease Burden and Treatment Outcome in Malaysian Psoriasis Patients: Data from the Malaysian Psoriasis Registry (MPR)

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Introduction & Objectives:

Psoriasis (PsO) is an immune-mediated, chronic inflammatory disease manifesting in the skin, joints or both. The estimated prevalence of PsO in Malaysia is 0.34% with the annual prevalence and incidence increasing steadily from 2010 to 2020. Psoriatic arthritis (PsA) risk is higher in PsO patients and rises with disease duration, severity, and PsO family history. Up to 30% of PsO patients are prone to develop PsA. This study aims to evaluate the patient demographics, clinical characteristics, and treatment outcomes of adult PsO patients in Malaysia who are on biologic and methotrexate (MTX) treatment.

Materials & Methods:

This was a multicenter, cross-sectional, observational study based on the nationwide Malaysian Psoriasis Registry (MPR) data, which is an ongoing, prospective, collection of PsO patients' data treated at 36 public and 2 private hospitals. All adult PsO patients registered between January 2020 to December 2022 who had completed at least 6 months of treatment with MTX or biologics [TNFi, IL-17i (secukinumab) or IL-12/23i (ustekinumab)] were included in this study. Descriptive analysis for patient demographics, clinical characteristics and treatment outcomes was performed at baseline (patient enrolment into registry) and at 12 months. Statistical analysis was performed using the two-sided t test and two proportion z test; p values were calculated against MTX using medcalc® software. A sub-analysis was conducted to compare the risk of a new onset of PsA in PsO patients, defined as a new PsA diagnosis established by a rheumatologist after 12-months of treatment with MTX or biologics. In this analysis, PsO patients without a diagnosis of PsA at baseline and who had completed 12 months of treatment were included. Patients with a new onset of PsA within 12 months of treatment initiation were excluded to eliminate potential confounding bias.

Results:

This analysis included 794 PsO patients in total. At baseline, patients on biologics were younger, had longer disease duration, and more severe disease compared to the MTX group (Table 1). In patients treated with biologics, most were biologic naïve (84.21%), and patients in the IL-17i treated group had worst skin disease severity (body surface area (BSA) and Psoriasis area and severity index (PASI) scores). At baseline, about two thirds of patients had nail and one third had concomitant PsA in both the biologic and MTX groups (Table 1).

At 6 and 12 months, a statistically significant improvement from baseline was observed in the BSA involvement

and PASI scores of patients on biologics vs. MTX, with the highest improvement in the IL-17i treated group (Figure 1); despite 37% being on the 150 mg dosing (Table 1). In the subanalysis of PsO patients without PsA, the risk of new PsA onset was lower among PsO patients on biologics vs. MTX after 12-months of treatment (OR, 0.72 (95% CI: 0.24-2.13) (Table 2).

Conclusion:

PsO patients on biologic treatment had significantly better BSA and PASI improvement, compared to MTX, irrespective of duration and severity of disease at baseline. Among the biologic treated group, patients on IL-17i demonstrated numerically higher improvement in disease severity. Patients on biologics had lower risk of developing new onset PsA compared to those on MTX treatment at 1 year, despite high disease severity at baseline and family history of PsO. Early biologic treatment initiation may help improve treatment outcome and reduce the risk of new onset of PsA in PsO patients up to 1 year.

Table 1 – **Baseline demographics and clinical characteristics of adult PsO patients in Malaysia according to treatment groups**

Demographics and clinical characteristics	Methotrexate N=661	All Biologics (IL-17i, IL-12/23i, TNFi) N=133	IL-17i N=79	IL-12/23i N=40	TNFi N=14
Mean age (years) ± SD	48.67±15.15	43.35±14.81*	41.95±14.60*	45.34±15.88	45.51±12.74
Female - n (%)	282 (42.66)	66 (49.62)	44 (55.69)*	17 (42.5)	5 (35.71)
BMI (kg/m^2) ± SD	28.11±5.97	29.54±6.96*	30.09±7.41*	29.10±6.70	27.66±4.63
Mean age of PsO onset ± SD	34.34±14.98	26.47±12.05**	26.48±12.03**	26.73±12.70*	25.64±11.06*
Mean age of diagnosis ± SD	36.24±14.88	27.90±12.43**	27.58±12.08**	28.78±13.60*	27.21±11.58*
Duration of PsO (years, mean) ± SD	14.32±10.35	16.78±10.76*	15.30±11.03	18.59±10.65*	19.86±8.55*
Family history of PsO - n (%)	154 (23.3)	35 (26.31)	20 (25.31)	12 (30)	3 (21.42)
Nail involvement, n/N (%)	426 / 661 (64.45)	88 / 133 (66.16)	56 / 79 (70.88)	28 / 40 (70)	4 / 14 (28.57)
Psoriatic Arthritis (PsA), n/N (%)	209 / 661 (31.6)	42 / 133 (31.57)	31 / 79 (39.24)	2 / 40 (5)**	9 / 14 (64.28)*
Enthesitis/ dactylitis, n/N (%)	23 / 209 (11)	6 / 42 (14.28)	6 / 31 (19.35)	0 / 2 (0)	0 / 9 (0)
Ischemic heart disease – n (%)	33 (4.99)	6 (4.51)	2 (2.53)	3 (7.5)	1 (7.14)
Cerebrovascular disease (stroke) – n (%)	11 (1.66)	0 (0)	0 (0)	0 (0)	0 (0)
Diabetes mellitus - n (%)	140 (21.18)	33 (24.81)	16 (20.25)	13 (32.5)	4 (28.57)
Hypertension - n (%)	235 (35.5)	48 (36.09)	28 (35.44)	14 (35)	6 (42.85)
Hyperlipidemia - n (%)	194 (29.34)	41 (30.82)	19 (24.05)	16 (40)	6 (42.85)
Fatty liver (NAFLD) – n (%)	40 (6.05)	18 (13.53)	10 (12.65)	7 (17.5)	1 (7.14)
Biologic naïve - n (%)	-	112 (84.21)	66 (83.54)	35 (87.5)	11 (78.57)
Biologic experienced - n (%)	-	21 (15.79)	13 (16.46)	5 (12.5)	3 (21.43)
Secukinumab dose 300 mg - n (%)	-	-	50 (63.29)	-	-
Secukinumab dose 150 mg - n (%)	-	-	29 (36.71)	-	-

Note: **P<0.0001 vs. methotrexate (non-biologic); *P<0.05 vs. methotrexate (non-biologic)
PsO - Psoriasis, IL-17i – Interleukin-17 inhibitor, IL 12/23i – Interleukin 12/23 inhibitor, TNFi – Tumor necrosis factor inhibitor, BSA – Body surface area, PASI – Psoriasis area and severity index, SD – Standard deviation, BMI-body mass index, NAFLD – Non-alcoholic fatty liver disease

Figure 1 – **Treatment outcome (BSA and PASI) in adult PsO patients in Malaysia on biologics and methotrexate therapy at 6 and 12 months**

Figure 1a – Body surface area (BSA)

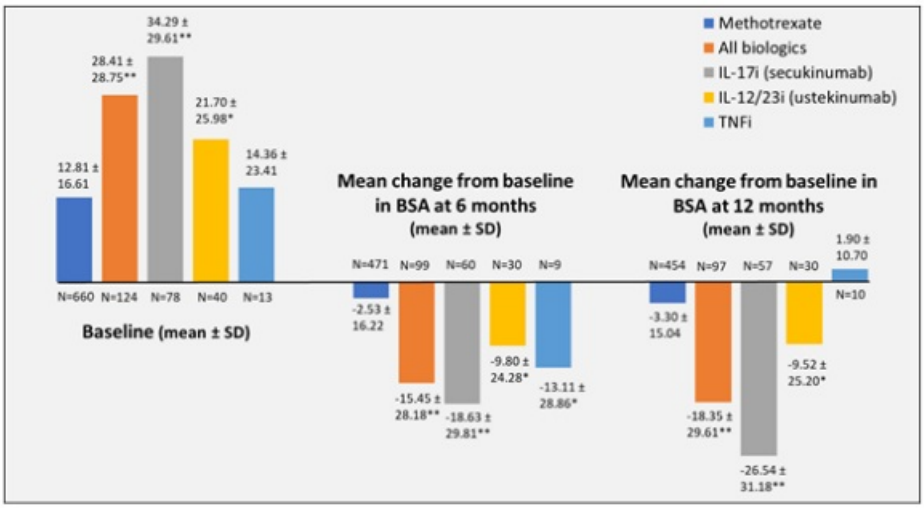
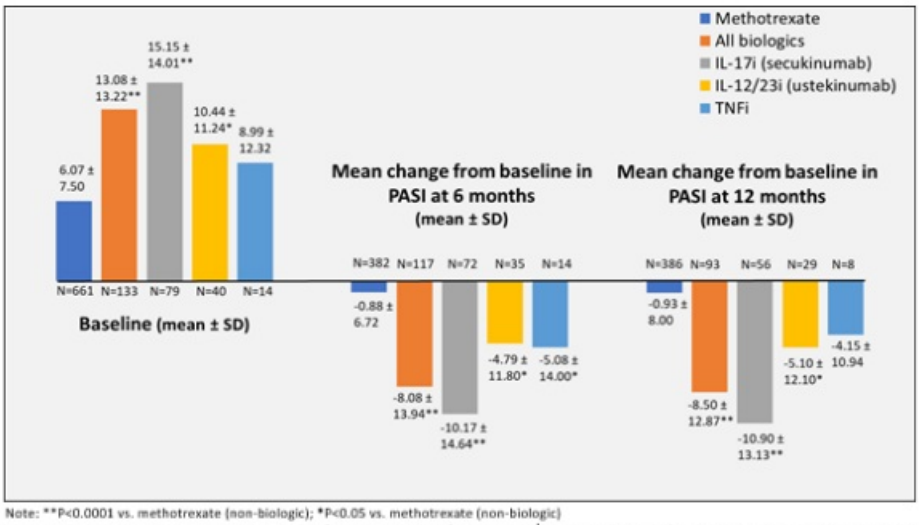


Figure 1b – Psoriasis area and severity index (PASI)



Note: **P<0.0001 vs. methotrexate (non-biologic); *P<0.05 vs. methotrexate (non-biologic)
PsO - Psoriasis, IL-17i – Interleukin-17 inhibitor, IL 12/23i – Interleukin 12/23 inhibitor, TNFi – Tumor necrosis factor inhibitor SD – Standard deviation, BSA – Body surface area, PASI – Psoriasis area and severity index

Table 2 - **PsA incidence rate and odds ratio at 12 months post treatment in adult PsO patients on biologic and methotrexate therapy**

Parameter	Methotrexate N=312	All Biologics (IL-17i, IL-12/23i, TNFi) N=56
New onset (incidence) of psoriatic arthritis (PsA) post 12 months treatment, n, %	30 / 312 (9.61)	4 / 56 (7.14)
PsA incidence rates per 1000 patient-years (95% CI)	96.1 (64.87 – 131.27)	71.43 (19.46 – 182.89)
PsA incidence- Odds ratio (95% CI)	1	0.723 (95% CI: 0.244-2.138)

PsO - Psoriasis, IL-17i – Interleukin-17 inhibitor, IL 12/23i – Interleukin 12/23 inhibitor, TNFi – Tumor necrosis factor inhibitor, PsA - Psoriatic arthritis, CI – Confidence interval

EA DV CONGRESS
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3510

Establishing UK consensus to define a treat-to-target (T2T) outcome set that optimises psoriatic patient wellbeing

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Introduction & Objectives:

Psoriasis, a chronic immune-mediated inflammatory disease, is associated with a significant impact on patients' well-being.

Treatment options for plaque psoriasis include topicals, phototherapy, oral treatments, and biologics. However, variation of outcomes still exists in the UK. There is an opportunity to define appropriate care based on expert and peer reviewed consensus.

With the definition of a novel treat-to-target (T2T) composite outcome for psoriasis, clinicians and patients can make shared decisions on the treatment goals they envisage, as a guidance for future treatment steps, leading to a tighter management of their disease and improved patient wellbeing.

The objective of this modified Delphi consensus project was to define a T2T outcome set that optimises psoriatic patient wellbeing. This outcome set can be used to complement future guideline development and patient care.

Materials & Methods:

Using a Delphi consensus approach, a panel of psoriasis experts met virtually to develop 58 statements across six key themes. Post-meeting, statements were then ratified and prioritised individually and anonymously by the expert panel.

Based on the outputs, a further round of consensus was delivered via an online 4-point Likert scale Delphi survey that was sent to healthcare professionals working in dermatology across the UK to assess agreement (consensus) with these statements.

Consensus was pre-defined as ≥75% and high consensus if ≥90% of respondents agreed with a statement. Stopping criteria for the Delphi consensus rounds included 150 responses, a two-month window for response (March to April 2023), and 80% of statements passing consensus threshold (agreed at ≥75%).

Results will be shared and discussed with the original panel of psoriasis experts (virtually) to develop a final definition as the final round of consensus.

Results:

A total of 180 responses was received from HCPs including dermatology consultants, dermatology registrars, dermatology specialist nurses, and general practitioners. There were responses received from across the UK (i.e., all devolved nations), with most responders having been in their role between 10-15 year.

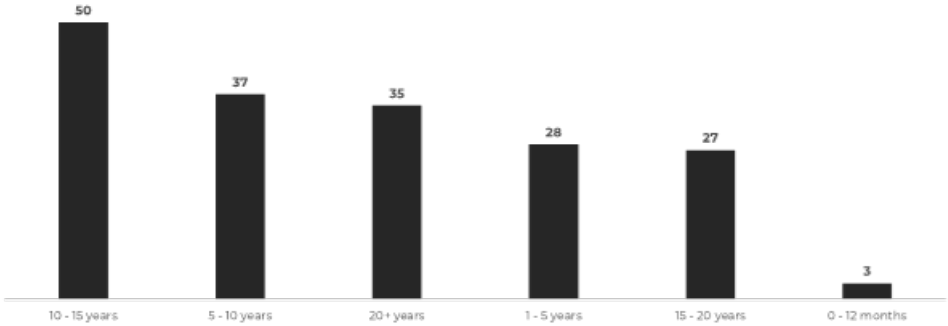

Fig 1: Responder time in role

Consensus amongst respondents was achieved in 50/58 statements. Thirty-six (62%) statements achieved >90% agreement, fourteen (24%) statements achieved <90 and >75% agreement and consensus was not achieved in eight (14%) statements.

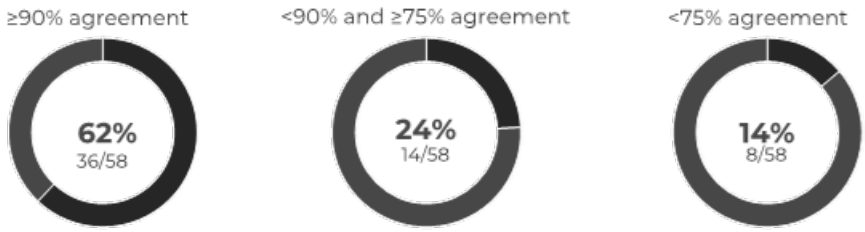

Fig 2: Summary of results achieved.

95% of all responders agreed that a treat-to-target strategy should result in improved patient outcomes including the impact on patient quality of life and mental wellbeing. 95% of all responders also agreed that wellbeing and mental health should be considered in all part of patient management with 91% of respondents agreed that assessment of wellbeing and mental health should include validated measures. High consensus was also reached for the quality-of-life target should be at least a 5-point decrease of the DLQI score.

Conclusion:

Implementation of these recommendations and measures across the care pathway in the UK has the potential to provide agreed psoriatic disease outcome targets that optimise psoriatic patient wellbeing, mitigate the potential variation of care, and complement future guideline development.

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Abstract N°: 3526

Prescription patterns, treatment experience, and prescription preferences for systemic treatments for moderate to severe psoriasis among Chinese dermatologists: A cross-sectional survey study

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Introduction & Objectives: To assess Chinese dermatologists' prescription patterns, treatment experience, and prescription preferences for systemic treatment of moderate to severe psoriasis (msPsO).

Materials & Methods: 50 dermatologists from 5 tertiary hospitals were surveyed on their prescription patterns, clinical experience, and preferences for systemic treatment for msPsO (oral drugs [acitretin, methotrexate, cyclosporine, apremilast] and biologics [adalimumab, infliximab, etanercept, secukinumab, ixekizumab, ustekinumab, guselkumab]). We assessed systemic treatments prescribed and treatment pathways. Treatment experiences were evaluated for effectiveness, safety, and convenience. Prescription preferences were evaluated by a choice-based conjoint (CBC) questionnaire with seven medication attributes (administration route, frequency, effectiveness, loss of effectiveness, and safety). Descriptive statistics methods were used to summarize the information. Counting analysis, hierarchical bayesian analysis, and conjoint simulation analysis were conducted to assess prescription preference.

Results: No treatment predominated. The treatment persistence time of oral drugs and biologics were 4.1-5.7 months and 9.7-16, respectively. Dermatologists' oral drug concerns included the restrictions of dosage and duration (96%), monitoring (94%) and treatment for adverse events (AEs, 82%). Specific concerns for apremilast included titration (64%), treating patients with kidney failure (39%), and treatment for AE (58%). Concerns for biologics included injection site reaction (72%), treatment administration in hospitals (48%), and needle phobia (40%). Accessibility challenges for biologics included high price (86%) and the requirement for cold-chain transportation (80%). The most common reasons for discontinuation were unsatisfying effectiveness and AE occurrence for apremilast (77.8% and 59.3%) and other oral drugs (92% and 92%), and loss of effectiveness (76%), comorbidity development (62%), and paradoxical reaction (60%) for biologics. When oral drugs and subcutaneous injection biologics had comparable medication attributes, oral drugs were preferred over biologics for both moderate (74% vs. 26%) and severe psoriasis (80% vs. 20%).

Conclusion: Chinese dermatologists' prescription patterns for msPsO are diverse. Chinese dermatologists perceive treatment challenges with both oral drugs and biologics and prefer to prescribe oral drugs for msPsO when oral drugs and biologics had comparable attributes.

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Abstract N°: 3529

Characteristics of patients with moderate to severe psoriasis initiating systemic drug therapy in France and evolution of treatment sequences: A national observational study

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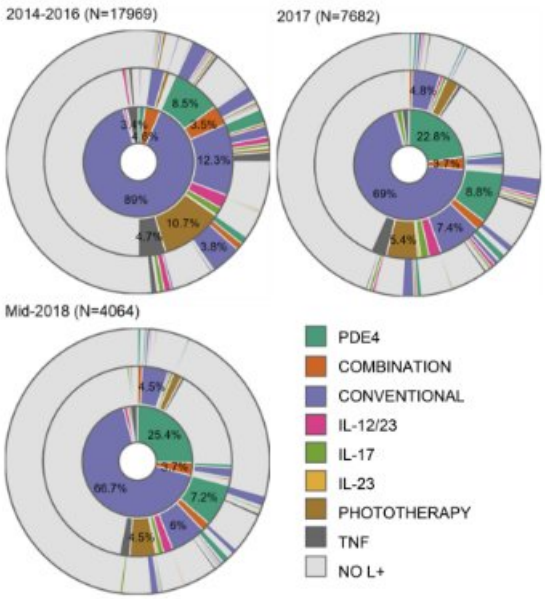
Introduction & Objectives: New treatments for psoriasis, notably phosphodiesterase 4 (PDE4) inhibitors, have impacted therapeutic strategies. Few studies have documented real-life treatment sequences. The objectives of this study were to describe the characteristics and treatment sequences of adult patients with moderate to severe psoriasis initiating systemic drug therapy in France.

Materials & Methods: A retrospective observational study was performed using medico-administrative data from the Système National des Données de Santé (SNDS). The index date was the first dispensing of systemic drug treatment between 2014 and mid-2018 to account for the arrival of different therapeutic classes over time. The first dispensing had to have been prescribed by a dermatologist or followed within 1 year by 2 dermatology visits, or administered during a hospitalization for psoriasis. A 2-year history was considered to verify the delivery of topical psoriasis treatment and the absence of systemic drug treatment before the index date, and to identify comorbidities via ICD-10 and ATC codes. Patients' treatment sequences were described from the index date to the end of follow-up or end of 2020, and during 2014-2016, 2017, and 2018. Any change in treatment was considered a new line.

Results: A total of 29,715 patients were included (60% from 2014 to 2016, 26% in 2017, and 14% in mid-2018). The mean age at the index date was 51.9 years (standard deviation [SD], 15.3), and 60.1% of patients were men (N=17,852). The 2 most frequent comorbidities were hypertension and dyslipidemia, with a prevalence of 28.8% (N = 8544) and 19.3% (N = 5724), respectively. Over the follow-up period (median follow-up, 54.1 months), the mean (SD) number of lines of treatment was 2.0 (1.7). One fourth of patients (24.7%, N = 7329) received ≥3 lines of treatment. Treatment sequences changed over time. Among patients included between 2014 and 2016, for first-line (L1) treatment, 89% received conventional therapy (55.3% acitretin, 30.6% methotrexate, and 3.1% cyclosporine) and only 1.9% received PDE4 (Figure). For patients included in 2017, for L1, the percentage of patients receiving a PDE4 increased to 22.8% and the percentage receiving conventional therapy decreased to 69%. The decline in L1 use was greater for acitretin than for other conventional treatments. The treatment sequences of patients included in 2017 and 2018 were similar. During the study period, very few biologic treatments were used in L1 (4.5%, N = 1325), in agreement with recommendations. More than half of the patients on conventional therapy in L1 did not have a subsequent line of therapy (53.7%, N = 12,891).

Conclusion: This study comprehensively describes, at the national level, the evolution of treatment sequences for patients with moderate to severe psoriasis included between 2014 and mid-2018 in France. It shows a significant change in the sequence of treatment over time and the introduction of new therapeutic agents.

Figure 1. Description of treatment sequences in France for patients with moderate to severe psoriasis



Note: A total of 8.5% of patients included between 2014 and 2016 took conventional therapy in L1 and apremilast in L2. The category "NO L+" represents the percentage of patients who had no change in treatment from the previous line (taking the same treatment during follow-up, stopping treatment, or patients lost to follow-up). Conventional therapies include cyclosporine, methotrexate, and acitretin; IL-12/23 includes ustekinumab; IL-17s include secukinumab, ixekizumab, and brodalumab; IL-23s include guselkumab, tildrakizumab, and rizankisumab; and TNFs include etanercept, infliximab, adalimumab, and certolizumab pegol.

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Abstract N°: 3542

Trade-offs and decision-making in moderate to severe psoriasis for oral versus injectable treatment: data from Australian patients and dermatologists

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Introduction & Objectives: Despite many systemic treatments being approved and reimbursed for moderate to severe psoriasis (PsO) in Australia, many patients remain undertreated. There is limited evidence on how patients and physicians make trade-offs for oral and injectable treatments in the Asia-Pacific region. The goals of this study were to identify treatment features that patients and physicians value, evaluate the relative importance of different treatment features, and understand how patients and physicians trade-off in their decision-making for oral vs injectable treatment.

Materials & Methods: In Phase 1, a targeted literature review, 15 qualitative interviews, and clinician input were used to develop a survey including a discrete-choice experiment (DCE) to explore trade-offs. In Phase 2, Australian dermatologists and patients completed a 25-minute online survey. The DCE allowed a choice between two hypothetical treatment alternatives: "oral" and "subcutaneous injection." Nine DCE treatment features were displayed in each choice set: injection device, PsO reduction, times until initial and maximum improvement, risk of minor and severe adverse effects (AEs), frequency of administration, monitoring requirement, and storage condition.

Results: Phase 2 included 178 patients and 43 dermatologists. The DCE found that PsO reduction and mode of administration drive most decision-making. Needle fear also significantly affected treatment mode choice, and 35% of patients reported needle fear of 5 or more on a scale of 0 (don't mind them) to 10 (avoid at all costs) (median=3); 59.7% of patients (with a median needle fear) and 72.8% of physicians prefered oral vs injectable treatment with once-weekly dosing for moderate disease, holding all treatment features equal. For severe disease, 50.1% of patients and 55.6% of physicians prefered oral treatment, holding all treatment features equal.

Conclusion: These findings highlight the unmet need driven by patients' and physicians' preference for efficacious oral treatments.

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Abstract N°: 3548

The effect of age on biologic survival: a cohort study from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR)

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The effect of age on biologic survival: a cohort study from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR)

Introduction & Objectives:

Few studies have used real-world data to examine the safety and effectiveness of biologics in psoriasis patients across different age groups. Our aim was to explore whether the response to biologics is modified by age using BADBIR, a long-term pharmacovigilance register of patients designed to assess the long term safety and effectiveness of systemic treatments for psoriasis.

Materials & Methods:

Data from patients with moderate-to-severe psoriasis in the UK and the Republic of Ireland registering to BADBIR from 2007-2022 on a first course of adalimumab, etanercept, secukinumab or ustekinumab with at least 6 months' follow-up were analysed. Patients aged ≥18 years at enrolment were categorised into 18-24, 25-34, 35-44, 45-54, 55-64, and ≥65 years age groups with 45-54 years as the reference group. Biologic survival was defined as the duration between biologic initiation to discontinuation or censoring at the latest follow-up. Reasons for discontinuation were ineffectiveness or occurrence of adverse events (AEs). Adjusted hazard ratio (HR) with 95% confidence interval (CI) was estimated using a flexible parametric model to compare discontinuing therapy between age groups for each reason of discontinuation. Each model included exposure (biologics), effect modifier (age groups), interaction terms and adjusted for baseline demographic, clinical and disease severity covariates (sex, smoking, alcohol consumption, body mass index, disease duration, the presence of comorbidities, and psoriasis phenotype) using multiple imputed data.

Results:

A total of 11,849 subjects were included. The modal age group was 45-54 years 3,245 (27%) with 742 (6%) aged 18-24, 2,022 (17%) aged 25-34, 3,051 (26%) aged 35-44, 1,872 (16%) aged 55-64 and 917 (8%) aged ≥65 years. Patients aged 18-24 years compared with 45-54 years (reference) were more likely to discontinue biologics associated with ineffectiveness [HR (95% CI), 1.26 (1.08-1.47)], however, there was no difference for 25-34, 35-44, 55-64 and ≥65 years groups [1.11 (0.99, 1.23), 1.05 (0.96, 1.16), 0.99 (0.89, 1.10) and 1.02 (0.88, 1.18), respectively]. Compared with the reference group, older patients 55-64 and ≥65 years were at higher risk of biologic discontinuation associated with adverse events [HR (95% CI) 1.31 (1.13, 1.51) and 1.92 (1.63, 2.27), respectively], while those aged 35-44 were at lower risk of biologic discontinuation [0.84 (0.73, 0.97)] with no difference in those aged 18-24 and 25-34 years [0.95 (0.74, 1.21) and 0.90 (0.76, 1.07), respectively].

Conclusion:

Patients with moderate-to-severe psoriasis over 55 years old were more likely to discontinue biologics due to

adverse events compared with younger patients. However, those aged 18-24 years were more likely to discontinue biologics due to ineffectiveness. These findings provide important information to aid clinicians managing psoriasis patients with biologic therapies.

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Abstract N°: 3565

Dose escalation rates of biologics among patients with psoriasis in Germany: A retrospective analysis of InGef claims database

Andreas Pinter[1], Ahmed M Soliman[2], Karina Manz[3], Valeria Weber[3], Paul Ludwig[4], Anja Mocek[3], Ariane Hoer[3], Sven Richter[2], Mark Lebwohl[5]

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Introduction & Objectives:

Several biologic therapies such as anti-tumor necrosis factor (TNF) agents and anti-interleukin (IL) agents are available for the treatment of moderate to severe plaque *psoriasis (PsO) in Germany.* If a satisfactory treatment response is not achieved through standard dosing, dosing exceeding guidelines may be considered. This study aimed at evaluating above-label dosing for patients with PsO treated with anti-IL/TNF agents in Germany.

Materials & Methods:

Based on German health claims data, we carried out a retrospective, non-interventional cohort study covering the years 2016 to 2021. The source of data was the Institute for Applied Health Research Berlin (InGef) sample database, which comprises anonymized, longitudinal, and nationwide claims from approximately 4 million individuals insured by the German statutory health insurance (SHI).

Adult patients were included into 11 drug-specific cohorts if they initiated a biologic treatment (index date) and were diagnosed with PsO prior to or in the same quarter of the year as the index date. The considered drugs were risankizumab (RIS), guselkumab (GUS), tildrakizumab (TIL), ustekinumab (UST), brodalumab (BRO), ixekizumab (IXE), secukinumab (SEC), adalimumab (ADA), certolizumab (CER), etanercept (ETA), and infliximab (INF). Additionally, patients had to have at least three dispensations with the drug after having completed an induction period, and continuous insurance coverage for at least 182 days before and 365 days after the index date. Patients diagnosed with selected comorbidities, for which the respective drug was also approved, were excluded. Patients were included in each drug-specific cohort for which they met the inclusion criteria.

For each time interval between a dispensation claim and the next dispensation claim, we calculated the received daily dose (DDpat) by dividing the dispensed dose by the number of days until the subsequent dispensation claim. Dose escalation was defined to have occurred if the DDpat exceeded the European Medicines Agency label-recommended maintenance dose by a threshold of ≥20% (sensitivity analysis: ≥30%) in at least two time intervals.

The odds for experiencing a dose escalation based on the anti-IL/anti-TNF agent was evaluated using a multivariate logistic regression model adjusting for age and sex.

Results:

The study included 1,366 patients with PsO treated with RIS (n=92), ADA (n=171), CER (n=13), ETA (n=45), INF (n=7), UST (n=133), BRO (n=77), IXE (n=142), SEC (n=359), GUS (n=209), and TIL (n=118). Overall, 22.2% of patients received at least one dispensation with another biological agent within 182 days before their respective index date, with the highest proportion observed among patients treated with RIS (40.2%). The observed

proportion of patients with dose escalation was lowest for RIS (1.1%), TIL (4.2%), and UST (9.8%) (Figure 1). Compared to patients treated with RIS, the odds of experiencing a dose escalation were statistically significantly ($p<0.05$) higher in patients treated with all other treatments except TIL (controlling for age and sex) (Table 1).

Conclusion:

The relative frequency of dose escalation within 365 days after completion of the induction phase varied by biological agent. RIS (an IL-23 inhibitor) was associated with the lowest rates of dose escalation. Dose escalation may be associated with unmet clinical goals and incremental economic burden to the German SHI.

Figure 1: Proportion of patients experiencing a dose escalation within 365 days of completing induction with the respective biological agent.

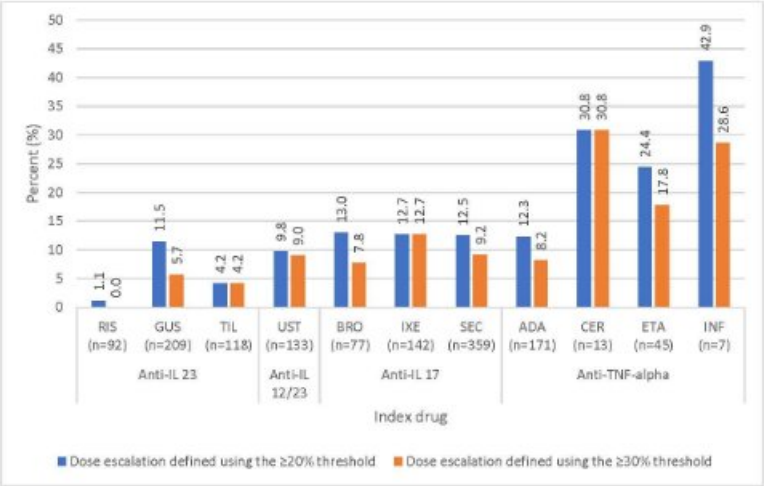

Table 1: Odds ratio estimates for dose escalation (using the ≥20% threshold to define dose escalation)

Table 1: Odds ratio estimates for dose escalation (using the ≥20% threshold to define dose escalation)

Effect		Crude (unadjusted) odds ratio estimates			Adjusted odds ratio estimates		
		Point estimate	95% CI	p-value	Point estimate	95% CI	p-value
Index drug (reference: RIS)							
Anti-IL 23	GUS	11.81	[2.44 - 212.70]	< 0.05	11.84	[2.44 - 213.51]	< 0.05
	TIL	4.03	[0.63 - 77.87]	0.21	4.04	[0.64 - 78.08]	0.21
Anti-IL 12/23	UST	9.86	[1.91 - 180.72]	< 0.05	9.67	[1.87 - 177.44]	< 0.05
Anti-IL 17	BRO	13.58	[2.51 - 252.28]	< 0.05	13.46	[2.48 - 250.10]	< 0.05
	IXE	13.21	[2.65 - 239.82]	< 0.05	13.08	[2.62 - 237.67]	< 0.05
	SEC	13.04	[2.79 - 232.63]	< 0.05	13.04	[2.78 - 232.77]	< 0.05
Anti-TNF-alpha	ADA	12.74	[2.60 - 230.29]	< 0.05	13.21	[2.69 - 239.04]	< 0.05
	ETA	29.44	[5.42 - 548.41]	< 0.05	28.96	[5.32 - 539.87]	< 0.05
Age		1.01	[1.00 - 1.02]	0.07	1.01	[1.00 - 1.02]	0.07
Sex (reference: female)							
male		0.70	[0.50 - 0.99]	< 0.05	0.73	[0.51 - 1.04]	0.08

Note: Certolizumab and infliximab were excluded from the regression analysis due to low patient numbers.

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Abstract N°: 3567

LIBERO VISIBLE: Disease Characteristics of Patients with Visible and/or Stigmatizing Psoriasis Lesions and Impact on Quality of Life

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Introduction & Objectives: Stigmatization is one of the key challenges for patients with psoriasis, but only limited real world evidence is available on co-localization of visible and/or stigmatizing localizations, as well as the effect of psoriasis treatments on those.

Materials & Methods: LIBERO VISIBLE is a German, prospective, multicenter, open-label, single-arm, observational, 60 weeks (W), non-interventional study (NIS) on brodalumab 210 mg in patients with stigmatizing and/or visible psoriasis lesions. In this interim analysis we describe the baseline characteristics of patients with different stigmatizing and/or visible lesions.

Results: 490 patients (61.4% male, mean age 47.0 ± 15.3 years, mean weight 88.2 ± 20.9 kg, disease duration 15.6 ± 13.3 years), who were enrolled between 09-2020 and 09-2022, were included in the interim analyses. At baseline mean affected Body Surface Area (BSA) was 21.2 ± 15.3 %, mean Psoriasis Area Severity Index (PASI) 15.9 ± 10.9 and mean Patient Global Assessment (PGA, 0-5 points) 3.9 ± 0.8. The majority of patients suffered from scalp psoriasis (79.4%), 46.9% from facial psoriasis and 46.7% from genital psoriasis, followed by fingernails (40.2%), toenails (29.6%), palms (24.3%) and soles (17.4%) as affected areas. Validated, area specific severity scores per localization were assessed in addition to overall severity scores. Co-manifestation different visible and/or stigmatizing localizations were frequently observed (Tab. 1), e.g., in scalp, face and nail psoriasis more than 50% of patients also had genital psoriasis. The main clinical symptom besides plaques was itch (86.5%), in particular in patients with genital psoriasis (92.1%). Other manifestations were psoriasis inversa (16.5%), eczematous psoriasis (13.7%) and psoriasis arthritis (12.0%). Mean Dermatological Life Quality Index (DLQI) was 13.3 ± 7.7 with 18.7% of patients presenting a DLQI > 10, indicating a very strong impact of visible/ stigmatizing lesions on patients´ quality of life. Regarding localizations strongest impact on quality of life was seen in face, genital and palmoplantar psoriasis.

Conclusion: LIBERO VISIBLE is the largest, prospective NIS in psoriasis patients with visible and/or stigmatizing manifestations. Baseline characteristics reveal that patients often suffer from psoriasis in different localizations and that visible and/or stigmatizing manifestations strongly impact quality of life. Genital psoriasis was observed more often than described in literature, which should be considered in daily practice.

Table 1: Baseline characteristics of the whole population and subgroups by location of patients with visible and stigmatizing psoriasis lesions (interim analysis, intention-to-treat population)

	all	*scalp*	*face*	*genital*	*fing.nails*	*toenails*	*palms*	*soles*
Number (%)	490 (100%)	389 (79.4%)	230 (46.9%)	229 (46.7%)	197 (40.2%)	145 (29.6%)	119 (24.3%)	85 (17.4%)
Disease duration at location, y (m ± SD)	15.6 ± 13.3	12.0 ± 12.0	9.4 ± 12.2	7.8 ± 9.4	8.7 ± 10.5	10.2 ± 11.2	8.8 ± 12.2	9.9 ± 11.5
Main co-affected areas (%)	scalp 79.4% face 46.9% genital 46.7%	face 54.2% genitals 49.6% fing.nails 41.7%	scalp 91.7% genitals 57.4% fing.nails 41.3%	scalp 84.3% face 57.6% fing.nails 47.2%	scalp 82.2% toe nails 64.5% genital 54.8%	fing. nail 87.6% scalp 79.3% genital 52.4%	scalp 63.9% soles 56.3% fing.nails 52.9%	palms 78.9% scalp 58.8% fing.nails 49.4%
PASI (0-72) m ± SD	15.9 ± 10.9	16.5 ± 10.9	17.5 ± 12.3	17.0 ± 11.8	16.5 ± 10.9	15.4 ± 11.1	17.0 ± 13.3	16.6 ± 12.8
Local severity score	PASI (0-72)	PSSI (0-72)	PFSI (0-72)	PGA-G (0-5)	tNAPSI (0-32)	tNAPSI (0-32)	PPASI (0-144)	PPASI (0-144)
m ± SD (n)	15.9 ± 10.9 (489)	21.4 ± 17.6 (389)	10.1 ± 9.3 (230)	2.8 ± 1.0 (229)	7.0 ± 4.9 (197)	8.1 ± 4.4 (145)	39.7 ± 37.9 (119)	44.5 ± 39.7 (85)
Itch (%)	86.5%	87.9%	87.4%	92.1%	85.3%	84.8%	79.8%	80.0%
Itch (NRS 0-10) m ± SD (n)	6.1 ± 2.8 (473)	6.3 ± 2.7 (376)	6.5 ± 2.6 (224)	6.6 ±2.4 (222)	6.1 ± 2.8 (190)	6.0 ± 2.7 (138)	6.4 ± 2.7 (118)	6.6 ± 2.6 (83)
DLQI (0-30) m ± SD (n)	13.3 ± 7.7 (471)	13.5 ± 7.7 (375)	14.2 ± 7.6 (224)	14.9 ± 7.1 (222)	12.9 ± 7.6 (189)	13.7 ± 7.8 (137)	14.8 ± 7.8 (116)	15.8 ± 8.1 (83)

Abbreviations: BL Baseline; DLQI Dermatological Life Quality Index; fing. finger; m mean; n number; PASI Psoriasis Area Severity Index; PFSI Psoriasis Face Area Severity Index; PPASI Palmoplantar Psoriasis Area Severity Index, PSSI Psoriasis Scalp Severity Index; SD standard deviation; tNAPSI target Nail Area Psoriasis Severity Index; W week; y years;

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Abstract N°: 3569

Assessing Psoriasis Patient Characteristics After Being Treated With 1st Line Advanced Therapy For 12 Months

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Introduction & Objectives:

Skin clearance rates form fundamental efficacy assessments of biologics/targeted oral (advanced) therapies in psoriasis (PsO); developmental molecules continue to be evaluated based on reductions in Psoriasis Area Severity Index (PASI) scores. The objective of this study was to highlight characteristics of patients not experiencing high skin clearance scores, despite receiving advanced therapy, to understand possible areas of unmet need.

Materials & Methods:

A multi-centre online medical chart review study of patients with PsO was conducted in Q4 2022 (Oct-Dec) among dermatologists from UK, France, Germany, Italy and Spain. Dermatologists were screened for practice duration, patient volume and ability to prescribe advanced therapies. Charts of patients with PsO who received their first ever advanced therapy for a duration of 12 months were included in the analysis.

Results:

221 sampled dermatologists were recruited and collectively reported 253 PsO patients treated with their first advanced therapy for a duration of 12 months. Among the reported patients, 98 were recorded as achieving PASI 75 and 155 not having achieved PASI 75.

Looking into recorded PsO disease severity at diagnosis and at most current consultation, reported patients who have achieved PASI 75 after 12 months of advanced therapy were more likely to be considered ‘severe’ at diagnosis and ‘mild’ at their most recent consultation, vs. patients not having achieved PASI 75.

Table 1: % of reported PsO patients with recorded disease severity at diagnosis and at most recent consultation

	Reported patients who achieved PASI 75	**Reported patients who did not achieve PASI 75**
Mild at diagnosis	10%	16%
Moderate at diagnosis	51%	57%
Severe at diagnosis	35%	22%
Mild at recent consultation	82%	13%
Moderate at recent consultation	13%	67%
Severe at recent consultation	5%	21%

Reported patients who achieved PASI 75 were more likely to be recorded as having concomitant metabolic conditions, whilst a greater proportion of reported patients who did not achieve PASI 75 were more likely to experience mental health burden. (Table 1)

Table 2: % of reported PsO patients recorded as experiencing specific co-morbidities

	Reported patients who achieved PASI 75	**Reported patients who did not achieve PASI 75**
Metabolic conditions	69%	50%
Mental health burden	17%	31%

Conclusion:

Comparisons in this study cohort highlight patients who achieved PASI 75 after 12 months of treatment were more likely to be deemed 'severe' at diagnosis and experience metabolic conditions – it may be that this patient cohort was deemed 'higher risk' and treated in a different manner to the cohort who had not achieved PASI 75. It is worth exploring if nuances in treatment occur depending on different patient characteristics, and if those patients with less severe disease could benefit from adjusted treatment paradigms. Further investigation using comparator cohort is warranted.

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Abstract N°: 3584

LIBERO VISIBLE: 12 Week Effectiveness of Brodalumab in Patients with Visible and/or Stigmatizing Psoriasis Lesions

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Introduction & Objectives: Patients with psoriasis often experience stigmatization based on the visibility or localization of their plaques. So far, only limited real world evidence has been available on effectiveness of treatments in those patients.

Materials & Methods: LIBERO VISIBLE is a German, prospective, multicenter, open-label, single-arm, observational, 60 weeks (W), non-interventional study (NIS) on brodalumab 210 mg in patients with stigmatizing and/or visible psoriasis lesions. In this interim analysis we describe the efficacy of brodalumab 210 mg after about 2, 4 and 12 W in patients with stigmatizing or visible lesions in different localizations.

Results: 490 patients (61.4% male, mean age 47.0 ± 15.3 years), who were enrolled between 09-2020 and 09-2022, were included in the interim analyses. At baseline mean affected Body Surface Area (BSA) was 21.2 ± 17.2%, Psoriasis Area Severity Index (PASI) 15.9 ± 10.9 and Dermatological Life Quality Index (DLQI) 13.3 ± 7.7. The majority of patients (70.2%) were treated with conventional systemic or UV therapy in the past and 22.5% with previous biologic therapy, mainly adalimumab (11.0%), secukinumab (6.3%), tildrakizumab (4.3%) and guselkumab (3.3%). Most patients suffered from scalp psoriasis (79.4%), followed by facial psoriasis (46.9%) and genital psoriasis (46.7%). Mean overall PASI was reduced from 15.9 to 8.6 at ~W2 and further improved to 3.1 at ~W12. Rapid and high response with mean improvement rates between 42.7 to 62.4% at ~W2 and 72.1 to 87.4% at ~W12 were shown with validated, area specific disease severity scores for scalp, face, genital and palmoplantar psoriasis. (Fig.1, Tab.1) In nail psoriasis improvement between 42.0 to 54.3% at ~W12 was observed, which is in line with expectations in slow growing nails. Quarterly analysis until ~W60 will further confirm long term effectiveness of brodalumab 210 mg in these patients.

Conclusion: LIBERO VISIBLE is the largest, prospective NIS in psoriasis patients with visible and/or stigmatizing manifestations treated with brodalumab 210 mg under daily practice conditions. It confirms the fast onset and the high clearance rates in patients with visible and/or stigmatizing lesions treated with brodalumab 210 mg, which has been seen in phase 3 studies and in daily practice for the general psoriasis patient population.

Figure 1: Mean improvement [%] of psoriasis severity scores by localization after about 2, 4 and 12 weeks of treatment with brodalumab 210 mg (interim analysis, intention-to-treat population, as observed analysis)

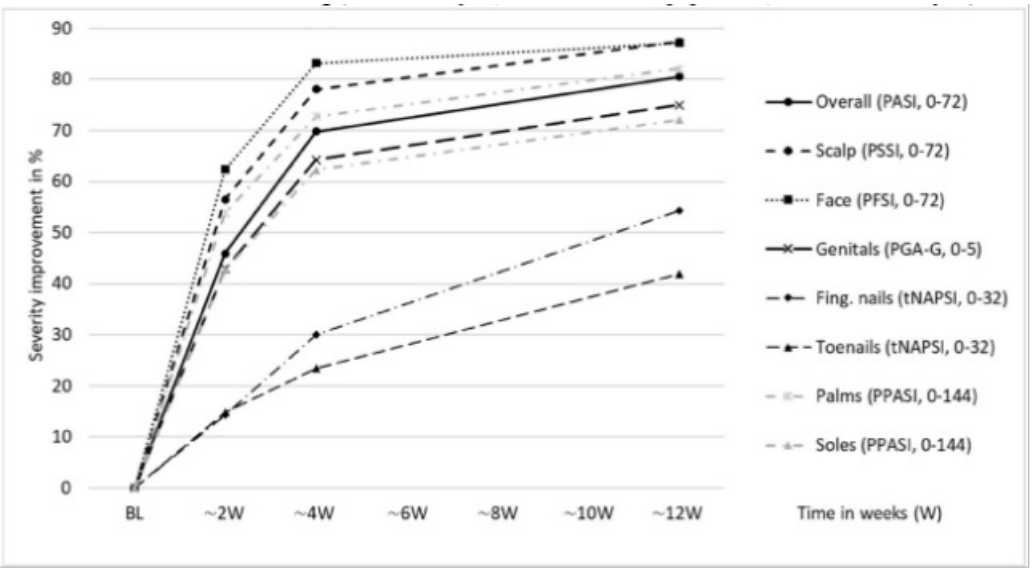

Table 1: Baseline characteristics and ~W12 response in patients with visible and stigmatizing psoriasis lesions treated with brodalumab 210 mg (interim analysis, intention-to-treat population, as observed analysis)

	all	*scalp*	*face*	*genital*	*fing.nails*	*toenails*	*palms*	*soles*
Number	490	389	230	229	197	145	119	85
(%)	(100%)	(79.4%)	(46.9%)	(46.7%)	(40.2%)	(29.6%)	(24.3%)	(17.4%)
PASI	15.9	16.5	17.5	17.0	16.5	15.4	17.0	16.6
m ± SD	± 10.9	± 10.9	± 12.3	± 11.8	± 10.9	± 11.1	± 13.3	± 12.8
(n)	(489)	(389)	(230)	(228)	(197)	(145)	(119)	(85)
Score	PASI	PSSI	PFSI	PGA-G	tNAPSI	tNAPSI	PPASI	PPASI
(range)	(0-72)	(0-72)	(0-72)	(0-5)	(0-32)	(0-32)	(0-144)	(0-144)
BL,	15.9	21.4	10.1	2.8	7.0	8.1	39.7	44.5
m ± SD (n)	± 10.9	± 17.6	± 9.3	± 1.0	± 4.9	± 4.4	± 37.9	± 39.7
	(489)	(389)	(230)	(229)	(197)	(145)	(119)	(85)
~12W,	3.1	2.7	1.3	0.7	3.2	4.7	7.1	12.4
m ± SD (n)	± 5.8	± 5.8	± 4.1	± 1.1	± 3.7	± 4.4	± 14.4	± 22.6
	(444)	(357)	(214)	(206)	(197)	(145)	(104)	(71)
DLQI, BL	13.3	13.5	14.2	14.9	12.9	13.7	14.8	15.8
m ± SD (n)	± 7.7	± 7.7	± 7.6	± 7.1	± 7.6	± 7.8	± 7.8	± 8.1
	(471)	(375)	(224)	(222)	(189)	(137)	(116)	(83)
DLQI, ~12W	3.6 ± 5.3	3.3 ± 4.9	3.0 ± 4.5	3.4 ± 4.9	3.7 ± 5.4	4.0 ± 5.7	4.5 ± 6.0	4.9 ± 6.5
m ± SD (n)	(471)	(347)	(207)	(200)	(177)	(122)	(101)	(68)

Abbreviations: BL Baseline; DLQI Dermatological Life Quality Index; fing. finger; m mean; n number; PASI Psoriasis Area Severity Index; PFSI Psoriasis Face Area Severity Index; PPASI Palmoplantar Psoriasis Area Severity Index, PSSI Psoriasis Scalp Severity Index; SD standard deviation; tNAPSI target Nail Area Psoriasis Severity Index; W week; y years;

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Abstract N°: 3588

Investigation of regional differences in medical care for generalized pustular psoriasis in Japan

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Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare disease showing extensive erythema with multiple pustules and systemic inflammation, which largely affects patients' quality of life. Access to professional medical care may be a key to the disease management. However, regional differences in GPP diagnosis and treatment have not been studied despite differences in the distribution of large hospitals and dermatologists. This study aimed to elucidate regional disparities in GPP practice in Japan using a questionnaire targeting dermatologists.

Materials & Methods:

A questionnaire-based study was performed by sending questionnaires to the 641 hospitals/facilities providing dermatological training under the certification of the Japanese Dermatological Association. The questionnaire included items such as the location of hospitals, its zonal classifications (large city, provincial city, and underpopulated area), hospital type (main hospital of medical school, branch hospital of medical school, national or public hospital, and other general hospitals), hospital scale based on bed number (<20 beds, 20 to 99 beds, 100 to 199 beds, 200 to 499 beds, and ≥ 500 beds), and the presence or absence of GPP patients. Information on the most recent three patients were provided by the respondents, which includes time from onset to diagnosis of GPP, number of medical institutions visited before GPP diagnosis, presence or absence of a referral form at the first visit, type of previous medical institution (general hospital, clinic, and others), speciality of the previous physician, diagnosis made by the previous doctor, GPP severity at the last visit, and use of biologics. These data were statistically analyzed.

Results:

Out of 641 institutions, 295 completed the questionnaire (46.0%). GPP patients were treated at 88 (29.8%) facilities in large cities, 147 (49.8%) in provincial cities, and 60 (20.3%) in depopulated areas. The proportion of facilities treating at least one GPP patient was higher in underpopulated areas (Chi-squared test, $p < 0.01$). A total of 314 patients' medical records were collected: 106 (33.8%) from large cities, 160 (51.0%) from provincial cities, and 48 (15.3%) from underpopulated areas. There were no statistically significant differences in time from onset to GPP diagnosis, proportion of patients with mild disease, or use of biologics among the three regions. Referred patients were 80 (75.5%) in large cities, 120 (75.0%) in provincial cities, and 27 (56.3%) in underpopulated areas, meaning that patients were more likely to visit dermatologists without a referral form in underpopulated areas (Chi-squared test, $p < 0.01$). The mean number of medical facilities patients visited before GPP diagnosis was 2.03 in large cities, 2.01 in provincial cities, and 1.72 in underpopulated area (Brown-Forsythe test, $p = 0.0035$). No differences were observed in the proportion of patients whose previous physician was a dermatologist. The proportion of patients with a previous diagnosis of GPP did not differ among the three regions.

Conclusion:

The results of this study indicate that there are few major regional disparities in the practice of GPP at the present time in Japan. Dissemination of the GPP guidelines may have reduced the potential healthcare gap between the large cities and underpopulated areas in Japan.

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Abstract N°: 3592

Bimekizumab response through 3 years in patients with plaque psoriasis who stopped and re-started treatment

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Introduction & Objectives:

Patients with plaque psoriasis may report interruptions in biologic treatment. Therefore, it is important to understand how long responses can be maintained after treatment withdrawal, and whether they can be re-captured and maintained upon retreatment.

In the BE READY phase 3 trial, median time to relapse (loss of PASI 75 [≥75% improvement from baseline Psoriasis Area and Severity Index]) in Week 16 PASI 90 responders from last bimekizumab (BKZ) dose was 32 weeks.1 Here, BKZ response through 3 years in 2 patient groups from this study who stopped and restarted BKZ treatment are reported.

Materials & Methods:

Data are reported from BE READY and its openlabel extension (OLE), BE BRIGHT.1,2 Included patients were initially randomised to BKZ 320 mg every 4 weeks (Q4W), achieved PASI 90 at Week 16, were rerandomised to placebo (PBO) for the 40-week randomised-withdrawal period, then entered the OLE (**Figure 1**).

Patients who maintained PASI 75 throughout the randomised-withdrawal period continued on PBO to Week 56, then entered the OLE (Week 16–56 PBO group), undergoing a mandatory switch to BKZ Q4W. Patients who relapsed (<PASI 75 response once between Week 20–56) while receiving PBO entered a 12week escape arm and were re-treated with openlabel BKZ Q4W; those who achieved PASI 50 after the 12 weeks entered the OLE (escape group), receiving BKZ Q4W or Q8W dependent on Escape Week 12 PASI 90 response. Proportions achieving PASI 90 and 100 are reported through OLE Week 96, as observed case.

Results:

Following 16 weeks of BKZ Q4W treatment, 105 patients who achieved PASI 90 were rerandomised to PBO; 31.4% (33/105) continued on PBO for 40 weeks without relapse until OLE entry at Week 56 (Week 16–56 PBO group; maintained PASI 75 at every visit while receiving PBO). Of these, 51.5% (17/33) maintained PASI 90 and 33.3% (11/33) achieved PASI 100 at Week 56 (OLE Week 0; **Figure 2**). Responses improved following BKZ retreatment: at OLE Week 48, PASI 90 and 100 were achieved by 96.9% (31/32) and 81.3% (26/32), respectively, when all patients began to switch to BKZ Q8W, then achieved 96.4% (27/28) and 85.7% (24/28) at OLE Week 96 (**Figure 2**).

Of the patients re-randomised to PBO, 62.9% (66/105) relapsed during the randomised-withdrawal period (lost PASI 75; escape group) and entered the escape arm before entering the OLE. Of these, 90.8% (59/65) re-gained PASI 90 and 63.1% (41/65) achieved PASI 100 after 12 weeks of BKZ retreatment (OLE Week 0; **Figure 2**). At OLE Week 48, 96.7% (58/60) and 83.3% (50/60) achieved PASI 90 and 100, respectively; following switch to BKZ Q8W, 93.2% (55/59) and 78.0% (46/59) achieved PASI 90 and 100 at OLE Week 96 (**Figure 2**).

Conclusion:

Almost a third of patients treated with BKZ Q4W who achieved PASI 90 at Week 16 maintained at least PASI 75 at every visit for 40 weeks upon withdrawal of BKZ; after re-starting BKZ treatment, rates of complete/near-complete skin clearance greatly improved. High proportions of patients who relapsed while receiving PBO achieved complete/nearcomplete skin clearance after 12 weeks of BKZ retreatment. In both groups, high responses were durable through 2 years of BKZ retreatment, indicating that stopping BKZ for up to 40 weeks and restarting did not meaningfully impact longterm disease control.

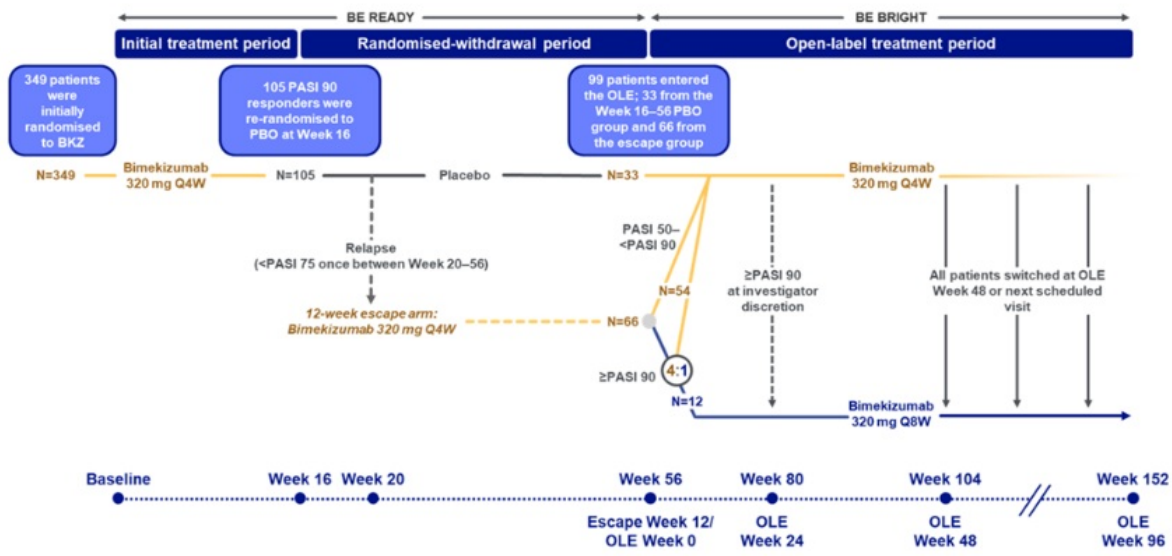
References:

1. Gordon KB. Lancet 2021;397:475–86, NCT03410992; **2.** BE BRIGHT: clinicaltrials.gov/ct2/show/NCT03598790.

Funding:

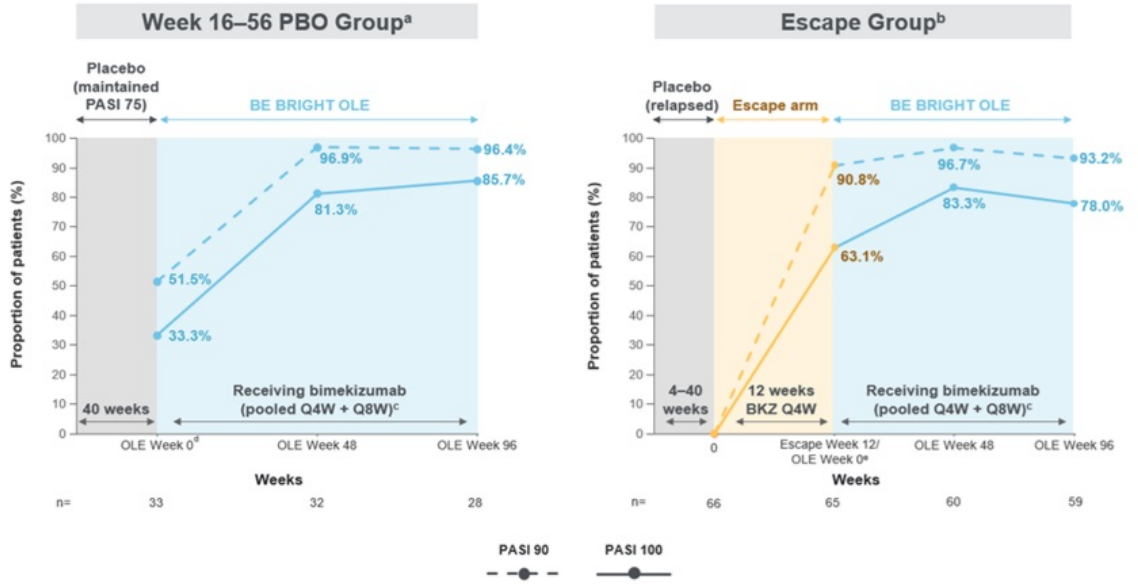
Study funded by UCB Pharma. Medical writing support by Costello Medical.

Figure 1. BE READY/BE BRIGHT study design



Full study procedures have been reported previously (Gordon KB. Lancet 2021;397:475–86).[1] BE READY treatment arms excluded from these analyses are not shown (PBO during the initial treatment period and BKZ 320 mg Q4W and Q8W during the randomised-withdrawal period). Following 16 weeks of treatment with BKZ Q4W, 105 patients who achieved PASI 90 were re-randomised to PBO for the start of the randomised-withdrawal period; 99 patients later entered the OLE (5 patients discontinued from BE READY and 1 patient was not treated in the OLE period). Patients in the Week 16–56 PBO group maintained PASI 75 at every visit until OLE entry at Week 56, at which point they received BKZ 320 mg Q4W (N=33). Patients in the escape group lost PASI 75 once between Week 20–56 (relapse) and entered a 12-week escape arm, in which they received open-label BKZ 320 mg Q4W. Patients who achieved PASI 50 were allowed to enter the OLE (N=66): patients who achieved PASI 90 were randomised 4:1 to receive either BKZ 320 mg Q4W or Q8W on OLE entry; patients who did not achieve PASI 90 received BKZ 320 mg Q4W on OLE entry. 54 patients from the escape group started the OLE on BKZ 320 mg Q4W and 12 started the OLE on BKZ 320 mg Q8W, before dose switching occurred from Q4W to Q8W at OLE Week 24 (≥PASI 90, at investigator discretion) and OLE Week 48 (or next scheduled clinic visit; mandatory switch). BKZ: bimekizumab; OLE: open-label extension; PASI 50/75/90: ≥50%/≥75%/≥90% improvement from baseline in Psoriasis Area and Severity Index; PBO: placebo; Q4W: every 4 weeks; Q8W: every 8 weeks.

Figure 2. Achievement of PASI 90 and PASI 100 in those who did not relapse throughout the randomised-withdrawal period (Week 16–56 PBO group) and those who relapsed and escaped to BKZ Q4W for 12 weeks (escape group), before entering the OLE to receive BKZ, through 3 years (OC)



[a] Week 16–56 PBO group patients were re-randomised to PBO at Week 16, continued on PBO throughout the randomised-withdrawal period to Week 56 without relapsing, and received BKZ Q4W on entry to the BE BRIGHT OLE; [b] Escape group patients were re-randomised to PBO at Week 16, subsequently relapsed (lost PASI 75 at Week 20 or later) and entered a 12-week escape arm in which they were re-treated with open-label BKZ 320 mg Q4W. Those who achieved PASI 50 after 12 weeks of escape treatment then entered the BE BRIGHT OLE, in which they received BKZ Q4W or Q8W, dependent on PASI 90 response at the end of escape treatment; [c] Data reported from the BE BRIGHT OLE are pooled from patients who received BKZ 320 mg Q4W and Q8W; [d] Patients in the Week 16–56 PBO group had their OLE Week 0 study assessments at the end of the 40-week randomised-withdrawal period (Week 56), having maintained PASI 75 at every visit throughout; [e] Patients in the escape group had their OLE Week 0 study assessments at the end of the 12-week escape arm, given they achieved PASI 50 at the end of the 12 weeks. BKZ: bimekizumab; OC: observed case; OLE: open-label extension; PASI 50/75/90/100: ≥50/≥75/≥90/100% improvement in baseline Psoriasis Area and Severity Index; PBO: placebo; Q4W: every 4 weeks; Q8W: every 8 weeks.

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Abstract N°: 3614

Real-world impact of achieving higher skin clearance on patient reported outcomes in risankizumab-treated patients with moderate to severe psoriasis – Evidence from an interim analysis of RisAnkizumab for the treatment of moderate to severe Psoriasis - An International meDical chart review (RAPID) study

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Introduction & Objectives:

The efficacy and safety of risankizumab (RZB), an interleukin-23 inhibitor, has been evaluated in phase 3 clinical trials in patients with psoriasis (PsO). However, information on the effect of RZB on patient-reported outcomes in patients with PsO in a clinical setting is limited, especially outside the US. The goal of this retrospective multi-country medical chart review study (RAPID) was to evaluate the impact of achieving high skin clearance on patient-reported outcomes.

Materials & Methods:

Data extraction from existing medical charts for the RAPID study began in September 2022 and is ongoing. Licensed dermatologists from Canada, Czech Republic, Germany, Japan and Poland participated in the study and had to be actively treating patients with PsO for ≥3 years. Patient medical charts were included if they initiated RZB on or after January 2019 (index date: first date of initiation with RZB) were ≥18 years old at index date, had moderate to severe PsO (ie, Investigator Global Assessment [IGA] or static Physician's Global Assessment [sPGA] score ≥3 at index date) and had ≥6 months of medical records pre-index date and ≥12 months of medical records post-index date. Records had to include ≥1 recorded Psoriasis Area and Severity Index (PASI), IGA, or sPGA score within 3 months of pre-index date, a score within 6 months of post-index date, and a score between 7–18 months of post-index date. Records also had to include ≥1 Dermatology Life Quality Index (DLQI) score within 3 months pre-index date and within 18 months post-index date. This analysis focused on the impact of achieving high skin clearance (PASI 100, PASI 90-99, IGA/sPGA 0/1) at months 12 and 18 post-index date on DLQI score reduction and DLQI = 0/1.

Results:

For the interim analysis, we analyzed data from 271 patients with moderate to severe PsO (severe: 68.6%; moderate: 31.4%). Nearly two-thirds (66.4%) were male and mean time since PsO diagnosis was 9.9±9.9 years (**Table 1**). Most patients (76.4%) were biologic-naïve, 73.4% had scalp PsO, 46.1% had nail PsO, and 41.3% had PsO on skin folds. Mean DLQI, mean PASI, and mean IGA/sPGA at baseline were 15.2±7.2, 23.1±12.1 and 3.7±0.5, respectively. Among patients who achieved skin clearance (PASI 100 or IGA/sPGA 0/1), a large percentage of patients also achieved DLQI = 0/1 at 12 and 18 months (**Figures 1 and 2**). Furthermore, a substantially greater reduction in mean DLQI at 12 and 18 months was observed for patients who achieved skin clearance (**Figures 3 and 4**).

Conclusion:

In this interim analysis, patients with moderate to severe PsO who received RZB demonstrated improvement in HRQoL over 18 months. High skin clearance (clear/almost clear skin) was associated with better HRQoL. Overall,

these results demonstrate the real-world patient-centric value of achieving higher skin clearance among patients with moderate to severe PsO.

Table 1: Baseline Demographic and Clinical Characteristics in Patients with Moderate to Severe PsO Receiving Risankizumab

Characteristic	Patients with Moderate to Severe PsO (IGA/sPGA ≥3) N=271
Age [years], mean ± SD	48.6 ± 11.9
Male, n (%)	180 (66.4)
Years from PsO diagnosis to index date, mean ± SD	9.9 ± 9.9
IGA/sPGA, mean ± SD	3.7 ± 0.5
Disease Severity, n (%)	
Moderate (IGA/sPGA=3)	85 (31.4)
Severe (IGA/sPGA=4)	186 (68.6)
BSA, mean ± SD	N=133 27.4 ± 15.8
PASI, mean ± SD	N=266 23.1 ± 12.1
DLQI, mean ± SD	N=265 15.2 ± 7.2
Itch VAS, mean ± SD	N=40 7.3 ± 6.0
Pain VAS, mean ± SD	N=14 5.2 ± 5.6
BMI, mean ± SD	N=234 25.4 ± 4.1
Country, n (%)	
Japan	102 (37.6)
Germany	69 (25.5)
Poland	53 (19.6)
Canada	45 (16.6)
Czech Republic	2 (0.7)
Biologic-naive, n (%)	207 (76.4)
Smoking status, n (%)	
Never	110 (40.6)
Past, but not current	81 (29.9)
Current	69 (25.5)
Unknown	11 (4.1)
Family history of PsO, n (%)	124 (45.8)
Family history of autoimmune disease excluding PsO, n (%)	38 (14.0)
Comorbidities, n (%)	
Cardiovascular diseases	74 (27.3)
Depression	49 (18.1)
Diabetes	38 (14.0)
Psoratic arthritis	33 (12.2)
Anxiety	31 (11.4)
PsO locations, n (%)	
Scalp	199 (73.4)
Nail	125 (46.1)
Skin folds	112 (41.3)
Facial	104 (38.4)
Palmoplantar	76 (28.0)
Genital	75 (27.7)
None of the above	19 (7.0)

BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; SD, standard deviation; sPGA, static Physician's Global Assessment.

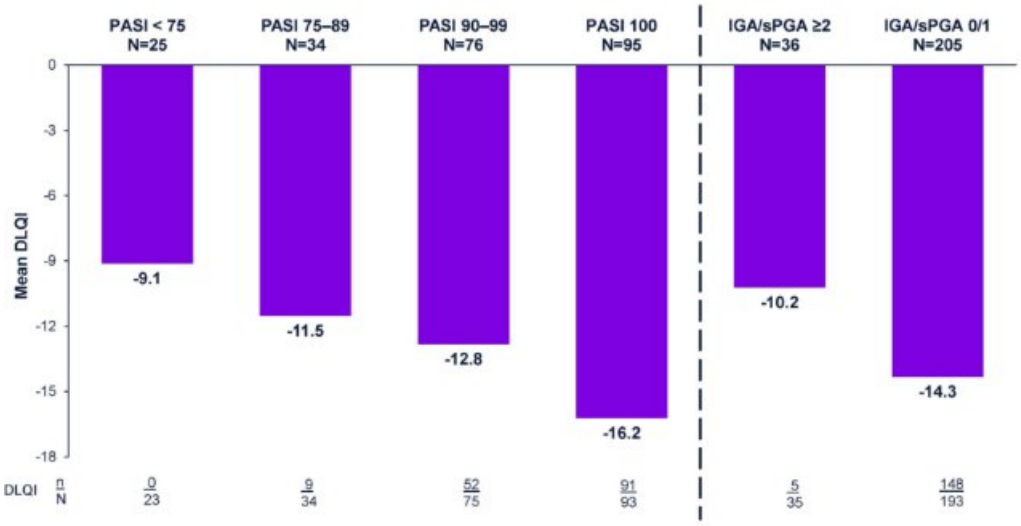
Figure 1. Impact of high skin clearance on percentage of patients achieving DLQI 0/1 at 12 months

DLQI, Dermatology Life Quality Index; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Figure 2. Impact of high skin clearance on percentage of patients achieving DLQI 0/1 at 18 months

DLQI, Dermatology Life Quality Index; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Figure 3. Impact of high skin clearance on mean DLQI reduction from baseline at 12 months



DLQI, Dermatology Life Quality Index; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Figure 4. Impact of high skin clearance on mean DLQI reduction from baseline at 18 months

DLQI, Dermatology Life Quality Index; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

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Abstract N°: 3620

Seasonality of psoriasis in the Oriental region of Morocco

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Introduction & Objectives:

Psoriasis is an inflammatory disease characterized by erythematous scaly patches that usually occur on the elbows, knees and scalp. The prevalence of psoriasis ranges from 0.09% to 11.4% worldwide. Although the pathophysiology of psoriasis is not completely understood, the involvement of genetic and environmental factors has been suggested. Infections, stress, diet, medication, smoking, alcohol consumption and cold weather can trigger psoriasis flares.

The aim of this study is to determine the seasonal variations of psoriasis in theOriental region of Morocco

Materials & Methods:

We conducted a retrospective and descriptive study, including all patients admitted to the dermatology department of the CHU Mohammed VI of Oujda for psoriasis during a 6-year period from January 2014 to November 2022.

Results:

We collected 135 patients, 72 women and 63 men, that is to say a sex ratio M/F =0.87, the average age of our patients was 42.23 ±13.7 years and 39% had a profession with sun exposure. Concerning the history: 19% of the patients were smokers, 4% alcoholics, 9% diabetics, 17% hypertensives and 11% had dyslipidemia. Forty-three percent of the patients consulted in winter, 24% in autumn, 19% in spring and 14% in summer. Among the patients who consulted in winter, 63% had no other risk factor apart from the cold, 18% had a metabolic syndrome, 16% were smokers and 3% had alcoholism. Vitamin D deficiency was noted in winter and autumn in 64% of cases.

Conclusion:

Our study shows that cold can worsen psoriasis symptoms in the presence or absence of other risk factors.

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Abstract N°: 3672

Real World Experience among Biologic-Experienced and Biologic-Naïve Patients with Psoriasis Treated with Ixekizumab

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Introduction & Objectives:

Real-world studies comparing treatment patterns among previous biologic-experienced psoriasis patients are limited. Efficacy of biologics among previous biologic-experienced patients with psoriasis may be reduced because of development of antibodies against the drug. In the clinical setting, Ixekizumab (IXE) has demonstrated comparable efficacy among patients with or without previous biologic treatment; however, head-to-head comparisons between biologic-experienced and biologic-naive patients are lacking. In this case, we reported based on real-world efficacy and safety of IXE among biologic-experienced and biologic-naïve patients with psoriasis.

Materials & Methods:

A case of 2 biologic-experienced patients (previously treated with Secukinumab) and 1 biologic-naïve patient was treated with IXE. Dosing schedule consisted of initial 160 mg at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12, and then 80mg every 4 weeks. To quantitatively evaluate treatment effectiveness, we measured the Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI) scores at the end of the 6 months observation.

Results:

Two biologic-experienced patients achieved PASI 90 in weeks 2 and PASI 100 in weeks 6. Meanwhile 1 biologic-naïve patient achieved PASI 90 in weeks 2 and PASI 100 in weeks 4. DLQI were also decreased in 3 patients within 2 weeks. Minor adverse events such as pain in the injection sites and diarrhoea were mild and reversible. These outcomes are consistent and no relapsed discovered until the end of the 6 months observation.

Conclusion:

The current findings in this study about the efficacy and safety among biologic-experienced and biologic-naïve IXE users were similar. IXE exhibits rapid and sustained clinical improvement without incremental adverse events. IXE, a humanized antibody, has a higher immunogenicity may account for its effectiveness even after the failure of Secukinumab, a fully human antibody belonging to the same class. The different epitopes targeted by these drugs may be the potential explanation for the effectiveness of its treatment. Limitation of these report are small number of cases reported with short observation period. Hence, these findings may assist medical professionals for considering biologic agents for biologic-experienced patients with psoriasis.

Keywords:

Biologic agent, ixekizumab, psoriasis, secukinumab

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Abstract N°: 3687

Characteristic features of microbial flora in patients with psoriasis

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Introduction & Objectives: Characteristic changes in the macroorganism state are reflected in the disorders of microbial landscape of all topographical skin zones. It should be noted that the study of the skin microbial landscape in patients with psoriasis have episodic and unstructured nature. Thus, it is claimed that the findings of the skin microbiocoenosis disorder in patients with psoriasis are characterized by changes in the quantitative and qualitative spectrum of microorganisms, in particular, by the appearance of *Staphylococcus haemolyticus* in the foci, probable increase in the number of *Corynebacterium spp., Micrococcus spp., Staphylococcus hominis, Staphylococcus capitis*, *Staphylococcus aureus* on the background of an oppression or a significant increase in the colonization of *Staphylococcus epidermidis*. *The purpose* of our work was to investigate the quantitative composition of microscopic flora and the degree of skin induration of patients with psoriasis, depending on the clinical course (clinical form, stage) and duration of the disease.

Materials & Methods: The study of the skin microscopic flora was performed from the lesions in 37 patients with psoriasis, which were under observation. 28 apparently healthy persons formed the control group. The material was taken using a replica plating method with subsequent microbiological identification of microorganisms.

Results: It has been established that patients with psoriasis, which were under observation, had the skin microbial landscape of the lesions formed mainly of *S. aureus, S. epidermidis, S. saprophyticus, Bacillus and Micrococcus genera.* The clearest microbial contamination of the lesions has been observed in psoriatic erythroderma, slightly less accentuated skin microbial contamination has been found in patients with the widespread form of dermatitis and the presence of arthropathy, and the least number of microorganisms have been found in patients with common psoriasis without complicated phenomena. The progressive stage of psoriasis has been characterized by a higher level of microbial contamination. It has been established that patients with psoriasis have a very significant dependence of contamination degree of *S.aureus, S.epidermidis and S.saprophyticus* from the duration of dermatitis course, the growth of which had contributed to the intensification of microbial contamination. Thus, the highest level of microbial contamination have been observed in patients with erythroderma, progressive stage of the pathological progress and duration of the disease for more than 20 years.

Conclusion: Analyzing the obtained results, we observed a tendency that *Staphylococcus aureus* and *Staphylococcus epidermidis* are the dominant components of the skin microbial landscape of lesions in patients with psoriasis, which allows us to consider them as trigger factors of the pathological process.

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Abstract N°: 3700

Interaction between angiogenesis and endothelial cell proliferation in patients with psoriasis

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Introduction & Objectives: Psoriasis is a skin disease that is accompanied by systemic inflammation and affects about 1 to 5% of the population worldwide.

The **aim** of our research was to determine morphological peculiarities of skin lesions in patients with common psoriasis, investigation of the levels of expression of immunohistochemical markers of vascularization.**

Materials & Methods: 80 patients with psoriasis were observed. The control group consisted of 20 practically healthy people (donors) of the same age. Skin biopsy with histological evaluation of biopsy materials was performed for all patients to establish form and severity of the course of psoriasis according to requirements of morphological chapter of contemporary classification.

Results: Applying the scale of intensity of skin vascularization according to Amin M.M. et. al. (2012), it was detected that damaged dermal areas due to psoriasis, on average, had 17.25±5.34 micro vessels at magnification (×400), which corresponds to the level of moderate vascularization (11-20 capillaries). Normal skin in control group had mean index 4.32±2.01 at (×400) at the level of weak vascularization (4-10 capillaries), which statistically reliably differs from general group ($p<0.05$). Analysis of the condition of vascular bed at different levels of severity of psoriasis course showed that a number of cells at moderate degree of severity (22.65±5.87) was considerably higher than at mild psoriasis (10.09±3.22), and even more numerous than in CG (4.32±2.01). Statistically reliably both groups differ between them ($p<0.05$), and with CG ($p<0.05$).

According to Fisher's exact test, distribution of absolute meanings of monitoring of intensity of cytoplasmic staining with VEGF marker in all groups between them had a reliable difference ($p<0.05$). We detected a moderate correlation connection between increased intensity of VEGF expression and amplification of the severity of psoriasis course ($r=+0.430$). According to Fisher's exact test, distribution of monitoring of intensity of cytoplasmic staining with MMP-9 marker in all groups between them had a reliable difference ($p<0.05$); a moderate correlation connection between increased intensity of MMP-9 marker expression and amplification of the severity of psoriasis course was detected ($r=+0.532$).

Conclusion: The results of conducted clinical, morphological and immunohistochemical investigations enable to consider importance of neoangiogenesis processes in pathogenesis of this dermatosis and need in elaboration of therapeutic measures with direct influence on this aspect of pathogenesis.

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Abstract N°: 3856

Effectiveness and safety of bimekizumab for psoriasis treatment in real-world setting

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Introduction & Objectives:

Bimekizumab is the first and only dual selective inhibitor of both IL-17A and IL-17F that has been approved for the treatment of moderate to severe plaque psoriasis. Its novel mechanism of action leads to high levels of complete skin clearance that have shown superiority versus adalimumab, ustekinumab, and secukinumab in head-to-head clinical trials. A network meta-analysis published by Armstrong et al. in 2022, ranked bimekizumab as the drug with the highest probability of achieving PASI 75, PASI 90, and PASI 100 response among all approved treatments for psoriasis. Due to the recent approval of bimekizumab by regulatory agencies, there is limited evidence of bimekizumab's effectiveness in real-world setting. The objective of this study is to assess the effectiveness and safety of bimekizumab in psoriasis patients in our routine clinical practice.

Materials & Methods: We conducted a retrospective study of 20 patients with moderate to severe psoriasis treated with bimekizumab according to bimekizumab summary of product characteristics. Patients were followed as per current clinical practice. Psoriasis activity scores, including Psoriasis Area Severity Index (PASI), Body Surface Area (BSA), and Physician's Global Assessment (PGA) scores were evaluated at baseline, week 4, and week 16. The patients' quality of life was assessed using Dermatology Life Quality Index (DLQI) score. Safety information was also reported.

Results: We present a series of 20 patients with moderate to severe psoriasis who were treated with bimekizumab in routine clinical practice conditions. All 20 patients showed rapid and sustained skin clearance with good tolerability and no remarkable adverse events. The resolution of psoriasis was observed in all our patients, regardless of their profile and the location of psoriasis.

Conclusion: Our study suggests that bimekizumab is effective in treating psoriasis in real-world setting, with no new safety concerns identified. Our findings are consistent with those of pivotal clinical trials, highlighting the combination of bimekizumab's efficacy, speed, durability, convenient posology, and safety that lead to better outcomes for patients.

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Abstract N°: 3934

Peripheral blood eosinophilia in association with pustular psoriasis : A rare observation.

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Introduction & Objectives:

The association between psoriasis and peripheral blood eosinophilia is still a controversial issue. Although several studies have demonstrated the undeniable role of eosinophils in autoimmune inflammatory diseases. Studies examining the presence of peripheral blood eosinophilia in psoriasis came to contrasting conclusions with low rates. We report a patient with generalized pustular psoriasis (GPP) with a very high peripheral blood eosinophilia.

Materials & Methods:

Results:

A 42-year-old woman without any significant past medical history, was referred to our department for generalized pustular eruption developing over 4 days. Clinical examination revealed generalized erythema and desquamation around the axillae, face, genitalia, lip, and trunk. Dozens of pustules were developing on the arms, face, legs, flexural areas, trunk and the palmar-plantar regions.

Complete blood count showed anemia and leukocytosis with significant hypereosinophilia >2×109/l (Normal eosinophil count <0.4×109/l). The remaining laboratory examinations showed no significant abnormalities.

The echocardiogram showed no signs of cardiac alterations. Chest X-ray was unremarkable. A limb skin biopsy was performed for diagnostic purpose, with histopathological findings consistent with pustular psoriasis.

The patient was treated with preparation of topical corticosteroids and emollient. She progressed with significant improvement of her symptoms, with complete remission of the skin changes. The dermatology team decided to initiate methotrexate after the clinical improvement.

Conclusion:

GPP is one of the most serious variants of psoriasis, since it is usually not restricted to the skin and has variable systemic manifestations. Clinically, GPP has two forms: Acute GPP of von Zumbusch and generalized annular pustular psoriasis. The von Zumbusch GPP type is characterized by disseminated pustules on the trunk, extremities, and palmar-plantar regions that coalesce and then resolve, leaving erythema and extensive scaling.

Although there is increasing evidence, it hasn't been established yet, whether peripheral blood eosinophilia is found in the psoriasis especially in severe forms such as GPP. Eosinophils are cells that mainly reside in tissues. It is estimated that for every one blood eosinophil, there are 100 tissue eosinophils. Therefore, a high peripheral blood eosinophil count might be expected to correlate with a heavy tissue eosinophil infiltration in lesions of severe psoriasis, but this was not observed consistently in previous studies.

The co-occurrence of peripheral blood eosinophilia and generalized pustular psoriasis seems to be an uncommon situation. The importance of this association remains to be established.

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Abstract N°: 3946

Comprehensive Protocol for Evaluating Generalized Pustular Psoriasis and Palmoplantar Pustulosis Patients through Diagnostic Confirmation Biopsies: Insights from a 10-Year Retrospective Study in a Dermatology Department

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Introduction & Objectives:

Generalized Pustular Psoriasis (GPP) and Palmoplantar Pustulosis (PPP) are rare and debilitating dermatological conditions characterized by the formation of sterile pustules on the skin. This study aims to establish a comprehensive protocol for evaluating and diagnosing GPP and PPP in patients with confirmed diagnoses through diagnostic confirmation biopsies in a Dermatology Department. The objective is to improve the understanding, management, and treatment outcomes of these challenging diseases.

Materials & Methods:

A retrospective analysis of patients with confirmed GPP or PPP cases, diagnosed through diagnostic confirmation biopsies in a Dermatology Department in Lisbon, Portugal, over a 10-year period (2013-2022), will be conducted. Variables including clinical features, treatment regimens, suspected triggers, and long-term outcomes will be analyzed.

Results:

A comprehensive descriptive analysis of the study population characteristics will be presented, incorporating relevant past medical history and, where available, genetic testing results. The suspected precipitating factors will be compared, providing insights into potential triggers. The need for hospitalization, including hospitalization duration and associated complications, will be explored. At diagnosis, clinical and laboratory abnormalities will be described, and commonly used disease severity scores will be assessed. Additionally, details of treatment approaches, reasons for treatment discontinuation, and any medication-related adverse events will be documented.

Conclusion:

The development of a standardized protocol for evaluating GPP and PPP through diagnostic confirmation biopsies in a Dermatology Department represents a significant advancement in our understanding and management of these challenging dermatological conditions. By providing a robust framework backed by scientific evidence, this protocol holds the potential to improve patient outcomes and guide future therapeutic advancements.

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Abstract N°: 3958

Impact of psychological intervention on disease management in psoriasis

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disorder with a complex etiology, involving both genetic and environmental factors. In addition to physical symptoms, psychological factors play a significant role in disease progression and maintenance. However, psychological aspects are often overlooked in clinical settings. This study aims to investigate the psychological aspects of psoriasis patients and evaluate the efficacy of an intervention in improving their psychological well-being

Materials & Methods:

A cohort of 78 psoriasis patients visiting the dermatology clinic of Kandy National Hospital was selected based on specific inclusion criteria. A questionnaire, developed through adaptation of validated instruments, was administered to assess various dimensions of psychological well-being. The questionnaire consisted of 10 items, each offering four response options graded based on a point system. Pre-intervention scores were obtained, and patients were then provided with counseling sessions conducted by medical officers from the hospital's psychiatry unit. After a predetermined period, the same questionnaire was re-administered to evaluate post-intervention scores. Statistical analyses, including paired t-tests and chi-square tests, were performed to examine the significance of score changes.

Results:

Pre-intervention assessment revealed a distribution of patients across grades: 11 patients achieved grade A, 26 patients grade B, 33 patients grade C, and 8 patients grade D. Post-intervention analysis demonstrated improvements, with 19 patients achieving grade A, 34 patients grade B, 22 patients grade C, and 3 patients grade D. Statistical analysis indicated a significant overall increase in scores following intervention ($p < 0.001$). Additionally, patients' feedback regarding the counseling sessions was predominantly positive, with 54 participants reporting that the sessions were "very helpful."

Conclusion:

This scientific study highlights the importance of addressing the psychological aspects of psoriasis patients, which significantly contribute to disease management and quality of life. By utilizing a comprehensive questionnaire tailored for clinical settings, we were able to assess patients' psychological well-being effectively. The intervention, consisting of counseling sessions, proved to be beneficial, leading to statistically significant improvements in patients' psychological scores. These findings emphasize the significance of integrating psychological support into the management of psoriasis patients, thereby enhancing overall treatment outcomes and patient satisfaction. Further research is warranted to explore long-term effects and identify optimal strategies for addressing psychological factors in psoriasis care.

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Abstract N°: 4022

Alcohol consumption and risk of psoriasis: results from observational and genetic analyses in more than 100,000 individuals from the general population

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Introduction & Objectives:

Psoriasis is associated with high alcohol consumption, but the causality of this relationship is unclear. The genes *ADH1B* and *ADH1C* are involved in alcohol metabolism and individuals with fast-metabolizing alleles of these genes have been shown to have lower alcohol consumption. Therefore, the genes *ADH1B* and *ADH1C* can be used as a proxy for alcohol consumption in a Mendelian Randomization approach to assess causality in an observational setting because genes are not prone to reverse causation or confounding. The objective of this study was to use a Mendelian Randomization approach to investigate the causal effects of alcohol on incident psoriasis in a large prospective general population study.

Materials & Methods:

We included 102,655 adult individuals from the general population. Information on alcohol consumption was self-reported in an extensive questionnaire during inclusion in the study, subsequently reviewed together with an investigator to ensure validity. First, we tested if alcohol consumption was observationally associated with incident psoriasis by dividing participants into three groups based on alcohol consumption (low: 1-112 g/week, moderate: 113-224 g/week, high: > 224 g/week) in a multivariable adjusted Cox-proportional-hazards model. We then created a genetic instrument based on the number of fast-metabolizing alleles of *ADH1B* and *ADH1C* to test whether alcohol consumption was causally associated with incident psoriasis.

Results:

Of the 102,655 individuals included in this study, 534 (0.5%) were diagnosed with psoriasis prior to inclusion and 615 (0.6%) were diagnosed during the follow-up period (median follow-up 9 years). Observationally, we found an increased risk of psoriasis among individuals with high alcohol consumption (hazard ratio (HR) 1.29, 95% confidence interval (CI) 1.03-1.63) compared to those with low consumption. Moderate consumption did not significantly increase the risk of psoriasis (HR 1.10, 95% CI 0.89-1.63), though there was a significant trend across the three alcohol groups (p = 0.02). Using genetic data as a proxy for alcohol consumption, we found no association between number of fast-metabolizing alleles and risk of psoriasis with an odds ratio of 0.93 (96% CI 0.60-1.43) in individuals with 3 fast-metabolizing alleles compared to individuals with no fast-metabolizing alleles (*p* for trend = 0.66).

Conclusion:

Alcohol consumption was found to be observationally associated with risk of developing psoriasis. However, using genetic variants as a proxy for alcohol consumption, we did not find evidence of a causal relation. This indicates that the observational association is due to unmeasured or residual confounding or reverse causation.

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Abstract N°: 4041

Long-Term Efficacy and Safety of Risankizumab for Active Psoriatic Arthritis: 148-Week Results from the KEEPsAKE 2 Trial

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Introduction & Objectives: Psoriatic arthritis (PsA) is a chronic systemic inflammatory disease that affects 30% of patients diagnosed with psoriasis, with a clinical burden that includes dactylitis, enthesitis, cutaneous manifestations, chronic pain, progressive joint damage, and disability. Risankizumab (RZB), an antibody that targets the p19 subunit of interleukin-23 with high affinity and specificity, is approved for the treatment of adult patients with active PsA. RZB has been previously reported to show efficacy across several disease domains up to week 100 (Kristensen, et. al. 2022 EADV Congress). Here, we report the efficacy and safety results through week 148.

Materials & Methods: KEEPsAKE 2 is an ongoing phase 3 global, multicenter clinical trial evaluating the efficacy and safety of RZB versus placebo (PBO) in patients with active PsA, defined as ≥5 tender joints and ≥5 swollen joints, meeting the Classification Criteria for Psoriatic Arthritis (CASPAR), with symptom onset of ≥6 months before screening, and active plaque psoriasis or nail changes consistent with psoriasis at screening. Eligible patients were 18 years or older and had previous inadequate response or intolerance to 1 or 2 biological therapies (Bio-IR) and/or ≥1 conventional synthetic disease-modifying antirheumatic drug (csDMARD-IR). Patients were randomized in a 1:1 ratio to receive double-blinded treatment with subcutaneous RZB 150 mg or matched placebo for 24 weeks, administered at weeks 0, 4 and 16. Starting at week 24, all patients in the ongoing trial receive open-label RZB 150 mg every 12 weeks through week 316. Efficacy and safety analyses were conducted in all randomized patients who received one or more doses of the study drug. Statistical reporting and imputation methods for efficacy assessments are defined in the figures. Safety assessments were based on monitoring of treatment emergent adverse events (TEAEs) and are summarized using exposure-adjusted event rates (EAERs, events/100 patient-years [PYs]).

Results: Patients in KEEPsAKE 2 (RZB N=224; PBO/RZB N=219) maintained similar efficacy results at week 148 to those reported at week 52 and week 100 (**Table 1**). **Figure 1** presents the percentage of patients achieving ACR20, 50, and 70 responses over time. 33.9% of RZB and 28.8% of PBO/RZB patients achieved ACR50 response at week 148. 65.9% of RZB and 58.8% of PBO/RZB patients achieved PASI 90 response at week 148. A consistent change from baseline in HAQ-DI (RZB -0.24, PBO/RZB -0.27), SF-36 PCS (RZB 6.09, PBO/RZB 5.60) and FACIT-Fatigue (RZB 6.0, PBO/RZB 5.1) was observed at 148 weeks. 33.0% of RZB patients and 28.3% of PBO/RZB patients achieved MDA at week 148, consistent with results reported at week 52 and week 100. For those patients with enthesitis at baseline, resolution was observed in 53.1% of RZB and 47.5% of PBO/RZB patients at week 148. For

patients with dactylitis at baseline, resolution was observed in 82.5% of RZB and 61.4% of RZB/PBO patients at week 148. The overall rates of TEAEs, serious TEAEs and AEs leading to discontinuation of study drug remained stable and was consistent with the rates reported for the placebo-controlled period (**Table 2**).

Conclusion: Long-term treatment with RZB 150mg shows durable efficacy in patients with PsA through 148 weeks, with no new safety findings.

Table 1. Efficacy Results for KEEPsAKE 2 at Week 52, Week 100 and Week 148

	KEEPsAKE 2					
	Week 52		Week 100		Week 148	
	RZB 150 mg (N=224)	PBO to RZB 150 mg (N=219)	RZB 150 mg (N=224)	PBO to RZB 150 mg (N=219)	RZB 150 mg (N=224)	PBO to RZB 150 mg (N=219)
ACR20, % (n)[a]	59.9 (134)	55.7 (122)	57.1 (128)	52.5 (115)	54.0 (121)	46.6 (102)
ACR50, % (n)[a]	33.3 (75)	32.0 (70)	34.8 (78)	33.8 (74)	33.9 (76)	28.8 (63)
ACR70, % (n)[a]	17.4 (39)	21.0 (46)	21.4 (48)	17.4 (38)	19.6 (44)	16.4 (36)
Change in HAQ-DI, mean (95% CI)[b,f]	-0.26 (-0.33, -0.19)	-0.34 (-0.42, -0.27)	-0.26 (-0.33, -0.18)	-0.31 (-0.39, -0.23)	-0.24 (-0.32, -0.16)	-0.27 (-0.36, -0.19)
PASI 90, % (n/N)[a,c]	65.0 (80/123)	59.7 (71/119)	67.5 (83/123)	61.3 (73/119)	65.9 (81/123)	58.8 (70/119)
MDA, n (%)[a]	27.2 (61)	33.8 (74)	33.0 (74)	33.3 (73)	33.0 (74)	28.3 (62)
Change in SF-36 PCS score, mean (95% CI)[b,f]	6.27 (5.22, 7.33)	7.34 (6.26, 8.42)	6.44 (5.28, 7.60)	6.46 (5.25, 7.66)	6.09 (4.83, 7.36)	5.60 (4.27, 6.92)
Change in FACIT-Fatigue score, mean (95% CI)[b,f]	5.7 (4.6, 6.9)	7.0 (5.8, 8.2)	5.4 (4.1, 6.7)	6.4 (5.0, 7.7)	6.0 (4.6, 7.5)	5.1 (3.6, 6.6)
Resolution of enthesitis, % (n/N)[a,d]	43.5 (64/147)	52.5 (83/158)	51.7 (76/147)	52.5 (83/158)	53.1 (78/147)	47.5 (75/158)
Resolution of dactylitis, % (n/N)[a,e]	67.5 (27/40)	70.9 (40/57)	77.5 (31/40)	68.4 (39/57)	82.5 (33/40)	61.4 (35/57)

All changes are least square mean changes from baseline.

[a]Results for binary endpoints are based on as-observed (AO) data with missing data imputed as non-responder imputation incorporating multiple imputation (NRI-MI) if there are missing data due to COVID-19.

[b]Results for continuous endpoints are reported by mixed-effect model repeated measurement (MMRM).

[c]Reported for patients with ≥ 3% of body surface area (BSA) affected by psoriasis at baseline (RZB, N=123; PBO/RZB, N=119).

[d]Defined as Leeds Enthesitis Index (LEI)=0 and reported among patients with LEI >0 at baseline (RZB, N=147; PBO/RZB, N=158).

[e]Defined as Leeds Dactylitis Index (LDI)=0 and reported among patients with LDI>0 at baseline (RZB, N=40; PBO/RZB, N=57).

[f]Number of unique patients contributing to MMRM model estimates: patients with at least one available change from baseline value and no missing data for the factors and covariates in the model. The MMRM N is not visit-specific and is displayed for model estimates for all visits. For change in HAQ-DI (RZB, N=224; PBO/RZB, N=215); for change in FACIT-Fatigue score and change in SF-36 PCS score (RZB, N=223; PBO/RZB, N=213).

ACR20/50/70, ≥20/50/70% improvement in American College of Rheumatology score; BSA, body surface area; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy-Fatigue Questionnaire; HAQ-DI, Health Assessment Questionnaire-Disability Index; LDI, Leeds Dactylitis Index; LEI, Leeds Enthesitis Index; LS, least square; MDA, minimal disease activity; PASI 90, ≥90% reduction in Psoriasis Area and Severity Index; PBO, placebo; RZB, risankizumab; SF-36 PCS, 36-Item Short Form Health Survey Physical Component Summary.

Table 2. Safety Summary for KEEPsAKE 2 through Week 148

	RZB Week 24[a] N=224 PYs=104.3	PBO Week 24[a] N=219 PYs=101.3	RZB and PBO/RZB Week 148 N=419 PYs=1059.0
Any TEAE	286 (274.2)	292 (288.3)	1874 (177.0)
Serious TEAE	14 (13.4)	15 (14.8)	99 (9.3)
TEAE leading to discontinuation of study drug	2 (1.9)	6 (5.9)	12 (1.1)
COVID-19 related TEAE	1 (1.0)	0	124 (11.7)
Any MACE	1 (1.0)	0	4 (0.4)
Cardiovascular death due to acute myocardial infarction	0	0	1 (<0.1)
Non-fatal myocardial infarction	0	0	2 (0.2)
Non-fatal stroke	1 (1.0)	0	1 (<0.1)
Any serious infection	3 (2.9)	5 (4.9)	18 (1.7)
Any serious hypersensitivity	0	0	1 (<0.1)[b]
Opportunistic infections excluding TB and herpes zoster	0	0	2 (0.2)
Active TB	0	0	0
Herpes zoster	0	1 (1.0)	5 (0.5)
Malignant tumors	1 (1.0)	3 (3.0)	17 (1.6)
Including NMSC	1 (1.0)	3 (3.0)	15 (1.4)
Excluding NMSC	0	0	2 (0.2)
Any adjudicated anaphylactic reaction	0	0	0
All Deaths	0	0	1 (0.1)[c]

Treatment-emergent adverse events (TEAE) were defined as any AE with an onset date that was on or after the first dose of risankizumab and up to 140 days after the last dose of risankizumab if the patient discontinued the study drug prematurely.

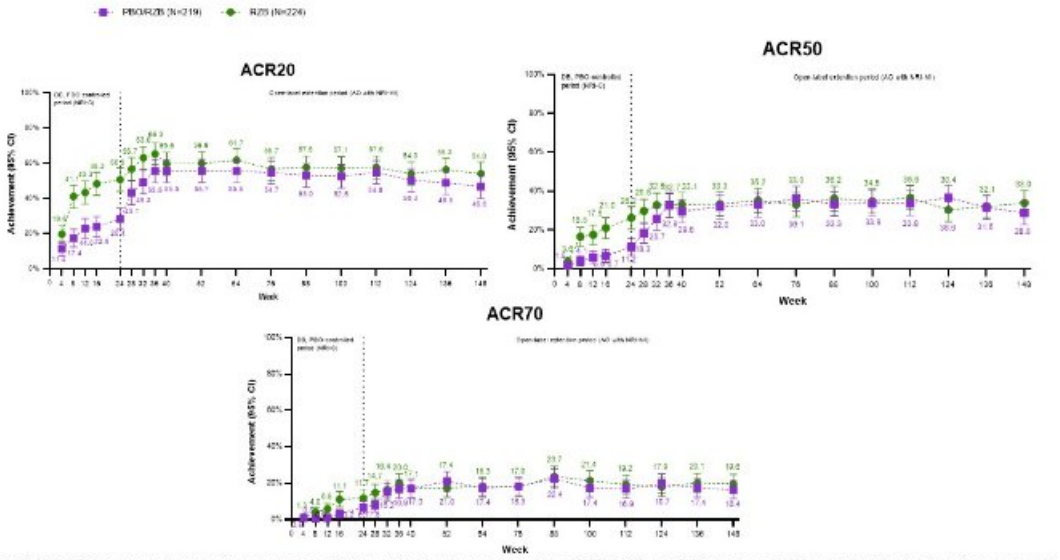
[a]24 week data from KEEPsAKE 2 was previously published in Östör A, et. al. Ann Rheum Dis. 2022;81:351-358.

[b]Event of idiopathic thrombocytopenic purpura assessed as NRP per investigator. Patient remained on study drug.

[c]One death was caused by coronary artery plaque rupture in a patient who had multiple risk factors, including obesity, a long history of smoking, hypertension, hypercholesterolemia, and a family history of cardiovascular disease.

MACE, major adverse cardiovascular events; NMSC, non-melanoma skin cancer; PYs, patient-years; RZB, risankizumab; TB, tuberculosis; TEAE, treatment-emergent adverse events.

Figure 1. ACR20, 50, and 70 Achievement Over 148 Weeks



DB, double-blind; NRI-C, non-responder imputation incorporating multiple imputation to handle missing data due to COVID-19; AO with NRI-MI, as-observed (AO) data with missing data imputed as non-responder imputation incorporating multiple imputation (NRI MI) if there are missing data due to COVID-19; PBO, placebo; RZB, risankizumab.

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Abstract N°: 4061

The Built Environment and Risk of Psoriasis: A Systematic Review

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Introduction & Objectives:

Psoriasis affects 1-5% of North American population and has a bidirectional relationship with metabolic syndrome. The association between behavioural risk factors (e.g., physical activity, diet, alcohol, smoking) with psoriasis and its comorbidities is well established. However, it is increasingly recognized that these behavioural risk factors arise in the context of larger social, cultural, economic, and environmental determinants of health. Population-health research in chronic diseases highlighted the importance of human-made buildings and spaces, or built environment, as a critical element to address population-level health differences and promote health equity. We conducted a systematic review to understand the impact of the built environment on psoriasis incidence, prevalence, and severity.

Materials & Methods:

MEDLINE, EMBASE, Web of Science, and CINAHL databases were searched on September 20, 2022. Two reviewers independently screened studies evaluating the built environment's impact on the prevalence, incidence, and/or severity of psoriasis. Duplicates were deleted and retrieved articles were housed on Rayyan. PRISMA guidelines were followed. Two reviewers independently assessed study quality using the Quality Assessment Tool for Quantitative Studies.

Results:

Eight studies were retrieved. Of them, n=4/8 assessed the impact of neighborhood factors on psoriasis. Of these, n=2/4 reported on psoriasis risk based on urban vs. rural residence with conflicting results, and n=2/4 investigated socioeconomic deprivation demonstrating that people residing in high and medium deprivation neighborhoods were more likely to have psoriasis whereas patients from the lowest income quartiles had a more severe disease. Four studies researched the effect of neighborhood air quality on psoriasis exacerbations. Air pollution, in particular particulate matter (PM2.5 and PM10) and NO2, was associated with a modest increase in outpatient visits and hospital admissions in South Korea and China. Italian studies demonstrated higher concentrations of all air pollutants (e.g. PM2.5, PM10, CO, NO2, other nitrogen oxides, benzene) prior to psoriasis flares vs. regular outpatient visits as well as daily increases in air pollutants were associated with therapeutic decisions such as such as dose increments or treatment changes. Regarding quality rating, n=1/8 study was identified as "weak", and n=7/8 as "moderate". None was identified as "strong".

Conclusion:

Our findings suggest that neighborhood material deprivation may be associated with higher psoriasis risk and severity, whereas air pollution might increase the risk of psoriasis exacerbations and poor treatment response. This

data should be interpreted with caution as all studies were of moderate to weak quality. Despite psoriasis disproportionately affecting North American, Western European, and Australasian populations, we identified no studies from these regions. Studying the environmental (e.g., ultraviolet radiation, air/noise/light pollution) and built environment (e.g., greenness, active living environment, material/social deprivation) determinants of psoriasis with technologies capable of handling large datasets while holding each variable constant is important to advance our understanding of population-level determinants of psoriatic disease spectrum. This is essential to reduce health disparities in chronic skin disease such as psoriasis.

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Abstract N°: 4063

Burden of topical treatment and criteria of choice preferred: Results from 766 psoriasis patients living in Europe

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Introduction & Objectives:

Topical treatment (TT) is the mainstay of psoriasis (PsO) management. Patient satisfaction with TT is a major determinant of treatment adherence, which in turn increases effectiveness and health-related quality of life (QoL).1,2 Thus, patient preferences should be considered when prescribing TT to favor adherence and improve outcomes.3,4 The aim of this study was to assess the burden of TT, its convenience, criteria of choice and impact on daily life / QoL in a large sample of PsO patients.

Materials & Methods:

Between January and March 2023, 766 patients from five European countries (France, Germany, Italy, Spain United Kingdom) were recruited by Wefight and International Federation of Psoriasis Associations (IFPA) to take part in an online survey (29 -item questionnaire).

Results:

The survey was completed by 766 patients (53 years old on average; 54% women) having Pso with (23%) or without (77%) psoriatic arthritis (PsA). Among all the respondents average, psoriasis affected 7% of their body surface area, with the scalp and elbows being particularly affected. On average, they have been living with PsO for 18 years. Psoriasis had an impact on QoL in 85% of patients. Study participants generally sought information about TT from their healthcare professional, used on average two different topicals, mainly corticosteroids, combination treatments and emollients, applied twice daily, and were globally satisfied with their current TT (80%), although a large majority (61%) were “somewhat satisfied” only. The most important criteria for choosing TT were “good tolerability” and “absence of itching/burning” (important for ≈80% of patients), followed by “does not run off”, “does not leave stains on clothes”, “ease of application”, “good absorption” and “quick to apply” items (>70%).

Regarding QoL, nearly one third of patients answered that the TT impacts their daily activities and routine, since the topicals can make them **“**feel different from others” (43%), “avoid clothes that they would like to wear” (42%) and modify the span of physical and leisure activity (e.g., avoid “going to the pool”, 41%). Patients with a complex disease (e.g., PsO with PsA; using biotherapy) or recent diagnosis reported even a stronger impact on QoL.

Conclusion:

TT can be burdensome for many PsO patients, causing marked routines disruption. Before prescribing TT, physicians should engage in discussion with patients to identify their preferences and choice criteria. Such individualized treatment approach could potentially lead to improved adherence and better TT outcomes.

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\3. Bewley A, Page B. J Eur Acad Dermatol Venereol. 2011 Jun;25 Suppl 4:9-14.

\4. Vasconcelos V et al. J Dermatolog Treat. 2019 Nov;30(7):659-663.

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Abstract N°: 4070

Refractory psoriasis successfully treated with brodalumab

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Introduction:

83-year-old patient with severe psoriasis affecting special localizations, refractory to multiple treatments, whom presented rapid improvement after starting treatment with brodalumab.

Case report:

At the time of the consultation, the patient presented erythematous and infiltrated plaques, with whitish scaling, on the distal part of the legs, the back of the thighs, and elbows, with significant involvement of the entire scalp, palms, and soles, with significant hyperkeratosis and painful fissures that prevented him from walking and affectation in the genital and intergluteal area. In the scales of severity evaluation, a PASI of 21, BSA of 23.2%, DLQI of 12 and VAS pruritus of 9 were obtained.

Given the significant affectation despite the prescribed treatment, it was decided to start brodalumab according to the usual dosage regimen, showing rapid improvement after 8 weeks, with almost complete clearing of the lesions on the scalp, genitals, arms, and palms, and great improvement of the lesions on the legs and soles, persisting hyperkeratosis in the heels and metatarsals area, but without neither fissures nor pain. Severity indexes improved, with scores of PASI=3, BSA = 5%, EVA=2, and DLQI=3

Conclusion:

Brodalumab is a monoclonal antibody that binds to the IL-17A receptor, blocking the action of several cytokines of the IL-17 family, thus having an unique mechanism of action. In clinical trials it has shown rapid and significant improvements, with a good safety profile. In addition, this drug has demonstrated in numerous cases efectiveness after treatment failure with other biologics and in special localizations such as scalp and palmoplantar involvement.

In this case report, we present a patient with a good response just 8 weeks after initiating brodalumab therapy in a patient with previous failure ~~of~~ to multiple biological treatments, including TNF inhibitors, anti-IL23 and anti-IL-17. Nevertheless, it has shown a remarkable efficacy on the scalp, genitals and palmoplantar involvement. Therefore, this experience is consistent with the literature and both patient and physician remain satisfied with this response

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Abstract N°: 4072

Observational study to assess the real-life descriptive effectiveness in patients with moderate to severe plaque psoriasis treated with brodalumab. The BROACTIVE Study. 1-year results.

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Introduction & Objectives:

Brodalumab is a fully human recombinant monoclonal antibody type IgG2 that binds with high affinity to IL-17RA and has been shown to be an effective and safe treatment in clinical trials for treating moderate to severe plaque psoriasis. This study aims to obtain real world data on effectiveness in patients treated with brodalumab.

Materials & Methods:

BROACTIVE is a prospective, observational, non-interventional, multicenter, non-comparative cohort study with retrospective data collection, currently being conducted in Spain under routine clinical practice conditions. Patients included were aged ≥18 years, had a diagnosis of moderate-to-severe plaque psoriasis and at least had received one previous systemic treatment. Data were collected from medical records at Spanish public hospitals: from 12 ±4 weeks after brodalumab initiation to patient inclusion in the study (retrospectively) to a follow-up period of 24 months, including a baseline and 6 follow-up visits (prospectively). In the current analysis data collected from and after 3, 6, 9 and 12 months of treatment initiation has been analyzed. Quality of life (QoL) is measured by the Dermatology Life Quality Index (DLQI). Treatment persistence is defined as number of patients who discontinued brodalumab during the period of time analyzed.

Results:

172 patients have been recruited, and 116 have attained the 1-year follow-up period. Mean (SD) Body Mass Index (BMI) was 30.0 (±6.2). Scalp was the most common location of moderate-to-severe plaque psoriasis prior to treatment initiation (51.2%). Comorbidities were present in 108 (62.8%; N=172) of patients, being dyslipidemia the most prevalent (28.5%), followed by hypertension (23.8%). Concerning brodalumab efficacy, absolute PASI ≤1 was achieved by 103 (59.9%; N=172) patients at 3 months of treatment compared with 4 (2.4%; N=166) patients prior to treatment initiation. At 6, 9, and 12 months of treatment, absolute PASI ≤1 was reached by 84 (63.2%; N=133), 72 (66.1%; N=109) and 66 (71.0%; N=93) patients. Absolute PASI ≤3 response rates were achieved by 125 (72.7%; N=172), 106 (79.7%; N=133), 90 (82.6%; N=109) and 81 (87.1%; N=93) patients at 3, 6, 9, and 12 months of treatment, respectively. Brodalumab efficacy was also assessed by PASI 90 and PASI 100 response rates. PASI 90 was achieved by 94 (56.6%; N=166), 81 (62.3%; N=130), 66 (62.3%; N=106) and 60 (67.4%; N=89) patients after 3, 6, 9 and 12 months of treatment, respectively. PASI 100 was reached by 80 (48.2%; N=166), 60 (46.2%; N=130), 56 (52.8%; N=106) and 50 (56.2%; N=89) patients at 3, 6, 9 and 12 months, respectively. There was an important decrease in DLQI score, from 3.2 (±5.3) at 3 months to 2.0 (±3.6) atter 12 months of treatment. Persistence rates for brodalumab at 6, 9 and 12 months, were found to be 96.2%, 93.6%, and 92.5%, respectively.

Conclusion:

The findings of our ongoing study provide real-world evidence on brodalumab effectiveness and low rates of treatment discontinuation in patients with moderate-to-severe plaque psoriasis in Spanish public hospitals.

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Abstract N°: 4091

Characterization of biophysical and biochemical changes in psoriatic lesions under different environmental conditions through image and biomarker analysis and clinical evaluation

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Introduction & Objectives:

Psoriasis is a chronic inflammatory disease affecting skin and joints characterized by silvery thick scales on underlying erythematous base. Current modality to assess disease progression or effect to treatment is visual evaluation by dermatologist and requires clinical set up. In context of clinical trials, it may be highly valuable having an additional objective method to support clinical observations and raise precision for drugs performance and comparison. Previous studies have suggested that psoriatic patients experience worsening of condition due to exposure to environmental stressors. In line with these observations, a clinical study was postulated with following aims:

\1. To objectively and remotely measure via image analysis the psoriatic lesions using SkinCam® (Nomad imaging system), in a clinical set up.

2. To evaluate effect of exposomes on psoriatic lesions using a CIDP Controlled Pollution Exposure System (CCPES).

Materials & Methods:

Volunteers with confirmed clinical diagnosis of moderate to severe psoriasis were enrolled in the study. Three psoriatic lesions along with healthy adjacent zones were selected. Clinical assessment of the lesions (erythema, scaling and induration) was performed by a trained dermatologist at D0 and D28. The tape stripping was performed on lesioned and adjacent area and SkinCam® images were taken before and after. The three lesions were monitored at D7, D14, D28. At D0 and D28, images were captured at the study centre while on D7 and D14, images were captured by volunteer at home using SkinCam®. Image analysis was compared with clinical evaluations. Tape strips (corneocytes) collected at D0 and D28 were split in two and each half was exposed to controlled, standardized concentration of pollutants using CCPES. Different biomarkers (psoriasin, ceramides expression, NMF) were monitored.

Results:

High correlation was observed between colorimetric measurement, roughness parameter and clinical evaluations. A novel pattern of colour parameters describing inflammation and scaling was revealed in psoriatic lesions.

Our results confirmed that the nomadic camera is more sensitive in detecting minimal changes than visual evaluations . We also demonstrated that, when compared to healthy skin, lesional skin exhibits lower levels of ceramides and a defect in skin differentiation. Exposure to pollution via CCPES further compromises skin integrity in corneocytes.

Conclusion:

This study characterizes biophysical and biochemical changes in psoriatic lesions under different environmental conditions through image analysis and different biomarkers.

Although visual evaluation by dermatologist is the gold standard for assessment of various skin lesions, our localised high-resolution imaging can bring quantifiable precision to clinical evaluations, drug performance and comparison even in context of minimal changes.

Using the CCPES approach, a higher degree of compromised skin integrity was observed in psoriatic lesion compared to healthy skin. A more prominent decrease in mechanical resistance and hydrophobicity was also noted when exposed to pollution.

The proposed methodologies could be of high interest in assessing evolution of various inflammatory dermatoses, eczemas, acne etc.

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Abstract N°: 4095

Baseline characteristics of patients included in the BeNeBio study: an international, pragmatic, multicentre, randomized, controlled, non-inferiority study on dose reduction of IL-17 and IL-23 inhibitors in psoriasis.

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease for which treatment with biologics is highly effective. Tightly controlled dose reduction (DR) of the first-generation biologics has proven successful for a more efficient and cost-effective use of these drugs. The present study evaluates whether controlled DR of IL-17 and IL-23 inhibitors in psoriasis patients with low disease activity is non-inferior (NI) to usual care (UC).

Materials & Methods:

In this pragmatic non-inferiority study, 244 patients using secukinumab, ixekizumab, brodalumab, bimekizumab, guselkumab, risankizumab, or tildrakizumab on standard dose with stable low disease activity (Psoriasis Area and Severity Index (PASI) ≤5 for at least 6 months), and PASI and Dermatology Life Quality Index (DLQI) ≤5 at time of inclusion, are randomized (2:1) to DR or UC. With DR, dosing intervals are stepwise prolonged to achieve 66% and 50% of the original dose. In case of disease flare, treatment is adjusted to the previous effective dose. Primary outcome is the difference in cumulative incidence of persistent flares (PASI >5 for ≥3 months). Secondary outcomes include proportion of patients with successful DR, (course of) PASI and DLQI, serious adverse events, health related quality of life, costs, and pharmacokinetic profile.

Results:

Inclusion started in August 2020. In April 2023, 231 patients (95%) have been included: 14% used secukinumab, 26% ixekizumab, 6% brodalumab, 1% bimekizumab, 30% guselkumab, 21% risankizumab, and 2% tildrakizumab. Of included patients, mean age is 53 years at inclusion, mean BMI is 27.4, and 70% is male. Of all patients, 14% has concomitant psoriatic arthritis. Median disease duration at inclusion is 21.5 years (IQR 20). Previously used anti-psoriatic treatments involves topical corticosteroids (86%) and topical vitamin D derivates (37%), UV-light therapy (84%), methotrexate (86%), ciclosporin (49%) and at least one biological treatment (53%). At baseline, median

PASI is 0.0 (IQR 1.2) and DLQI is 0.0 (IQR 1.0).

Conclusion:

Here, we describe baseline characteristics of included patients in the BeNeBio trial (95% inclusion on April 20, 2023), which is designed for DR of the newer biologics: IL-17 and IL-23 inhibitors. The current results highlight that, although the threshold for inclusion was PASI and DLQI ≤5, patients have been included with a very low PASI and DLQI (both median 0). Additionally, patients show a relatively low mean BMI compared to general biologic cohorts, and the proportion of biologic naive vs. non-naive patients is well balanced. In clinically stable patients, DR may lead to more efficient and rational use of biologics. Final results will be available in 2024.

Fundings by the BeNeFIT (Belgium – Netherlands Funding of International Trials) programme of the Belgian Health Care Knowledge Centre (KCE) and the Dutch organisation ZonMw (Care Research Netherlands and the Medical Sciences domain of the Dutch Research council).

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Abstract N°: 4120

First results of a non-interventional observational study to investigate the effectiveness of Brodalumab in patients with psoriasis on difficult-to-treat body regions in everyday clinical practice – ODIN.

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Introduction & Objectives: # Brodalumab (BRO), a human monoclonal antibody that selectively inhibits the IL-17 receptor subunit A, is approved for the treatment of moderate to severe plaque psoriasis (PsO) in adults. The rapid onset of action and high PASI clearance have already been proven in multiple clinical studies. However, multi centric data on the effectiveness of difficult-to-treat areas, especially in a real world setting, are scarce.

Materials & Methods:

In a non-interventional study (ODIN) a total of 9 centers included patients who were treated with brodalumab (BRO) in everyday clinical practice. Included patients were observed at 9 visits over a period of 60 weeks. Clinical assessments occurred at weeks 0, 2, 4, 8, 12, 24, 36, 48 and 60. The co-primary endpoints were the proportion of patients reaching PSSI75 at week 12 and/or NAPSI75 at week 24 after treatment initiation in order to describe effectiveness of BRO treatment for scalp and nail PsO. Secondary endpoints included general skin improvement and patient satisfaction.

Results:

A total of 87 patients were screened and enrolled.* 62 patients with a post-baseline assessment at W12 or later were included in the exploratory analysis of effectiveness.

90.3% (n=56) of patients achieved NAPSI75 by week 24. PSSI75 was achieved by 93.5% (n=58) of patients at week 12. Both PSSI75 and NAPSI75 were achieved by 87.1% (n=54) of all 62 patients after 24 weeks of therapy. Mean BSA improved from 14% at baseline to 1.5% at week 12 and 1.0% at week 24. Severity of Psoriasis measured by IGA (0-4) improved from baseline 3.1 to 1.1 at week 12 and 1.0 at week 24. Quality of life (QoL) also clearly improved during the first 24 weeks. Mean DLQI score at baseline was 16 and decreased to 2 at week 12 and to 1 at week 24. PHQ9 score to determine signs and symptoms of depression improved markedly from 5 at baseline (mild signs of depression) to 1.5 and 2 after week 12 and 24 – reflecting no indication of depression. BRO was well tolerated – most common reasons for discontinuation were insufficient effectiveness (11.5%), other reasons (8.1%) (missing appointment), or intolerance of therapy (3.5%).

Conclusion:

In the ODIN study, the positive effect of BRO on difficult-to-treat areas, especially scalp psoriasis and nail involvement, was clearly shown. After 12 and 24 weeks of therapy, the majority of patients showed significant healing of all aspects of psoriasis and a very good improvement in QoL.

Funding statement:

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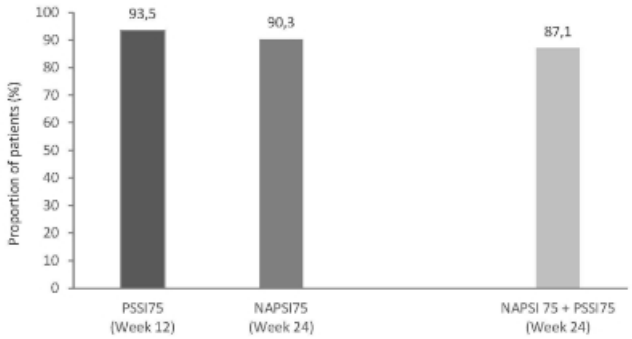
100
90
80
70
60
50
40
30
20
10
0
Proportion of patients (%)
93,5
90,3
87,1
PSSI75
(Week 12)
NAPSI75
(Week 24)
NAPSI 75 + PSSI75
(Week 24)

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Abstract N°: 4123

Functional, social and sexual impairments in psoriasis: a comparative study between patients with and without anogenital lesions

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Introduction & Objectives:

The prevalence of isolated genital psoriasis has been estimated between 2-5%. However, a substantial portion of patients with different forms of psoriasis experience genital lesions at a certain time point of assessment (7-42%) and during the course of psoriasis (33-63% of psoriasis cases), resulting in additional psychosocial burden to these patients. This study aimed (1) to compare the clinical characteristics, as well as quality of life (QoL), social and sexual impairments, between patients with psoriasis with and without lesions in the anogenital area; and (2) to test the associations between clinical characteristics and patient-reported outcomes (PROs) of disease burden.

Materials & Methods:

The multicentre PsoGen study had a cross-sectional case-control design and included German patients aged ≥18 years with moderate to severe psoriasis. Cases with current anogenital psoriasis and controls without anogenital involvement were defined based on physician's report. The physicians also assessed psoriasis severity, and reported on current treatment(s) and comorbidities. The patients assessed the intensity of symptoms and reported on the frequency and limitations in sexual activity, QoL impairments, perceived stigmatization, and sexual/ relationship impairments.

Results:

The participants were 320 patients: 161 cases with anogenital lesions and 159 controls without anogenital involvement. Comparative analyses (Table 1) showed that patients with anogenital psoriasis had higher disease severity, more intense symptoms of pain, itching and burning, and more comorbidities. However, they were less often treated with biological systemic therapy. No significant differences were found in the frequency of sexual activity, but they reported more limitations in sexual activity because of psoriasis, as well as more QoL, social and sexual impairments. Regression analyses (Table 2) demonstrated that higher disease severity, involvement of the anogenital area, comorbidities, more intense symptoms of itching and burning, and frequent limitations in sexual activity explained 67% of the variance in QoL impairments. Higher disease severity and frequent limitations in sexual activity also explained 24% of the variance in perceived stigmatization. 54% of the variance in sexual impairments were explained by older age, higher disease severity, topical treatment, anogenital involvement, absence of sexual activity and more limitations in sexual activity.

Conclusion:

The burden of psoriasis resulting from clinical severity, but also from the functional, social and sexual impairments, was higher in patients with anogenital psoriasis. These findings suggest that treatment focused only on the clearance of the anogenital skin might be insufficient to improve the psychosocial and sexual functioning of these

patients. Instead, comprehensive patient-centred healthcare should include psychosocial assessment and intervention, in order to improve patients' overall health.

Table 1 | Comparison of socio-demographic characteristics, clinical features and patient-reported symptoms and outcomes between patients with psoriasis with and without anogenital involvement.

		No anogenital involvement (n = 159)	Anogenital psoriasis (n = 161)	χ^2/ t
Socio-demographic characteristics				
Age (years), M ± SD		42.48 ± 14.61	42.73 ± 13.43	-0.16
Gender, n (%)	Male	111 (69.8%)	104 (64.6%)	0.99
	Female	48 (30.2%)	57 (35.4%)	
Clinical features				
Disease severity [PASI], M ± SD		2.55 ± 4.60	7.57 ± 6.88	-7.66***
Disease duration (years), M ± SD		19.70 ± 14.00	18.73 ± 13.78	0.62
Treatment, n (%)	Biologic	119 (74.8%)	72 (44.7%)	30.17***
	Conventional systemic	19 (11.9%)	41 (25.5%)	9.59**
	Topical	67 (42.1%)	106 (65.8%)	18.09***
	Phototherapy	5 (3.1%)	31 (19.3%)	20.79***
	Other	6 (3.8%)	6 (3.7%)	0.00
	None	1 (0.6%)	4 (2.5%)	1.79
Comorbidities (yes), n (%)		73 (45.9%)	100 (62.1%)	8.45**
Patient-reported symptoms and outcomes				
Intensity of pain (NRS), M ± SD		1.20 ± 2.10	3.51 ± 2.99	-7.96***
Intensity of itching (NRS), M ± SD		2.40 ± 2.83	5.57 ± 2.85	-9.96***
Intensity of burning (NRS), M ± SD		1.65 ± 2.50	4.14 ± 3.13	-7.83***
Sexual frequency [GenPS-SFQ item 1] [a], n (%)	None/zero	52 (32.7%)	70 (43.5%)	2.53
	Once, two or more	92 (57.9%)	85 (52.8%)	
	Missing	15 (9.4%)	6 (3.7%)	
Limitation in sexual activity [GenPS-SFQ item 2] [b], n (%)	Never/rarely	125 (78.6%)	82 (50.9%)	42.51***
	Sometimes/ often/ always	17 (10.7%)	72 (44.7%)	
	Missing	17 (10.7%)	7 (4.3%)	
QoL impairments [DLQI], M ± SD		4.09 ± 5.65	10.79 ± 7.28	-9.14***
Perceived stigmatization [PSQ], M ± SD		0.90 ± 0.59	1.14 ± 0.62	-3.55***
Sexual impairments [RSS], M ± SD		14.57 ± 5.36	18.94 ± 6.47	-6.36***

DLQI: Dermatology Life Quality Index (range 0-30); GenPS-SFQ: Genital Psoriasis Sexual Frequency Questionnaire; NRS: numeric rating scale (range 0-10); PASI: Psoriasis Area and Severity Index (range 0-72); PSQ: Perceived Stigmatization Questionnaire (range 0-4); RSS: Relationship and Sexuality Scale (range 0-36).

[a] In the past week, how many times did you engage in sexual activity?; [b] In the past week, how often did your genital psoriasis limit the frequency of your sexual activity?

Chi-square tests for categorical variables/ independent samples t-tests for continuous variables. *p < 0.05; **p < 0.01; ***p < 0.001, two-tailed.

Table 2 | Regression analyses explaining the variance in functional, social and sexual impairments.

	QoL impairments [DLQI]		Perceived stigmatization [PSQ]		Sexual impairments [RSS]	
	ß	t	ß	t	ß	t
Step1: Socio-demographic characteristics	$\Delta R^2 < 0.01$ $\Delta F_{2,280} = 0.44$		$\Delta R^2 = 0.01$ $\Delta F_{2,277} = 0.68$		$\Delta R^2 = 0.02$ $\Delta F_{2,274} = 2.35$	
Age	< -0.01	-0.03	-0.07	-1.12	**0.12**	**2.07***
Gender [a]	0.06	0.93	0.01	0.20	0.05	0.85
Step 2: Clinical features	$\Delta R^2 = 0.39$ $\Delta F_{8,272} = 21.90^{***}$		$\Delta R^2 = 0.16$ $\Delta F_{8,269} = 6.18^{***}$		$\Delta R^2 = 0.20$ $\Delta F_{8,266} = 8.72^{***}$	
Disease severity [PASI]	**0.40**	**7.36*****	**0.32**	**4.92*****	**0.28**	**4.46*****
Disease duration	-0.04	-0.71	0.11	1.65	-0.08	-1.17
Biologic treatment [b]	-0.05	-0.89	0.03	0.49	0.10	1.47
Conventional systemic treatment [b]	0.08	1.50	-0.06	-1.01	-0.05	-0.80
Topical treatment [b]	0.05	0.94	-0.01	-0.13	**0.15**	**2.44***
Phototherapy [b]	0.02	0.30	0.07	1.21	-0.03	-0.55
Anogenital involvement [b]	**0.22**	**3.99*****	0.09	1.40	**0.23**	**3.66*****
Comorbidities [b]	**0.14**	**2.73****	0.04	0.57	0.05	0.79
Step 3: Patient-reported symptoms	$\Delta R^2 = 0.28$ $\Delta F_{5,267} = 44.93^{***}$		$\Delta R^2 = 0.08$ $\Delta F_{5,264} = 5.50^{***}$		$\Delta R^2 = 0.32$ $\Delta F_{5,261} = 35.49^{***}$	
Intensity of pain	0.06	1.05	0.01	0.15	-0.01	-0.09
Intensity of itching	**0.19**	**2.76****	0.05	0.44	0.14	1.64
Intensity of burning	**0.31**	**4.55*****	0.15	1.38	0.01	0.05
Sexual frequency [GenPS-SFQ item 1] [c]	-0.05	-1.45	-0.01	-0.25	**-0.42**	**-9.56*****
Limitation in sexual activity [GenPS-SFQ item 2] [d]	**0.23**	**5.49*****	**0.22**	**3.45****	**0.37**	**7.55*****
Model summary	$R^2 = 0.67$ $F_{15,267} = 36.26^{***}$		$R^2 = 0.24$ $F_{15,264} = 5.52^{***}$		$R^2 = 0.54$ $F_{15,261} = 20.13^{***}$	

DLQI: Dermatology Life Quality Index; GenPS-SFQ: Genital Psoriasis Sexual Frequency Questionnaire; PASI: Psoriasis Area and Severity Index; PSQ: Perceived Stigmatization Questionnaire; RSS: Relationship and Sexuality Scale.

[a] 0 = male, 1 = female; [b] 0 = no, 1 = yes; [c] 0 = none/zero, 1 = once, two or more; [d] 0 = never/rarely, 1 = sometimes/ often/ always.

Hierarchical linear regression analyses. $^{*}p < 0.05$; $^{**}p < 0.01$; $^{***}p < 0.001$, two-tailed.

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Abstract N°: 4140

Effectiveness of Secukinumab Among Chinese Adult Patients with Moderate Plaque Psoriasis: Interim Results from the UNMASK2 Study

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease. 35.8% of psoriasis patients were diagnosed as moderate psoriasis[1]. Moderate patients may have high systemic inflammation severity and comorbidity risks[2, 3]. However,

the treatment needs are usually underestimated due to current severity classification[4]. Secukinumab has demonstrated sustained efficacy with a favourable safety profile for treating moderate-to-severe plaque psoriasis. But the evidence specifically for moderate psoriasis is still limited. This analysis aims to evaluate the effectiveness of secukinumab for moderate psoriasis in China.

Materials & Methods:

UNMASK2 is a large, ongoing, prospective, observational study conducted at 42 sites in China. The study recruited adult patients with moderate-to-severe plaque psoriasis and initiating secukinumab treatment from December 2021 to October 2022. Patients who completed the week 16 visit or exited study prior to week 16 by February 3rd, 2023, were included in this analysis. Moderate psoriasis was defined as patients with body surface area (BSA) ≥3% and <10%[5]. The endpoints included psoriasis area and severity index (PASI), investigator's global assessment (IGA), BSA and dermatology life quality index (DLQI).

Results:

A total of 135 patients were included with mean (SD) age of 38.32 (12.26) years at baseline. The baseline PASI was (mean ± SD) 9.2 ± 4.54, IGA was (mean ± SD) 3.0 ± 0.50, BSA was (mean ± SD) 6.5 ± 1.89 and DLQI was (mean ± SD) 10.8 ± 6.49. After 4 weeks treatment, PASI75, PASI90 and PASI100 were achieved in 49.58%, 21.01% and 11.76% patients, respectively. And the PASI75, PASI90 and PASI100 reached 93.14%, 83.33% and 69.61% at week 16 (Figure 1). The proportions of patients achieving PASI≤3 and PASI≤1 were 61.34% and 30.25% at week 4, 93.33% and 77.14% at week 12, 97.06% and 85.29% at week 16. IGA 0/1 were achieved in 41.67%, 83.81% and 87.74% patients at week 4, week 12 and week 16 respectively. The mean changes of BSA from baseline were -2.8 at week 4 (P<0.001), -5.4 at week 12 (P<0.001) and -6.1 at week 16 (P<0.001). There were 28.33% patients achieving BSA≤1% at week 4, 76.92% at week 12, and 87.74% at week 16. Similar trend was observed for BSA≤3% (53.33%, 89.42%, 95.28%). In addition, 33.05%, 59.05% and 67.89% patients achieved DLQI 0/1 response at week 4, week 12 and week 16, respectively (Table 1).

Conclusion:

This study is the first real-world study of secukinumab in Chinese moderate psoriasis patients. The high baseline DLQI indicates strong treatment needs for patients with limited skin lesion. The results show secukinumab can rapidly improve moderate psoriasis patients' disease severity and quality of life at week 4 and continuously improve these clinical outcomes up to week 16. In summary, this analysis demonstrates that secukinumab is an effective treatment for moderate psoriasis patients in China.

Table 1. Clinical Outcomes of PASI, IGA, BSA and DLQI at Week 4, Week 12 and Week 16

	Week 4	Week 12	Week 16
PASI change from baseline, mean (SD)	-6.6 (4.40)****	-8.9 (4.73)****	-9.0 (4.59)****
PASI, n/N (%)			
≤1	36/119 (30.25)	81/105 (77.14)	87/102 (85.29)
≤2	55/119 (46.22)	95/105 (90.48)	93/102 (91.18)
≤3	73/119 (61.34)	98/105 (93.33)	99/102 (97.06)
≤5	97/119 (81.51)	103/105 (98.10)	102/102 (100.00)
IGA 0/1 response, n/N (%)	50/120 (41.67)	88/105 (83.81)	93/106 (87.74)
BSA change from baseline, mean (SD)	-2.8 (4.02)****	-5.4 (2.44)****	-6.1 (2.11)****
BSA, n/N (%)			
≤1%	34/120 (28.33)	80/104 (76.92)	93/106 (87.74)
≤3%	64/120 (53.33)	93/104 (89.42)	101/106 (95.28)
DLQI change from baseline, mean (SD)	-6.3 (6.00)****	-8.5 (6.82)****	-9.0 (6.39)****
DLQI 0/1 response, n/N(%)	39/118 (33.05)	62/105 (59.05)	74/109 (67.89)

N, the number of patients with non-missing data; n, the number of patients achieving specific endpoint; SD, standard deviation; ****, P<0.0001

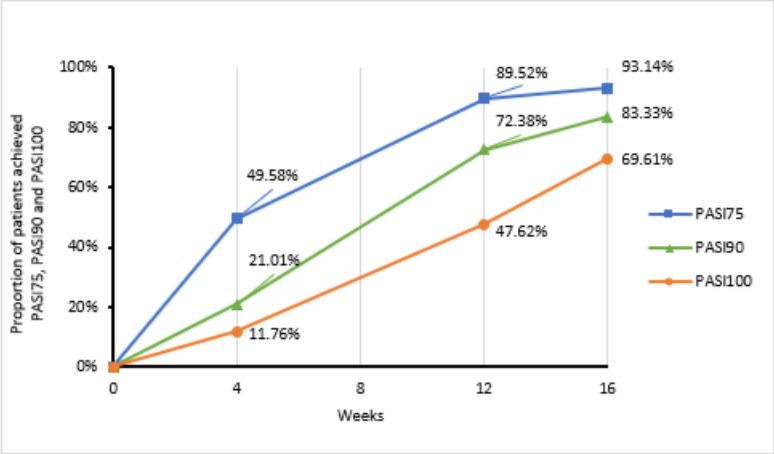

Figure 1. Proportions of Chinese Adult Patients with Moderate Plaque Psoriasis Achieving PASI75, PASI90 and PASI100 at Week 4, Week 12 and Week 16

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Abstract N°: 4141

Disease burden and patient-defined treatment needs and benefits in patients with psoriasis with and without anogenital involvement

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Introduction & Objectives:

Clinical decisions are routinely based on the Psoriasis Area and Severity Index (PASI) and the Dermatology Life Quality Index (DLQI). However, these instruments do not capture the additional burden of anogenital psoriasis and the specific needs of these patients, particularly in terms of their interpersonal and sexual relationships. This study aimed (1) to compare patient-reported outcomes (PROs) of disease burden between patients with psoriasis with and without anogenital involvement; (2) to identify the specific treatment needs of patients with anogenital psoriasis; and (3) to examine which clinical and psychosocial variables contribute to more patient-defined treatment benefits.

Materials & Methods:

The PsoGen study had a cross-sectional case-control design. Patients aged ≥18 years, with moderate to severe psoriasis vulgaris, were recruited in four German dermatology centres. Disease characteristics, including current involvement of the anal and/or genital body area(s), were reported by the physicians. The patients reported on their quality of life (QoL) impairments, perceived stigmatization, sexual impairments, and treatment needs and benefits.

Results:

Participants were 320 patients with psoriasis (age = 42.6±14.0 years; 67.2% male), of which 161 (50.3%) had anogenital lesions. Comparative analyses showed that patients with anogenital involvement had higher disease burden, both in terms of clinical indicators (e.g., disease severity, comorbidities; Table1), but also in terms of QoL and sexual impairments (Table 2). However, they were less often treated with biologics, more often treated with conventional systemic drugs, topical therapy and phototherapy (Table 1), and reported less patient-defined treatment benefits (Table 2). The analysis of patient needs by subscale yielded no significant differences between the groups (Table 2), but the individual analyses revealed that patients with anogenital psoriasis rated the needs to “be free of itching”, “sleep better”, “be less burdened in your partnership”, “be able to have a normal sex life”, and “need less time for daily treatment” as more important (Figure 1). Regression analysis (Table 3) explained 55% of the variance in patient benefits. Specifically, more patient benefits were associated with lower severity of psoriasis and of anogenital lesions, being treated with biologic agents and not with conventional systemic drugs, less DLQI impairments, higher perceived stigmatization, and no anogenital involvement.

Conclusion:

The higher disease burden and the lower treatment benefits in patients with anogenital psoriasis highlight the utmost importance of considering the specific patient needs in clinical decisions, sideways with disease severity

and functional impairments. Several biologic systemic drugs, namely IL-17 and IL-23 inhibitors, have demonstrated efficacy, not only regarding the clearance of the genital lesions, but also in reducing sexual limitations.

Table 1 | Comparison of sociodemographic and clinical characteristics between patients with psoriasis with and without anogenital involvement.

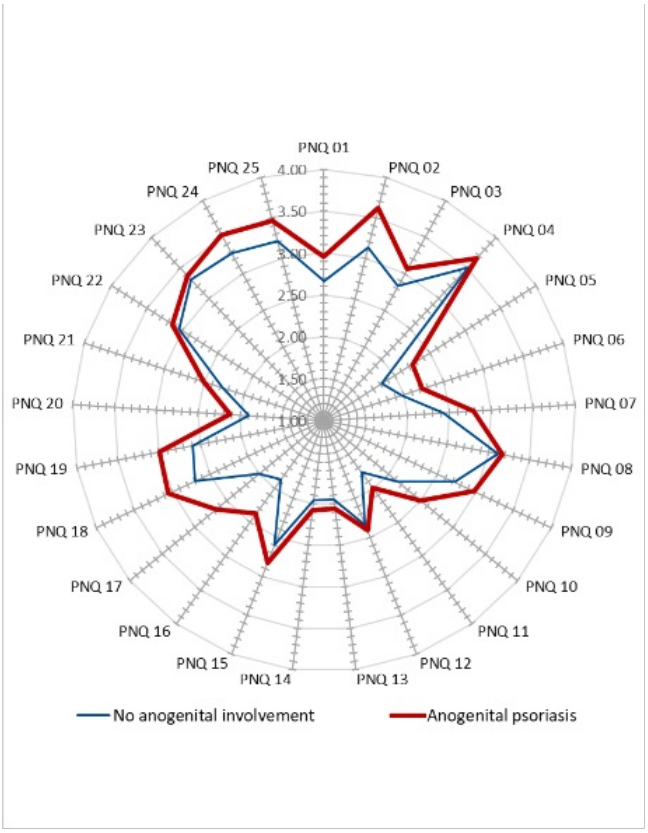
		No anogenital involvement (n = 159)	Anogenital psoriasis (n = 161)	χ^2/ t
Socio-demographic characteristics				
Age (years), M ± SD		42.48 ± 14.61	42.73 ± 13.43	-0.16
Gender, n (%)	Male	111 (69.8%)	104 (64.6%)	0.99
	Female	48 (30.2%)	57 (35.4%)	
Clinical characteristics				
Disease severity [PASI], M ± SD		2.55 ± 4.60	7.57 ± 6.88	-7.66***
Severity of anogenital lesions [sPGA-G], M ± SD		0.11 ± 0.31	2.30 ± 0.95	-27.63***
Disease duration (years), M ± SD		19.70 ± 14.00	18.73 ± 13.78	0.62
Treatment, n (%)	Biologic	119 (74.8%)	72 (44.7%)	30.17***
	Conventional systemic	19 (11.9%)	41 (25.5%)	9.59**
	Topical	67 (42.1%)	106 (65.8%)	18.09***
	Phototherapy	5 (3.1%)	31 (19.3%)	20.79***
Comorbidities (yes), n (%)		73 (45.9%)	100 (62.1%)	8.45**

PASI: Psoriasis Area and Severity Index (range 0-72); sPGA-G: Static Physician's Global Assessment of Genitalia (range 0 = clear to 5 = very severe).
Chi-square tests for categorical variables/ independent samples t-tests for continuous variables. *p < 0.05; **p < 0.01; ***p < 0.001, two-tailed.

Table 2 | Comparison of disease burden and patient-defined needs and treatment benefits between patients with psoriasis with and without anogenital involvement.

	No anogenital involvement (n = 159)	Anogenital psoriasis (n = 161)	F
PROs of disease burden			
QoL impairments [DLQI], M ± SD	4.09 ± 5.65	10.79 ± 7.28	23.38***
Perceived stigmatization [PSQ], M ± SD	0.90 ± 0.59	1.14 ± 0.62	2.50
Sexual impairments [RSS], M ± SD	14.57 ± 5.36	18.94 ± 6.47	16.50***
Patient needs [PNQ][a]			
Reducing physical impairments, M ± SD	2.80 ± 1.15	3.12 ± 0.88	2.45
Reducing psychological impairments, M ± SD	2.33 ± 1.37	2.59 ± 1.24	0.19
Reducing social impairments, M ± SD	2.04 ± 1.41	2.36 ± 1.25	1.12
Reducing impairments due to therapy, M ± SD	2.36 ± 1.31	2.69 ± 1.04	1.79
Having confidence in healing, M ± SD	3.17 ± 1.16	3.24 ± 1.05	0.03
Patient benefits [PBI], M ± SD	**3.10 ± 1.05**	**2.01 ± 1.24**	**19.90*** **

DLQI: Dermatology Life Quality Index (range 0-30); PBI: Patient Benefit Index (range 0-4); PNQ: Patient Needs Questionnaire (range 0-4); PSQ: Perceived Stigmatization Questionnaire (range 0-4); RSS: Relationship and Sexuality Scale (range 0-36).
[a] Multivariate analysis of covariance: Wilks' Lambda = 0.98, F(5, 298) = 1.06, p = 0.382.
F: Univariate analysis of covariance, controlling for disease severity, treatment and presence of comorbidities. *p < 0.05; **p < 0.01; ***p < 0.001, two-tailed.



As a result of therapy, how important is it for you to...		Z
PNQ 01	... be free of pain	-1.23
PNQ 02	... be free of itching	-2.89**
PNQ 03	... no longer have burning sensations on your skin	-1.29
PNQ 04	... be healed of all skin defects	-0.87
PNQ 05	... sleep better	-2.33*
PNQ 06	... feel less depressed	-1.37
PNQ 07	... experience greater enjoyment of life	-1.61
PNQ 08	... have no fear that the disease will get worse	-0.41
PNQ 09	... lead a normal everyday life	-1.15
PNQ 10	... be more productive in everyday life	-1.75
PNQ 11	... be less of a burden to relatives and friends	-1.32
PNQ 12	... engage in normal leisure activities	-0.19
PNQ 13	... be able to lead a normal working life	-0.50
PNQ 14	... be able to have more contact with other people	-0.59
PNQ 15	... be more comfortable showing yourself in public	-0.99
PNQ 16	... be less burdened in your partnership	-2.57**
PNQ 17	... be able to have a normal sex life	-3.21***
PNQ 18	... be less dependent on doctor and clinic visits	-1.76
PNQ 19	... need less time for daily treatment	-2.23*
PNQ 20	... have fewer out-of-pocket treatment expenses	-1.23
PNQ 21	... have fewer side effects	-0.88
PNQ 22	... find a clear diagnosis and therapy	-0.38
PNQ 23	... have confidence in the therapy	-0.28
PNQ 24	... get better skin quickly	-1.91
PNQ 25	... regain control of the disease	-0.83

PNQ: Patient Needs Questionnaire.
Z: Z-score for non-parametric Mann-Whitney U tests. *p < 0.05; **p < 0.01; ***p < 0.001, two-tailed.

Figure 1 | Pattern of specific patient needs comparing patients with psoriasis with and without anogenital involvement.

Table 3 | Regression analyses explaining the variance in patient-defined treatment benefits [PBI]‡.

	Step 1: Covariates		Step 2: Disease burden		Step 3: Anogenital involvement		Step 4: Interaction effects	
	ß	t	ß	t	ß	t	ß	t
Age	0.08	1.13	0.08	1.28	0.08	1.29	0.08	1.29
Gender [a]	-0.01	-0.20	0.01	0.16	0.00	0.00	-0.01	-0.15
Disease severity [PASI]	-0.21	-2.94**	-0.10	-1.55	-0.15	-2.19*	-0.16	-2.35*
Severity of anogenital lesions [sPGA-G]	-0.15	-2.07*	-0.06	-0.89	0.17	1.61	0.17	1.53
Disease duration	0.13	1.96	0.10	1.57	0.09	1.56	0.11	1.78
Biologic treatment [b]	0.27	4.11***	0.24	3.85***	0.23	3.76***	0.21	3.54***
Conventional systemic treatment [b]	-0.16	-2.75**	-0.10	-1.96	-0.10	-1.94	-0.11	-2.08*
Topical treatment [b]	-0.06	-0.99	-0.03	-0.58	-0.05	-0.88	-0.05	-0.84
Phototherapy [b]	0.01	0.16	0.03	0.59	0.05	0.83	0.02	0.44
Comorbidities [b]	-0.09	-1.65	-0.03	-0.63	-0.03	-0.51	-0.04	-0.73
QoL impairments [DLQI]			-0.45	-6.47***	-0.44	-6.41***	-0.48	-4.78***
Perceived stigmatization [PSQ]			0.15	2.55*	0.16	2.76**	0.09	1.24
Sexual impairments [RSS]			-0.05	-0.89	-0.03	-0.54	-0.08	-0.95
Anogenital involvement [b]					-0.26	-2.76**	-0.24	-2.39*
DLQI * Anogenital							0.02	0.24
PSQ * Anogenital							0.13	1.75
RSS * Anogenital							0.05	0.67
Model summary	$\Delta R^2 = 0.40$ $\Delta F_{10, 211} = 14.01^{***}$		$\Delta R^2 = 0.12$ $\Delta F_{3, 208} = 17.29^{***}$		$\Delta R^2 = 0.02$ $\Delta F_{1, 207} = 7.64^{**}$		$\Delta R^2 = 0.01$ $\Delta F_{3, 204} = 1.99$	
Total model summary	$R^2 = 0.55$ $F_{17, 204} = 14.63^{***}$							

PBI: Patient Benefit Index; DLQI: Dermatology Life Quality Index; PASI: Psoriasis Area and Severity Index; PSQ: Perceived Stigmatization Questionnaire; RSS: Relationship and Sexuality Scale; sPGA-G: Static Physician's Global Assessment of Genitalia.

‡ The PBI was computed from the arithmetic mean of all rated patient benefit items (i.e., Patient Benefit Questionnaire), weighted by the relative importance of each corresponding patient needs items (i.e., Patient Needs Questionnaire), ranging from 0 (no benefit) to 4 (maximum benefit).

[a] 0 = male, 1 = female; [b] 0 = no, 1 = yes.

* p < 0.05; ** p < 0.01; *** p < 0.001, two-tailed.

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Abstract N°: 4143

Real-world patient characteristics and prior treatment history of bimekizumab patients in Germany

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Introduction & Objectives

Bimekizumab (BKZ), a dual interleukin (IL)-17A/F inhibitor,1 became accessible to patients with moderate to severe plaque psoriasis in Germany in September 2021. Whilst case studies show BKZ is efficacious in a real-world setting,2 no data describing the profile of patients treated with BKZ in clinical practice are available. Hence, patient characteristics and treatment history of new BKZ users in Germany are reported here.

Materials & Methods

This longitudinal, observational cohort study used data from a German database of nationwide prescription data provided by Insight Health, claiming a coverage of 77% of the publicly insured German population (i.e., 64 million patients), and included adults who started BKZ treatment between 1 September 2021 and 31 December 2022.

A 33-month lookback period prior to first BKZ prescription was used to describe treatment history, including use of biologics, nonbiologic systemic treatments, and history of treatment switch (biologics and apremilast only). Treatments proximal to first BKZ index (in 1 month prior) were also assessed. Nonpsoriasis treatment history in the 12 months prior was described for key therapeutic classes.

Results

From the database, 1,002 patients were included who received their first BKZ prescription in the specified period. The mean age was 48.6 years; 53.5% were identified as male (**Table**). The most common specialties prescribing BKZ were dermatologists (73.1%) and ambulatory clinics (25.0%).

In the 12 months prior to first BKZ prescription, 10.8% of patients had also received a prescription for an antidiabetic treatment, 14.5% a lipid-modifying treatment, and 12.6% an antidepressant (**Table**).

Proximal to first BKZ prescription, 30.7% of patients received a prescription for a topical treatment, 2.1% an oral corticosteroid, 2.8% a conventional systemic non-biologic psoriasis treatment and 0.2% apremilast (**Table**). In the 33 months prior to first BKZ prescription, 48.5% had received a biologic therapy; the most common prior biologic classes were IL-17 (28.9%), IL23 (21.1%), and tumour necrosis factor (14.9%) inhibitors. Prior systemic therapies are reported in the **Table**.

Among patients with prior use of a biologic/apremilast (n=531), 36.2% had switched their biologic/apremilast treatment at least once and 10.0% at least twice. Of the patients with prior biologic/apremilast use, 24.3% were not exposed to any biologics besides IL-17 inhibitors prior to first BKZ prescription, and 17.3% were not exposed to any biologics besides IL-23 inhibitors.

Conclusion

The mean age of the patients identified via the database was largely aligned with that of the populations enrolled in BKZ in plaque psoriasis phase 3/3b clinical trials.3,4

The heterogeneity of prior biologic therapy and treatment switch profiles suggests there is no consistent profile of patients prescribed BKZ in clinical practice. Approximately half of all patients were biologic-naïve or had not received prior non-biologic systemic treatments, suggesting that BKZ is often used as a firstline therapy. Notable proportions of patients received nonpsoriasis therapies prior to BKZ index, potentially reflecting the prevalence of comorbidities in this population.

References

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Funding

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Table. Patient characteristics and treatment history

	Study cohort (N=1,002)
Age (years), mean (SD)	48.6 (14.3)
Gender,[a] n (%)	
Male	536 (53.5)
Female	374 (37.3)
Unknown/missing	92 (9.2)
Proximal[b] prior non-biologic treatment for psoriasis, n (%)	
Any non-biologic systemic treatment	51 (5.1)
Apremilast	2 (0.2)
Conventional systemic	28 (2.8)
Acitretin	4 (0.4)
Ciclosporin	5 (0.5)
Fumarate	7 (0.7)
Methotrexate	12 (1.2)
Oral corticosteriods	21 (2.1)
Any topical treatment	308 (30.7)
Prior biologic treatment for psoriasis,[c] n (%)	
Any	486 (48.5)
Anti-IL-12/23	42 (4.2)
Anti-IL-17	290 (28.9)
Anti-IL-23	211 (21.1)
Anti-TNF	149 (14.9)
Prior non-biologic systemic treatment for psoriasis,[c] n (%)	
Any	493 (49.2)
Apremilast	72 (7.2)
Conventional systemic	342 (34.1)
Oral corticosteroids	194 (19.4)
Prior treatment switch (biologic or apremilast only),[c] n (%)	
Any	531 (53.0)
≥1 prior switch	192 (36.2)[d]
≥2 prior switches	53 (10.0)[d]
Prior non-psoriasis treatments,[e] n (%)	
Any	303 (30.2)
Antidepressants	126 (12.6)
Antidiabetics	108 (10.8)
Antihypertensives	16 (1.6)
Anxiolytics	19 (1.9)
Lipid-modifying agents	145 (14.5)

[a] Gender was estimated by pharmacy coding centers based on first name; [b] In 1 month prior to first BKZ prescription; [c] In the 33 months prior to first BKZ prescription; [d] Percentage of those with a prior treatment switch (n=531); [e] In the 12 months prior to first BKZ prescription.
BKZ: bimekizumab; IL: interleukin; SD: standard deviation; TNF: tumour necrosis factor.

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Abstract N°: 4156

Prevalence of comorbidities among patients using biologic agents for psoriasis in the ABC region of São Paulo – Brazil

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Introduction:

Psoriasis is a chronic inflammatory skin disease characterized by scaly indurated erythema. It has been recognized not only as a skin disease but as a systemic disease.

Recently, "psoriatic march", the concept of a causal link between psoriasis and cardiovascular disease, has been recognized. Systemic inflammation may cause insulin resistance, which in turn triggers endothelial cell dysfunction, leading to atherosclerosis and finally myocardial infarction or stroke.

Other articles indicated that obesity is associated with the onset, exacerbation, and intractability of psoriasis. The severity of psoriasis is still correlated with high blood glucose levels, and anti-IL-17A monoclonal antibody therapy reduced HbA1c levels significantly in these patients.

Given this context, it is important to describe the prevalence of hypertension, diabetes and dyslipidemia in patients with severe psoriasis that are in use of biologic agents in Dermatological reference service in Brazil.

Materials & Methods:

The research was conducted at the Dermatology service, a reference in the public health system in the region, where monthly are seen between 1345 and 1897 patients. We analysed 238 patients with moderate to severe psoriasis in use of biologic agents in the month of April 2023.

Results:

In one of the outpatient clinics for patients using Biologics for psoriasis, there are a total of 238 patients. Of these, 65 patients (27.3%) use medication for systemic arterial hypertension, 50 (21%) are being treated for insulin resistance and 48 (20.1%) use medication for dyslipidemia.

Conclusion:

According to World Health Organization statistics, while the prevalence of coronary artery disease and vascular lesions is greatest in diabetes and hypertension, mortality is highest with psoriasis. This may be because diabetes and hypertension are commonly recognized as risk factors for vascular lesions, so patients and physicians proactively seek and provide treatment, whereas psoriasis is not generally known as a risk factor for vascular lesions, and is therefore often untreated or overlooked.

A recent cohort study from the UK found that patients with moderate to severe psoriasis have lifespans around 6 years shorter than those of healthy individuals, and this is postulated to be due to cardiovascular pathologies (myocardial or cerebral infarction) caused by inflammation.

In 2019, the Ministry of Health outlined the profile of Brazilians in relation to the most common chronic diseases in the country: 7.4% have diabetes and 24.5% have hypertension. It is worrying, therefore, to compare these data

with those found among our patients with psoriasis using biologic agents, among which there is a higher prevalence of hypertension, diabetes and dyslipidemia.

Patients with psoriasis exhibit decreased high-density lipoprotein (HDL) levels and/or increased low-density lipoprotein (LDL). HDL has a reverse cholesterol transport function, anti-oxidative capacity, and anti-inflammatory properties. However, these properties are reduced during chronic inflammation, such as psoriasis. Conversely, anti-psoriatic therapy restores the composition and function of HDL.

Psoriasis is a systemic inflammatory disease with many complications, particularly metabolic syndrome. Among these, cardiovascular disease has been found to be the most important. While some biologics have been found to be effective in the treatment of them, we need to continue accumulating long-term case data.

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Abstract N°: 4164

White blood cell differential count reversal in psoriatic patients treated with biologicals

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White blood cell differential count reversal in psoriatic patients treated with biologicals

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Introduction & Objectives:

The widespread use of biological drugs among psoriatic and psoriatic arthritis patients has led to the gradual identification of unexpected side effects due to these drugs, including haematological alterations (eg. monoclonal gammopathy). Since biologicals are able to modulate the activity of inflammatory cells, mainly neutrophils, we investigated the impact of these drugs on white blood cell (WBC) differential count.

Materials & Methods:

Through a retrospective chart review, we examined the WBC differential count trend in 219 psoriatic and psoriatic arthritis patients during biologic treatment.

Results:

Notably, we found that 11 (6 males, 5 females) out of 219 (5%) patients gradually developed an inversion of the neutrophil to lymphocyte ratio (NLR). All these patients had a positive NLR value at baseline (mean value 1.5; SD 0.42); after 6 months of biological treatment, 8 patients had developed a WBC differential count reversal; two patients started showing inverted values from the twelfth month of treatment, and one patient developed a NLR<1 after 12 months of therapy. In all eleven patients once the WBC differential count reversal had developed, it was maintained for at least 2 years. Notably, all these patients were treated with tumor necrosis fator-alpha (TNF-α) antagonists (6 patients adalimumab, 5 patients etanercept) and none of the patients treated with other biologicals showed a similar NLR modification.

Conclusion:

NLR is an easily calculable, inexpensive, and accessible value which has been proposed as an index of subclinical systemic inflammation. Systemic therapies used in psoriasis showed to be able to reduce NLR; interestingly, Tumor Necrosis Factor alpha (TNF-α) antagonists have been shown to determine a greater reduction in NLR than interleukin (IL)-12/23 antagonists. This evidence suggests that WBC differential count values are heavily influenced by TNF-α pathway and, substantially, this is consistent with our findings. The WBC differential count reversal, that we observed in 11 out of 219 patients

treated with biologicals, might represent an amplification of the reported TNF- α antagonists' effect.

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Abstract N°: 4165

Damage to vascular innervation and functionality after hyperthermia and pulsed dye laser treatment

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Introduction & Objectives

Pulsed dye laser (PDL) treatment has proven effective in repressing specific forms of psoriasis and holds promise for managing other inflammatory skin conditions. However, the exact mechanism by which PDL treatment achieves its therapeutic effects remains unclear. Partial denervation results in remission of psoriasis, with a return of symptoms upon nerve lesion healing. It is becoming more accepted that neurogenic inflammation plays a role in psoriasis. One hypothesis is that reduced nerve activity in the skin may explain why thermal treatments aid in the remission of psoriasis. We recently published a review where we suggest a pathway on how PDL may target the (peri)vascular nerves in the skin. Through our continuous research, we aim to validate the hypothesis that hyperthermia causes nerve damage. At the EADV 2023 conference, we will show our findings from various research methodologies, including *in-vitro*, *ex-vivo*, *in-vivo*, and *in-silico* studies.

Materials & Methods

In vitro: We studied the thermal sensitivity of keratinocytes, endothelial, smooth muscle, and neuronal cells through exposure to hyperthermia (45–70 °C) for various time points (2-20 sec) after which viability was measured. *Ex-vivo:* Using wire myography, we tested three essential cell types in blood vessels: endothelial, smooth muscle cells, and vascular nerves. Blood vessels were exposed to hyperthermia (45–65°C) and cell-specific functionality was assessed before and after hyperthermia. *In vivo:* We obtained pre- and post-PDL treatment biopsies from psoriasis patients and conducted staining for tissue innervation, vascularization, and immune cells. Advanced imaging software generated 3D skin reconstructions that were also used in *in-silico* modeling of heat distribution in the skin during PDL.

Results

Both our *in-vitro* and *ex-vivo* data show that cell damage occurs, and blood vessel functionality decrease after exposure to 55-60°C, and neuronal cells and keratinocytes are more susceptible to hyperthermia than blood vessel-specific cells such as endothelial cells. Our *in-silico* modeling shows that heat dissipates to the perivascular spaces, reaching temperatures of 55°C and higher. Analysis of in-vivo biopsy data is underway and will be presented at the EADV(fig. 1). Our presentation will highlight the treatment-induced changes in vascular and innervation patterns, along with the variations in immune cell populations, observed in skin biopsies of patients pre- and post-treatment. We will show correlations between treatment outcomes and morphology of the vasculature and innervation of the psoriatic skin.

Conclusion

We have strong evidence that supports our hypothesis that PDL treatment heats not only the blood vessels but also causes thermal damage to the perivascular spaces where nerves reside. This understanding is crucial for the optimization and use of PDL treatment in the future.

Figure 1 Representative image of psoriatic skin (a.) stained for endothelial cells (CD31) in red (b.), and neuronal marker (PGP9.5) in green (c.). Psoriatic skin shows dense innervation of the epidermis by free nerve endings as well as perivascular innervation of the papillary vasculature (d.). Scalebar indicates 100 µm.

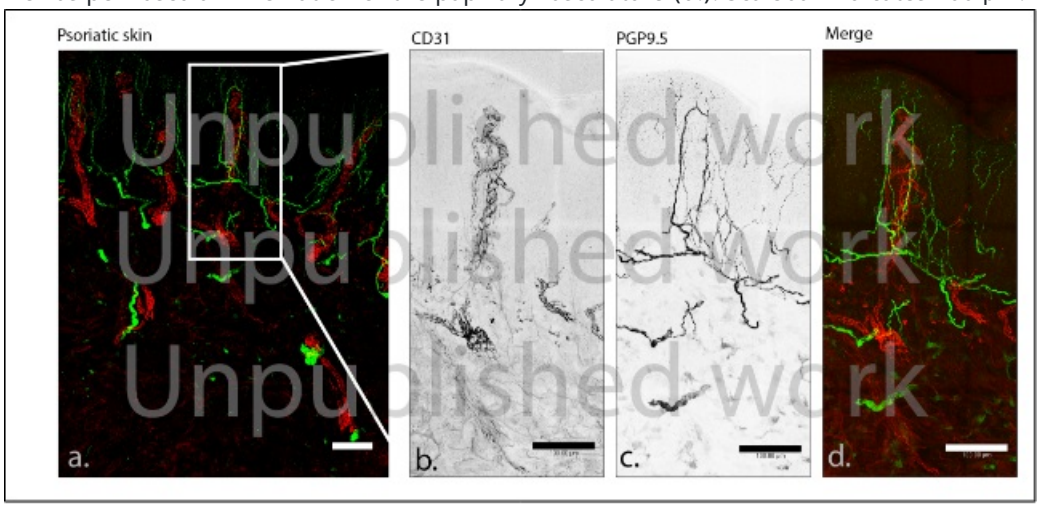

Figure 1 Representative image of psoriatic skin (a.) stained for endothelial cells (CD31) in red (b.), and neuronal marker (PGP9.5) in green (c.). Psoriatic skin shows dense innervation of the epidermis by free nerve endings as well as perivascular innervation of the papillary vasculature (d.). Scalebar indicates 100 µm.

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Abstract N°: 4181

Prevalence of HLA-B27 in patients with psoriasis and psoriatic arthritis

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Introduction & Objectives:

HLA-B27 is the one of important genetic biomarker of psoriatic arthritis, providing phenotypic differentiation in the patient population. According to the literature, HLA-B27 positive status correlates with a severe psoriatic arthritis** phenotype characterized by early onset of arthritis and severe damage to peripheral joints. In the Russian population, the prevalence of HLA-B27 has been described only for patients with psoriatic arthritis. The study of the prevalence of HLA-B27 in patients with psoriasis will help assess the feasibility of considering the carriage of various HLA-B27 alleles as a possible genetic predictor for the development of psoriatic arthritis.** The aim of the study is to investigate the prevalence of HLA-B27 in patients with psoriasis with and without joint involvement in Russian Federation.

Materials & Methods:

An open, uncontrolled study was conducted. 127 patients with plaque psoriasis were enrolled in the study (78 men, 49 women; mean ± SD age 39.04 ± 15.20 years, range 18-86). Mean PASI was 14.69 ± 11.12 (range 0.6-59.2). Mild severity of psoriasis was recorded in 34 (26.7%) patients, moderate - in 64 (50.5%), severe - in 29 (22.8%). 53 patients were diagnosed with psoriatic arthritis. Blood samples were collected from all 127 patients. HLA-B27 was detected by using an allele-specific polymerase chain reaction with real-time PCR product detection using linear degradable samples.

Results:

The prevalence of HLA-B27 in patients with psoriasis of varying severity and with and without joint damage was 10% (13 patients). Among patients with psoriatic arthritis, HLA-B27 positive status was found for 13% (7) patients, among patients without psoriatic arthritis – for 8% (6) patients. The frequency of HLA-B27 carriage did not depend on the gender of patients, amounting to 5.5% among women and 4.5% among men ($p>0.05$). It should be noted that for all 13 patients with a positive HLA-B27 status, the onset of psoriasis was noted on the scalp, nail psoriasis was observed only in 4 patients. Among patients with psoriatic arthritis and a positive status for HLA-B27, peripheral arthritis established in 6 patients, peripheral arthritis in combination with psoriatic spondylitis - in 1 patient. Early onset of arthritis and severe damage to the peripheral joints were found in 2 patients.

Conclusion:

Carriage of HLA-B27 is common throughout the world, but its frequency is not the same in different populations. According to the literature, in the natives of the Arctic and subarctic regions of Eurasia and North America, the carriage of HLA-B27 reaches 50%, while in the natives of Australia this figure is 0. The prevalence among healthy Europeans is up to 10%.

The next stage of the study is to expand the studied sample of patients and to determine the various HLA-B27 alleles in patients with psoriasis with and without joint damage in order to identify HLA-B27 alleles as a possible

genetic predictors for the development of psoriatic arthritis.

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 4187

Apremilast use in patients affected with psoriasis and primary biliary cholangitis

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Apremilast use in patients affected with psoriasis and primary biliary cholangitis

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Introduction & Objectives:

Primary biliary cholangitis (PBC) is a chronic, intrahepatic cholestatic, autoimmune disease with a variable progressive course. PBC can cause debilitating symptoms including fatigue and pruritus and, if untreated/misdiagnosed, is associated with a high risk of cirrhosis that can lead to liver failure, and death. The etio-pathogenesis has not been fully elucidated, and it is the result of complex interactions between genetic predisposition and environmental triggers leading to immune-mediated injury of biliary epithelial cells. Reduction of IL-10 levels and dysfunction of regulatory cells have been reported. Serum biomarkers of PBC are alkaline phosphatase (ALP) and glutamyl transpeptidase (GGT), positive antimitochondrial antibodies (AMA), and increased immunoglobulin M (IgM). Although there is no clear evidence of PBC as strict psoriasis comorbidity, the association between the two diseases is possible. Elevation of GGT in patients with psoriasis, besides the association with non-alcoholic fatty liver disease (NAFLD), should be properly investigated also to offer a correct therapeutic approach.

Materials & Methods:

We report three patients affected with moderate-to-severe psoriasis and PBC. All patients were treated with apremilast, an oral anti-PDE-4 approved for psoriasis and psoriatic arthritis, that has shown to modulate activity of regulatory B cells and to increase levels of IL-10. It has been also suggested that inhibition of PDE4 might be useful in preventing liver fibrosis, although preliminary studies on NAFLD and ALD (alcoholic liver disease) are not conclusive.

Results:

Safety data in psoriatic patients with special regard to concomitant PBC subgroup will be presented.

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Abstract N°: 4197

Ultra high frequency ultrasound imaging for the objective evaluation of nail psoriasis in patients treated with monoclonal antibodies

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Introduction & Objectives: Psoriatic onychopathy is one of the clinical presentations of psoriasis, whether or not associated with skin involvement. Changes in the nail apparatus are assessed by a purely clinical index, called NAil Psoriasis Score Index (NAPSI), and can sometimes result in a severe impact on the patient's quality of life. High-frequency ultrasonography (HFUS) has recently been used to evaluate the nail apparatus of healthy and psoriatic subjects.The aim of our study was to detect by means of ultra high-resolution ultrasonography (UHFUS) alterations of the nail bed and matrix in patients with psoriatic onychopathy and to monitor these parameters during the treatment with monoclonal antibody (mAb).

Materials & Methods: We enrolled 10 patients with psoriatic onychopathy and naive to previous biologic therapies. Patients were evaluated at baseline (t0), after 1 month (t1), after 3 months (t2), and after 6 months (t3) by a complete clinical assessment and US evaluation. An UHFUS examination with a 70 MHz probe was performed on the thumbnail (I), the index fingernail (II) and the nail with greater clinical impairment (W). The following measurements were analyzed: nail plate thickness (A), nail bed thickness (B), nail insertion length (C), nail matrix length (D) and nail matrix thickness (E).

Results: Among the various parameters analyzed, some measures showed statistically significant decrease with p-value <0.05 (t0 WA=0.52 mm vs. t2 WA=0.42 mm; t0 WB=2.8 mm vs. t2WB=2.4 mm; t0 WE=0.76 mm vs. t2 WE=0.64 mm; t0 IIA=0.49 mm vs. t2 IIA=0.39 mm). The other parameters showed a decreasing trend (measures IA, IB; IE, IIB, IIE) or an increasing trend (measures IC,ID, IIC, IIE, WC, WD) during the treatment.

Conclusion: In conclusion, UHFUS could represent a viable imaging technique for the evaluation and monitoring of psoriatic onychopathy. It is a repeatable, noninvasive exam that allows real-time assessment of the nail apparatus, thus supporting the clinical parameters and revealing any subclinical signs of early drug response, even before they are actually clinically detectable.

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Abstract N°: 4204

Bimekizumab 3-year maintenance of response in Week 16 responders with moderate to severe plaque psoriasis: Results from five phase 3/3b trials

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Introduction & Objectives:

As psoriasis is a chronic disease and losses of response are observed with some therapies over time, studying longterm efficacy of new treatments is important.1 As previously reported, a high proportion of moderate to severe psoriasis patients who achieved disease control after 16 weeks of bimekizumab (BKZ) 320 mg every 4 weeks (Q4W) maintained responses through 3 years of treatment.2 Here, maintenance of response over 3 years is reported in patients who achieved complete/nearcomplete skin clearance after 16 weeks of BKZ treatment, using the largest available data pool from five phase 3/3b trials.

Materials & Methods:

Data were pooled from the 52-week BE VIVID, 56-week BE READY, and 56-week BE SURE phase 3 trials, 96 weeks of their ongoing open-label extension (OLE), BE BRIGHT, as well as the BE RADIANT phase 3b trial (48-week double-blinded period, 96-week OLE).3–7

Included patients were randomised to BKZ 320 mg Q4W to Week 16, then either BKZ Q4W or Q8W until OLE entry (Week 48/52/56 depending on feeder study). All patients entered the OLE and received BKZ Q4W or Q8W based on Psoriasis Area and Severity Index (PASI) response and prior maintenance dose; all patients were re-assigned to BKZ Q8W in the third year of treatment via protocol amendment.

Maintenance of ≥90% improvement from baseline in PASI (PASI 90), PASI 100, and Investigator's Global Assessment (IGA) 0/1 responses through Year 3 (OLE Week 96) are reported in all Week 16 PASI 90, PASI 100, and IGA 0/1 responders, respectively. Data are also reported for the subsets of these patients who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE). Patients who discontinued due to lack of efficacy or treatment-related adverse events were considered nonresponders at subsequent timepoints; multiple imputation was used for all other missing data (modified non-responder imputation [mNRI]; NRI/observed case data in **Table** only).

Results:

Across the five phase 3/3b trials, 1,362 patients were randomised to BKZ Q4W for the initial treatment periods. At Week 16, 86.9%, 62.4%, and 86.9% achieved PASI 90, PASI 100, and IGA 0/1, respectively. Of these, 995, 719, and 985 entered the OLE and subsets of 348, 267, and 345 patients received BKZ Q4W/Q8W/Q8W (**Table**).

Among Week 16 PASI 90 responders, 96.0% maintained PASI 90 at Year 1 (Week 48), 93.9% at Year 2 (OLE Week 48), and 92.4% at Year 3 (OLE Week 96; **Table**). Among Week 16 PASI 100 responders, 88.7% maintained PASI 100 at Year 1, 83.4% at Year 2, and 78.0% at Year 3 (**Table**). Among Week 16 IGA 0/1 responders, 95.8% maintained IGA 0/1 at Year 1, 93.6% at Year 2, and 91.7% at Year 3 (**Table**). Similar high responses were observed in Week 16 responders who received BKZ Q4W/Q8W/Q8W (**Table**).

Conclusion:

Across the five trials, the vast majority of patients who achieved disease control after 16 weeks of BKZ 320 mg Q4W maintained their responses through 3 years of treatment. Maintenance of response was also seen in patients who received BKZ Q4W/Q8W/Q8W dosing, the approved dose for the vast majority of patients with psoriasis.

References:

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Table. Maintenance of PASI 90, PASI 100, and IGA 0/1 in Week 16 responders who entered the BE BRIGHT or BE RADIANT OLEs (mNRI, NRI, OC)

	All BKZ-treated Week 16 responders			BKZ 320 mg Q4W/Q8W/Q8W		
	mNRI, %	NRI, n (%)	OC, n/N (%)	mNRI, %	NRI, n (%)	OC, n/N (%)
PASI 90		**n=995**			**n=348**	
Year 1	96.0	934 (93.9)	934/962 (97.1)	99.1	337 (96.8)	337/340 (99.1)
Year 2	93.9	875 (87.9)	881/916 (96.2)	95.4	313 (89.9)	313/321 (97.5)
Year 3	92.4	819 (82.3)	826/862 (95.8)	95.6	290 (83.3)	290/295 (98.3)
PASI 100		**n=719**			**n=267**	
Year 1	88.7	632 (87.9)	632/704 (89.8)	90.7	240 (89.9)	240/262 (91.6)
Year 2	83.4	575 (80.0)	576/660 (87.3)	84.5	218 (81.6)	218/247 (88.3)
Year 3	78.0	527 (73.3)	528/626 (84.3)	78.1	194 (72.7)	194/229 (84.7)
IGA 0/1		**n=985**			**n=345**	
Year 1	95.8	923 (93.7)	923/952 (97.0)	98.6	332 (96.2)	332/337 (98.5)
Year 2	93.6	857 (87.0)	864/905 (95.5)	95.5	308 (89.3)	308/319 (96.6)
Year 3	91.7	800 (81.2)	808/852 (94.8)	95.4	285 (82.6)	285/294 (96.9)

Response rates for all outcomes are reported among patients who achieved the efficacy response of interest at Week 16 and entered the OLE. Year 1 data were recorded at Week 48, the last common timepoint for PASI and IGA assessment across BE VIVID, BE READY, BE SURE, and BE RADIANT before OLE entry. Year 2 data were recorded at OLE Week 48 in the BE BRIGHT and BE RADIANT OLEs, and Year 3 data were recorded at OLE Week 96. BKZ: bimekizumab; IGA 0/1: Investigator's Global Assessment score of 0 or 1; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

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Abstract N°: 4223

Short-term management outcome assessment of patients with moderate-to-severe plaque psoriasis treated with brodalumab in Greece: The ReSOLVE study interim analysis.

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Introduction & Objectives:

Brodalumab is a fully human anti–IL-17 receptor A (IL-17RA) monoclonal antibody, approved by the European Medicines Agency for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy.

This is an ongoing non-interventional (NIS), single, prospective, cohort real-world study of patients with moderate-to-severe plaque psoriasis who initiate brodalumab as part of routine clinical management of psoriasis (the ReSOLVE study).

This interim analysis focuses on short term outcomes (up to week 12 visit). The primary objective was to assess the short-term management outcome of patients with moderate-to-severe psoriasis treated with brodalumab by evaluating the proportion of patients achieving absolute Psoriasis Area Severity Index (PASI)≤3 at week 12.

Materials & Methods:

Other objectives were to describe patient profiles managed with brodalumab in the real-world setting concerning patient demographics, disease severity, previous treatment regimen and patients' satisfaction. All analyses were conducted using the as-observed data.

Results:

Ninety patients were included in the interim analysis: the mean age was 51.2 years; the mean duration of psoriasis was 13.2 years and most patients were male (70.0%) and of Greek origin (93.3%). At baseline, the majority of the patients had very severe, severe or moderate psoriasis (94,4%) as assessed by the static Physician Global Assessment (sPGA). The mean [Standard Deviation (SD)] total PASI score was 15.3 (10.4) and the mean (SD) Dermatology Life Questionnaire Index (DLQI) score was 13.0 (7.0). Eighty patients (88.9%) had received previous treatment for psoriasis and sixty nine (76,7%) were biologic naïve.

At week 12, the proportion of patients who achieved PASI≤3** was 80.0%. Regarding PASI 75/90/100 achievement, the respective proportions of patients were 81.1%, 68.9% and 53.3%. 75,6% of patients achieved sPGA 0-1 (clear-almost clear). The mean (SD) PASI total score from 15.3 (10.4) at baseline decreased to 3.0 (7.3) at week 12.

Main reasons for switching to brodalumab were physician's decision according to clinical practice (61.1%) and that the previous therapy was not efficient (45,6%). Eighty three patients completed the Patient's Global

Assessment (PaGA), with most of them being free/almost free of symptoms (73,5%). Eighty four patients completed the Treatment Satisfaction Questionnaire for Medication (TSQM-9), and the proportion of those being satisfied/very satisfied/extremely satisfied exceeded 83%. The DLQI questionnaire was completed by eighty three patients and the proportion of those reporting DLQI 0/1 was 61.4%; the mean (SD) DLQI from 13.0 (7.0) at baseline decreased to 4.0 (6.9) at week 12.

Conclusion:

This interim analysis revealed that 12 weeks following treatment with brodalumab provided clinically relevant short-term improvements in disease severity and psoriasis related symptoms as reflected by PASI reduction and improvement in the self-reported DLQI and TSQM-9.

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Abstract N°: 4239

Deucravacitinib, an oral, selective, tyrosine kinase 2 inhibitor: improvement in scalp psoriasis in patients from Asia in the phase 3 POETYK PSO-3 and PSO-4 trials

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Introduction & Objectives: Tyrosine kinase 2 (TYK2) is an intracellular enzyme that mediates signaling of cytokines (interleukin-23 and Type I interferons) involved in psoriasis pathogenesis. Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. The phase 3 POETYK PSO-3 (NCT04167462) and PSO-4 (NCT03924427) trials demonstrated the efficacy of deucravacitinib over 52 weeks in patients from Asian countries with moderate to severe plaque psoriasis. The current analysis evaluated the efficacy of deucravacitinib in patients from PSO-3 and PSO-4 with moderate to severe scalp psoriasis.

Materials & Methods: In PSO-3, adults with moderate to severe plaque psoriasis from mainland China, Taiwan, and South Korea were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily (QD). Patients randomized to placebo crossed over to deucravacitinib at Week 16; patients randomized to deucravacitinib continued treatment through Week 52. In PSO-4, adult Japanese patients with plaque psoriasis (and a small number of patients with generalized pustular or erythrodermic psoriasis, not included in this analysis) received open-label deucravacitinib 6 mg QD. Moderate to severe scalp psoriasis was defined as a scalp-specific Physician's Global Assessment (ss-PGA) score ≥3 at baseline. In both trials, scalp-related endpoints evaluated included ss-PGA score of 0 (clear) or 1 (almost clear) (ss-PGA 0/1), ≥90% reduction from baseline in the Psoriasis Scalp Severity Index (PSSI 90), change from baseline in PSSI, and ss-PGA 0/1 by prior treatment in patients with moderate to severe scalp psoriasis. Nonresponder imputation was used for missing data in binary endpoints; modified baseline observation carried forward was used for missing data in continuous endpoints. *P* values are nominal without multiplicity adjustment.

Results: In PSO-3, 72.6% (106/146) of patients randomized to deucravacitinib and 68.9% (51/74) of those randomized to placebo had an ss-PGA ≥3 at baseline; in PSO-4, 55.6% (35/63) of patients with plaque psoriasis receiving open-label deucravacitinib had ss-PGA ≥3 at baseline. In PSO-3, ss-PGA 0/1 and PSSI 90 response rates were significantly higher with deucravacitinib compared with placebo at Week 16 (ss-PGA 0/1, 62.9% vs 9.8%, respectively; PSSI 90, 51.4% vs 5.9%; *P*<0.0001 for both; **Table 1**). A greater mean change from baseline PSSI score was seen with deucravacitinib (−23.0) versus placebo (−6.0). Responses were maintained through Week 52 with continuous deucravacitinib (ss-PGA 0/1, 53.3%; PSSI 90, 52.4%; mean change from baseline PSSI, −24.5). Patients who crossed over from placebo to deucravacitinib saw similar responses to those with continuous deucravacitinib by Week 52 (ss-PGA 0/1, 49.0%; PSSI 90, 45.1%; change from mean baseline PSSI, −23.7). In PSO-4, 88.6% of patients achieved ss-PGA 0/1 at Week 16 and 80.0% at Week 52. PSSI 90 was achieved by 74.3% at Week 16 and

62.9% at Week 52. Mean PSSI score decreased from baseline by 30.2 at Week 16 and 28.7 at Week 52. Prior exposure to systemic antipsoriatic therapies did not affect ss-PGA 0/1 responses overall in either PSO-3 or PSO-4.

Conclusion: Deucravacitinib was effective across multiple scalp-related measures in Asian patients with moderate to severe scalp psoriasis at baseline.

Table 1. ss-PGA 0/1, PSSI 90, and change from baseline in PSSI in POETYK PSO-3 and POETYK PSO-4

	POETYK PSO-3				POETYK PSO-4	
	Deucravacitinib (n = 106)		Placebo (n = 51)	Placebo to deucravacitinib (n = 51)	Deucravacitinib (n = 35)	
Outcome	**Week 16**	**Week 52**	**Week 16**	**Week 52**	**Week 16**	**Week 52**
ss-PGA 0/1, % (95% CI)	62.9 (53.6, 72.1)	53.3 (43.8, 62.9)	9.8 (1.6, 18.0)	49.0 (35.3, 62.7)	88.6 (73.3, 96.8)	80.0 (63.1, 91.6)
PSSI 90, % (95% CI)	51.4 (41.9, 61.0)	52.4 (42.8, 61.9)	5.9 (0.0, 12.3)	45.1 (31.4, 58.8)	74.3 (56.7, 87.5)	62.9 (44.9, 78.5)
Change from baseline in PSSI, mean (SD)[a]	−23.0 (17.5)	−24.5 (17.2)	−6.0 (18.1)	−23.7 (18.8)	−30.2 (15.7)	−28.7 (14.8)

[a]In PSO-3, mean (SD) PSSI at baseline was 30.1 (16.8) for the deucravacitinib group and 33.1 (16.3) for the placebo group; in PSO-4, mean (SD) PSSI at baseline was 32.4 (14.9).

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Abstract N°: 4242

Time to Treatment Change in Patients Receiving Risankizumab and Other Biologics After 1 Year of Treatment in the Multi-Country Post-Marketing Observational VALUE Study

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Introduction & Objectives: Risankizumab (RZB), an IL-23 inhibitor, is approved for the treatment of moderate-to-severe plaque psoriasis (PsO) in adults. In the real-world post-marketing observational study VALUE, we assess the patient's time to treatment change.

Materials & Methods: Patients enrolled in VALUE received their biologic treatment as prescribed with an enrollment ratio of 2:1 for RZB vs other biologics. Treatment decisions were made independent of study enrollment. Results reported here are from an interim database lock on 26 Sept 2022. Treatment changes included discontinuation, dose escalation, dosing interval shortening, and changing biologic treatment between RZB and other biologics. Probability of patients without any treatment change is estimated from Kaplan-Meier curve for time to first treatment change. Propensity score matching (PSM) with 1:1 ratio using greedy algorithm and exact match for bio-naive/bio-experienced status was employed to account for imbalance between comparison groups.

Results: A total of 2296 patients are included in this analysis with 1532 receiving RZB and 764 receiving other biologics. Overall, patients that received RZB were significantly less likely to require a treatment change than patients receiving other biologics (10.0% vs 16.8%; $p<0.0001$) during the first 13 months. The probability of treatment change at month 13 was 0.11 for patients receiving RZB compared to 0.20 for patients receiving other biologics as estimated by Kaplan-Meir curve for time to first treatment change **(Table 1)**. The time to treatment change was also significantly longer in patients receiving RZB compared to other biologics (14.2 months vs 12.6 months; $p<0.0001$) **(Table 1)**. Similar trends were reported for the 1299 bio-naïve patients (RZB N=803; other biologics N=496). Bio-naïve patients receiving RZB (0.08) were significantly less likely to require a treatment change compared to bio-naïve patients receiving other biologics (0.21; $p<0.0001$) **(Table 1)**. Patients receiving RZB also had a significantly longer time to first treatment change (15.1 months vs 12.6; $p<0.001$) **(Table 1)**. Similar results were reported for the PSM population **(Table 1)**.

Conclusion: In VALUE, a real-world study, patients receiving RZB were significantly less likely to require treatment changes in the first 13 months than patients receiving other biologics. Additionally, when RZB patients required a treatment change, this change happened significantly later than in patients receiving other biologics.

Table 1. Treatment Survival

	Total Population		Bio-Naïve Population	
	RZB	*Other Biologics*	*RZB*	*Other Biologics*
Time to first treatment change, month, mean, (SD)				
All Patients [a]	14.2 (8.33)***	12.6 (8.27)	15.1 (8.16)***	12.6 (8.35)
	N=1532	N=764	N=803	N=496
PSM	14.4 (8.34)***	12.7 (8.27)	15.1 (8.11)***	12.8 (8.33)
	N=714	N=714	N=714	N=714
Cumulative treatment change probability at month 13 (95% CI)[b]				
All Patients	0.11***	0.2	0.08***	0.21
	(0.10; 0.13)	(0.17; 0.23)	(0.06; 0.10)	(0.17; 0.25)
	N=1532	N=764	N=803	N=496
PSM	0.10***	0.2	0.09***	0.21
	(0.08; 0.13)	(0.17; 0.23)	(0.06; 0.12)	(0.17; 0.26)
	N=714	N=714	N=714	N=714

*** p<0.001

[a]Reported by non-responder imputation

[b]Reported by log rank test for comparing Kaplan-Meier curves of time to first

PSM, propensity score matched; RZB, risankizumab

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Abstract N°: 4245

Evaluation of cosmetic properties of calcipotriol/betamethasone foam in scalp psoriasis: a case series

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Evaluation of cosmetic properties of calcipotriol/betamethasone foam in scalp psoriasis: a case series

Introduction & Objectives: The scalp is affected in 70-80% of patients with psoriasis. This location presents distinctive characteristics, including itching and scaling, which can result in great social discomfort and impairment of quality of life. Scalp psoriasis can be difficult to treat, and the initial treatment is based on topical corticosteroids. Choosing the right formulation is critical to increase efficacy, as hair hinders accessibility of treatments and patients have poor acceptance and compliance due to the limited cosmetic properties of the drugs. The use of calcipotriol/betamethasone** (Cal/BD) in a foam formulation has shown superior efficacy and faster onset of action than other formulations, but patients may initially be reluctant to use it in hairy areas. The main objective was to assess the cosmetic properties of Cal/ BD foam in patients with mild scalp psoriasis.

Materials & Methods: A prospective observational study was performed on patients with scalp psoriasis from November 1st, 2022, to January 31st, 2023 with a follow-up period of 2 months. A monthly phone questionnaire on quality of life (assessed by DLQI) and foam cosmetic properties (visual analog scale, VAS, from 0, a little cosmetic to 10, very cosmetic were performed.

Patients were classified by gender, scalp length (short/no hair; medium; long) and severity according to the European consensus into mild (<50% scalp surface area involvement (SSA), mild to minimal erythema, infiltration and pruritus), moderate (<50% SSA, moderate erythema, infiltration and pruritus) and severe (>50% SSA, moderate to severe erythema, infiltration and pruritus). Patients were trained on how to apply and remove Cal/BD foam, according to the patient leaflet.

Results: A total of 13 patients (8 men and 5 women) with ages between 23 and 62 years were included. Of these, 9 had mild psoriasis and 4 had moderate psoriasis. Regarding hair length, 7 men had short hair and 1 had medium-length hair; 2 women had medium-length hair and 3 had long hair. The mean DLQI was 7.7 at baseline and 4.2 at two months. The mean cosmetic feel in both genders was 6.9 (8 short hair; 6.7 medium hair and 4.6 for long hair). No major differences were seen in the VAS at two months of treatment (6.9 vs. 6.7, respectively). Asking about cosmetic properties, the dirty hair feeling when applying the product was the most reported complaint (5 patients), followed by discomfort when removing the product in the shower (4 patients). No relevant adverse effects were reported during follow-up and no cases of non-compliance were reported either.

Conclusion: The use of calcipotriol/betamethasone foam improves the quality of life and may be an effective alternative in the topical treatment of patients with scalp psoriasis with satisfactory acceptance, especially in patients with short/medium hair length.

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Abstract N°: 4279

Current status, patient profiles and impact on health care through the German Psoriasis Registry PsoBest

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Introduction & Objectives:

The Psoriasis Registry PsoBest documents the quality, safety, effectiveness and patient benefit of routine psoriasis care by longitudinal observation in Germany.

Materials & Methods:

PsoBest observes adult patients with moderate to severe psoriasis with or without psoriatic arthritis. Patients are enrolled at the start of naïve systemic treatment and followed for 10 years regardless of the subsequent course of treatment. In PsoBest, clinical parameters, e.g. the Psoriasis Area and Severity Index (PASI), patient-reported outcomes, e.g. the Dermatological Life Quality Index (DLQI), and drug-specific treatment data are documented in a standardised form. Drug safety data is generated via reports of serious and non-serious adverse events.

Results:

Until May 2023, 1,132 centres nationwide were cooperating with the registry, including 84 outpatient clinics (7.4%) and 1,048 (92.6%) dermatology practices. So far, more than 21,000 patients participated in the registry.

As of 30.06.2022, data from 15,083 patients were quality assured. Prospectively, 15,497 patient-years (PY) were observed with biologics, 648 PY with biosimilars and 16,217 PY with non-biologic therapy. Patients were predominantly male (58.5%), with a mean age of 47.7 years, and suffered psoriasis for an average of 17.3 years; 30.5% showed affection of joints. The mean PASI score was 15.1, which corresponds to a high clinical severity. The mean DLQI of 11.8 indicates a substantial disease burden. No relevant difference of drug safety has been observed so far in the comparison of therapy options.

Conclusion:

PsoBest is the largest registry in German dermatology and contributes to quality assurance and optimisation of care for a severe skin disease. The success is based on years of commitment of the project group, the participating dermatologists and the loyal patients.

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Abstract N°: 4281

Deucravacitinib, a selective allosteric TYK2 inhibitor, in plaque psoriasis: efficacy and maintenance of response over 3 years with continuous treatment in Asian patients in the global phase 3 POETYK PSO-1 trial

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, Japan, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was superior to placebo and apremilast in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) (N=666) and POETYK PSO-2 (NCT03611751) (N=1020) trials in patients with moderate to severe plaque psoriasis (baseline Psoriasis Area and Severity Index [PASI] ≥12, static Physician's Global Assessment [sPGA] ≥3, and body surface area involvement ≥10%). The PSO-1 trial included 106 (15.9%) patients from mainland China, Japan, South Korea, and Taiwan. PSO-2 did not include any patients from Asian countries. Upon completion of PSO-1 and PSO-2, patients could enroll in the ongoing POETYK long-term extension (LTE) (NCT04036435) trial. Deucravacitinib maintained long-term efficacy through 2 years with no new safety signals. Here, we report clinical efficacy for up to 3 years (148 weeks) with continuous deucravacitinib treatment in a subset of Asian patients from the PSO-1 trial who entered the LTE trial.

Materials & Methods: In PSO-1/PSO-2, patients were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily (QD), or apremilast 30 mg twice daily and at Week 52 could enter the POETYK LTE trial, in which open-label deucravacitinib 6 mg QD was administered. This analysis evaluated the efficacy of deucravacitinib through 3 years (Week 148) in Asian patients who received continuous deucravacitinib treatment from Day 1 (baseline) of PSO-1, achieved ≥75% reduction from baseline in PASI score (PASI 75) at Week 16 (the primary endpoint), completed 52 weeks of treatment, and enrolled in the LTE. Efficacy endpoints were assessed through the cutoff date of June 15, 2022 (Week 148) and included the proportion of patients (response rate) achieving PASI 75, ≥90% reduction from baseline in PASI (PASI 90), and sPGA score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1). Efficacy was reported using a modified nonresponder imputation for missing data. The Clopper-Pearson method was used to calculate 95% confidence intervals (CIs) for the response rates.

Results: A total of 32 Asian patients from PSO-1 were included in these analyses. Among these patients, high PASI 75 response rates were maintained from the start of the LTE (Week 52, 96.8%; 95% CI, not estimable [NE]–NE) to the cutoff date (Week 148, 91.8%; 95% CI, 80.3% to not applicable) with continuous deucravacitinib treatment. PASI 90 responses were maintained in more than half of this population from the start of the LTE (Week 52, 71.0%; 95% CI, NE-NE) to Week 148 (51.9%; 95% CI, 33.2%-70.5%). High sPGA 0/1 response rates were also maintained from Week 52 (80.6%; 95% CI, NE-NE) to Week 148 (67.5%; 95% CI, 49.7%-85.3%) in these patients.

Conclusion: Clinical efficacy was maintained at high levels for up to 148 weeks with continuous deucravacitinib

treatment in Asian patients who were Week 16 PASI 75 responders in PSO-1. These findings further support the long-term use of deucravacitinib, a once-daily oral treatment, as an effective treatment for Asian patients with moderate to severe plaque psoriasis.

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Abstract N°: 4288

Bimekizumab 3-year efficacy in high-impact areas in moderate to severe plaque psoriasis: Pooled results from five phase 3/3b trials

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Introduction & Objectives:

Psoriatic lesions of the scalp, nails, palms, and soles are associated with reduced health-related quality of life and treatment challenges.1 High levels of complete clearance in high-impact areas were reported over 2 years of bimekizumab (BKZ) treatment.2 Here, 3year scalp, nail, and palmoplantar (pp) outcomes are reported from five BKZ phase 3/3b trials in patients with moderate to severe plaque psoriasis.

Materials & Methods:

Data were pooled from the 52-week (wk) BE VIVID and 56-wk BE READY and BE SURE phase 3 trials, 96 wks of their ongoing open-label extension (OLE), BE BRIGHT, as well as the BE RADIANT phase 3b trial (48wk double-blinded period, 96-wk OLE).3–7

Data are reported for patients randomised to receive BKZ 320 mg every 4 wks (Q4W) to Wk 16, then received BKZ either Q4W or Q8W in the maintenance period and OLE (BKZ Total; BKZ dose switching possible in OLEs), and the subset who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE). All patients were re-assigned to BKZ Q8W in the third year of treatment via protocol amendment.

High-impact areas were analysed using the scalp Investigator's Global Assessment (scalp IGA; 5point scale, 0–4), modified Nail Psoriasis Severity Index (mNAPSI; total fingernail score, 0–130), and ppIGA (5-point scale, 0–4). Proportions of patients with psoriasis in high-impact areas at baseline (defined here as scalp IGA ≥3, mNAPSI >10, pp-IGA ≥3) who achieved complete regional clearance (scalp IGA 0, mNAPSI 0, ppIGA 0) are reported through Year 3 (OLE Wk 96), using modified nonresponder imputation (mNRI). Patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered nonresponders at subsequent timepoints; multiple imputation was used for all other missing data.

Results:

In total, 1,107 BKZ-randomised patients entered the OLEs; 821 (74.2%), 377 (34.1%), and 193 (17.4%) had baseline scalp IGA ≥3, mNAPSI >10, and ppIGA ≥3. Of those randomised, 374 received BKZ Q4W/Q8W/Q8W; 277 (74.1%), 129 (34.5%), and 52 (13.9%) had baseline scalp IGA ≥3, mNAPSI >10, and ppIGA ≥3.

In patients with baseline scalp IGA ≥3 (BKZ Total), 88.0% achieved scalp IGA 0 at Year 1 (Wk 48/52), 85.8% at Year

2 (OLE Wk 48), and 83.7% at Year 3 (OLE Wk 96; **Table**). Of those with baseline mNAPSI >10, 64.4% achieved mNAPSI 0 at Year 1, 68.7% at Year 2, and 69.5% at Year 3 (**Table**). Of patients with baseline ppIGA ≥3, 90.6% achieved pp-IGA 0 at Year 1, 90.0% at Year 2, and 91.6% at Year 3 (**Table**). Similarly high responses were observed in BKZ Q4W/Q8W/Q8W patients (**Table**).

Conclusion:

A high percentage of BKZ-treated patients achieved and maintained complete clearance of scalp and palmoplantar psoriasis over 3 years. The majority of patients achieved complete nail clearance, with numerical increases from Year 1 to 3 and results sustained between Year 2 and 3. Complete clearance rates in high-impact areas were comparable between the BKZ Total group and patients who received Q4W/Q8W/Q8W dosing, the approved label dose for the vast majority of patients with psoriasis.

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Table. Complete regional clearance of scalp, nail, or palmoplantar psoriasis over 3 years (mNRI)

	BKZ Total (%)[a,b]	BKZ 320 mg Q4W/Q8W/Q8W (%)[b,c]
Scalp IGA ≥3 at baseline	**n=821**	**n=277**
Scalp IGA 0 at Year 1[d]	88.0	91.1
Scalp IGA 0 at Year 2	85.8	88.7
Scalp IGA 0 at Year 3	83.7	88.0
mNAPSI >10 at baseline	**n=377**	**n=129**
mNAPSI 0 at Year 1[d]	64.4	69.1
mNAPSI 0 at Year 2	68.7	69.9
mNAPSI 0 at Year 3	69.5	75.0
pp-IGA ≥3 at baseline	**n=193**	**n=52**
pp-IGA 0 at Year 1[d]	90.6	94.2
pp-IGA 0 at Year 2	90.0	88.5
pp-IGA 0 at Year 3	91.6	92.5

[a] The BKZ Total group includes pooled data for all patients who were randomised to receive BKZ 320 mg Q4W to Week 16, then received BKZ either Q4W or Q8W in the maintenance period and OLE; [b] At OLE Week 48 in BE BRIGHT and OLE Week 16 in BE RADIANT, or at the next scheduled clinic visits, patients receiving BKZ 320 mg Q4W were switched to BKZ 320 mg Q8W, following a protocol amendment; [c] BKZ patients in BE VIVID could not receive Q8W dosing in the maintenance treatment period so were not included in the Q4W/Q8W/Q8W group; [d] Year 1 data are from Week 48 for BE SURE, BE READY and BE RADIANT and Week 52 for BE VIVID, due to differences in assessment schedules between the studies. BKZ: bimekizumab; IGA: Investigator's Global Assessment; mNAPSI: modified Nail Psoriasis Severity Index; mNRI: modified non-responder imputation; OLE: open-label extension; pp: palmoplantar; Q4W: every 4 weeks; Q8W: every 8 weeks.

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Abstract N°: 4290

Characterization of patients with psoriatic arthritis in dermatological and rheumatological care: An analysis of two nationwide disease registries

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Introduction & Objectives:

Psoriatic arthritis (PsA) is a chronic inflammatory disease affecting the musculoskeletal system, skin and nails. In Germany, dermatologists and rheumatologists offer systemic treatment of PsA. Close cooperation between these two specialties is important for the care of this multifaceted disease. PsA is observed by the German Psoriasis Registry PsoBest (PB) in dermatology and the German Disease Registry RABBIT-SpA (RS) in rheumatology.

Materials & Methods:

The aim of the analysis was to compare the sociodemographic and clinical characteristics as well as the health care of patients with PsA in dermatological and rheumatological settings.

Baseline data collected between 10/2017 and 12/2020 in PsoBest (PB) and RABBIT-SpA (RS) were analysed separately in each of the data-holding registries.

Results:

1,066 RS patients and 704 PB patients were included in the analysis. The proportion of women was higher in rheumatology (60% vs. 49%). The body surface area affected was higher in PB (20.8% vs. 8.5%), as was the proportion of patients with nail psoriasis (58% vs. 41%). However, the percentage of painful or swollen joints (85% / 67% vs. 71% / 55%) was higher in RS. The mean DLQI (Dermatology Life Quality Index) was higher in PB (7.6 vs. 6.2) and the mean HAQ (Health Assessment Questionnaire) was higher in RS (0.9 vs. 0.7).

Most patients received biologics at inclusion (RS: 71% and PB: 73%). IL-23 inhibitors were used more frequently in PB, TNF inhibitors in RS. Due to differences in documentation, no conclusions could be drawn about the number and characteristics of patients treated by either specialty.

Conclusion:

The differences observed may be explained by differences of patients and by differences in routine care of both specialities. Clearly, psoriatic arthritis should be treated in a multidisciplinary approach to take into account all facets of this complex disease. Identifying and characterising patients who do and do not receive multidisciplinary treatment would help to ensure optimal and comprehensive care.

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Abstract N°: 4307

Bimekizumab impact on cardiovascular inflammation markers in moderate to severe plaque psoriasis: Results from phase 3 trials

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Introduction & Objectives

High levels of inflammatory markers, such as neutrophil/lymphocyte ratio (NLR) and C-reactive protein (CRP), are observed in patients with psoriasis and are associated with poor cardiovascular (CV) outcomes.1–3 Systemic anti-inflammatory therapies, including interleukin (IL)-17 blockade with secukinumab (SEC) or bimekizumab (BKZ), may reduce levels of CV inflammation-associated markers and, consequently, lower mortality risk in patients with psoriasis.4

Dual inhibition of IL-17A and IL-17F with BKZ has shown efficacy in patients with moderate to severe plaque psoriasis.5,6 Here, the impact of BKZ on CV inflammation-associated markers was assessed vs placebo (PBO) over 16 weeks in the phase 3 BE VIVID trial, and vs SEC over 48 weeks in the phase 3b BE RADIANT trial.

Materials & Methods

In BE VIVID, patients were randomised to BKZ 320 mg every 4 weeks (Q4W), PBO to Week 16 followed by BKZ Q4W, or ustekinumab to Week 52.5 In BE RADIANT, patients were randomised to BKZ 320 mg Q4W to Week 16 followed by BKZ Q4W or Q8W, or SEC 300 mg weekly to Week 4 then Q4W, to Week 48.6

In BE VIVID, NLR was assessed to Week 16; CRP concentration was not systematically collected. In BE RADIANT, both NLR and CRP concentration were assessed.

Median observed results are reported to Week 16 for BKZ Q4W- and PBO-randomised patients only from BE VIVID, and to Week 48 for BKZ- and SEC-randomised patients grouped by baseline CRP level (overall, CRP <5 mg/L, CRP ≥5 mg/L) from BE RADIANT (BKZ-randomised patients are presented as BKZ Total: combined BKZ Q4W and Q8W** maintenance doses).

Results

In BE VIVID, 321 patients were randomised to BKZ 320 mg Q4W and 83 to PBO. Median baseline neutrophil and

lymphocyte concentrations were similar for BKZ Q4W and PBO patients (**Table 1**). At Week 16, median NLR was reduced from baseline with BKZ Q4W and was lower with BKZ Q4W vs PBO: baseline, 2.54 vs 2.55; Week 16, 2.07 vs 2.53 (**Table 1**).

In BE RADIANT, 373 patients were randomised to BKZ and 370 to SEC. Median baseline neutrophil and lymphocyte concentrations were similar for BKZ- and SEC-randomised patients (**Table 2**). Median NLR was reduced at Week 16 vs baseline with BKZ and SEC (**Table 2**). NLR was comparable at baseline and Week 16 with BKZ Total vs SEC: baseline, 2.44 vs 2.37; Week 16, 2.07 vs 2.04 (**Table 2**). These results were maintained to Week 48: 2.15 vs 2.07. Similar reductions in NLR from baseline to Week 16 were observed in subgroups of patients with baseline CRP <5 mg/L and CRP ≥5 mg/L, with both BKZ and SEC, in BE RADIANT.

Median CRP concentrations (mg/L) were reduced at Week 16 vs baseline with BKZ and SEC (**Table 2**). Week 16 CRP was comparable with BKZ Total vs SEC: 2.04 vs 2.04. These results were maintained to Week 48: 1.96 vs 2.03. Similar trends were observed in those with baseline CRP <5 mg/L and CRP ≥5 mg/L.

Conclusion

BKZ treatment was associated with rapid, stable reductions in CV inflammation-associated biomarkers. At Week 16, NLR was reduced with BKZ vs PBO, and NLR and CRP concentrations were reduced vs baseline in both BKZ and SEC groups, particularly in patients with high CRP at baseline. Both markers remained stable through 1 year of BKZ or SEC treatment.

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Funding

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Table 1: Median observed neutrophil and lymphocyte concentration and NLR through 16 weeks of BKZ or PBO treatment in BE VIVID (OC)

	Median observed neutrophil concentration (10^9/L)		Median observed lymphocyte concentration (10^9/L)		Overall median observed NLR	
	BKZ Q4W N=321	PBO N=83	BKZ Q4W N=321	PBO N=83	BKZ Q4W N=321	PBO N=83
Baseline	4.40	4.35	1.72	1.71	2.54	2.55
Week 16	3.69	4.00	1.77	1.66	2.07	2.53

Data presented are for all patients who were randomised at baseline. BKZ: bimekizumab; NLR: neutrophil/lymphocyte ratio; OC: observed case; PBO: placebo; Q4W: every 4 weeks.

Table 2: Median observed neutrophil and lymphocyte concentration, NLR, and CRP concentration through 48 weeks of BKZ or SEC treatment in BE RADIANT (OC)

	Median observed neutrophil concentration (10^9/L)		Median observed lymphocyte concentration (10^9/L)		Median observed NLR						Median observed CRP concentration (mg/L)					
					Overall		CRP <5 mg/L		CRP ≥5 mg/L		Overall		CRP <5 mg/L		CRP ≥5 mg/L	
	BKZ Total N=373	SEC N=370	BKZ Total N=373	SEC N=370	BKZ Total N=373	SEC N=370	BKZ Total[a] N=257	SEC N=262	BKZ Total[a] N=115	SEC N=108	BKZ Total N=373	SEC N=370	BKZ Total[a] N=257	SEC N=262	BKZ Total[a] N=115	SEC N=108
Baseline	4.57	4.42	1.81	1.88	2.44	2.37	2.29	2.20	3.07	2.72	2.31	2.71	1.50	1.69	10.04	9.81
Week 16	3.90	3.87	1.83	1.91	2.07	2.04	1.99	1.94	2.35	2.32	2.04	2.04	1.44	1.57	4.96	5.35
Week 32	3.97	3.96	1.83	1.94	2.14	2.06	2.01	1.98	2.53	2.29	1.97	2.04	1.41	1.55	4.14	5.07
Week 48	4.08	4.01	1.82	1.94	2.15	2.07	2.07	1.94	2.44	2.37	1.96	2.03	1.37	1.43	4.66	5.11

Data presented are for all patients who were randomised at baseline. BKZ: bimekizumab; CRP: C-reactive protein; NLR: neutrophil/lymphocyte ratio; OC: observed case; SEC: secukinumab. NLR and CRP results are presented for patients grouped by CRP concentration at baseline. [a] No numeric CRP concentration at baseline for one patient, excluded from the final data set.

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Abstract N°: 4325

Deucravacitinib, an oral, selective, allosteric, TYK2 inhibitor: influence of comorbidities on safety and efficacy in Asian patients in the phase 3 POETYK PSO-3 trial

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Introduction & Objectives: Tyrosine kinase 2 (TYK2) is an intracellular enzyme that mediates signaling of cytokines (interleukin-23 and Type I interferons) involved in psoriasis pathogenesis. Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. The phase 3 POETYK PSO-3 trial (NCT04167462) demonstrated the superiority of deucravacitinib to placebo at Week 16 and maintenance of efficacy through 52 weeks in Asian patients with moderate to severe plaque psoriasis (Zhang J, et al. Presented at the 31st EADV Congress; 7-10 September 2022; Milan, Italy). Here, the safety and efficacy of deucravacitinib are evaluated in the presence or absence of comorbidities commonly present in patients with psoriasis.

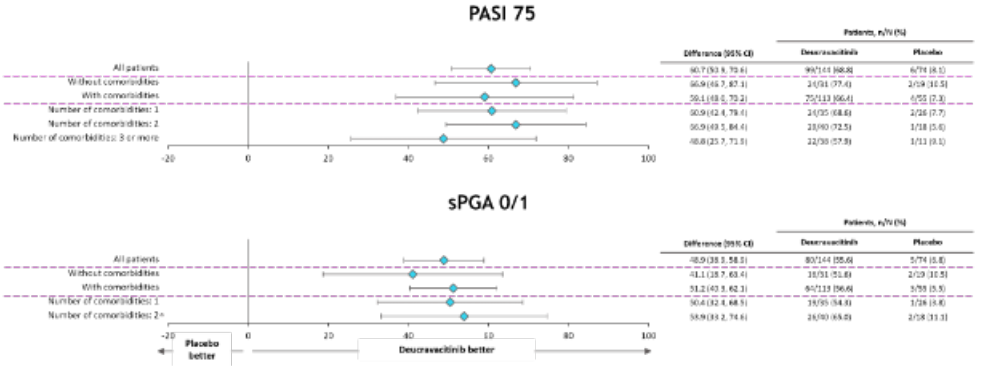
Materials & Methods: Adult patients with moderate to severe plaque psoriasis (baseline Psoriasis Area and Severity Index [PASI] ≥12; static Physician's Global Assessment [sPGA] ≥3; body surface area involvement ≥10%) from mainland China, Taiwan, and South Korea were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily. Patients randomized to placebo crossed over to deucravacitinib at Week 16; all patients then continued treatment through Week 52. Safety and efficacy were evaluated based on baseline presence of comorbidities, per medical history and demographics, known to occur at higher frequencies with psoriasis, including psoriatic arthritis, obesity, diabetes, hepatic steatosis, cardiovascular disease, and hyperlipidemia. Efficacy was reported using nonresponder imputation. The exposure-adjusted incidence rate (EAIR) was calculated as 100*(# of patients with adverse event [AE])/(total exposure time for all patients at risk [time to initial AE occurrence for patients with AE + total exposure time for patients without AE]).

Results: The frequency of comorbidities at baseline was similar in patients randomized to placebo (n/N=55/74 [74.3%]) and deucravacitinib (n/N=115/146 [78.8%]); rates of obesity (placebo, 51.4% and deucravacitinib, 63.7%), hyperlipidemia (32.4% and 41.1%, respectively), and psoriatic arthritis (13.5% and 10.3%, respectively) were also similar. At Week 16, AE rates were similar in patients treated with deucravacitinib in the absence (77.4%) or presence (73.9%) of baseline comorbidities. No serious AEs or discontinuations due to AEs were reported in patients without comorbidities; rates were low in patients with comorbidities (3.5% [4/115] and 1.7% [2/115], respectively) and were similar to rates in the overall population. At Week 52, there were minor differences in EAIRs (255.9 and 342.3 per 100 person years in the absence or presence of baseline comorbidities, respectively). Serum lipids (cholesterol [total, HDL, LDL], triglycerides) were similar in patients in the absence or presence of baseline hyperlipidemia over 52 weeks. Efficacy of deucravacitinib versus placebo was similar in the absence (PASI 75, 77.4% vs 10.5%; sPGA 0/1, 51.6% vs 10.5%, respectively) or presence (PASI 75, 66.4% vs 7.3%; sPGA 0/1, 56.6% vs

5.5%, respectively) of comorbidities (**Figure**).

Conclusion: Deucravacitinib was well tolerated and an effective treatment in Asian patients with moderate to severe plaque psoriasis, regardless of the presence of comorbidities frequently associated with psoriasis.

Figure. PASI 75 and sPGA 0/1 responses at Week 16 by baseline comorbidities



*Of the 11 patients in the placebo group with 3 or more comorbidities, none achieved an sPGA 0/1 by Week 16; 19 of the 38 patients (50.0%) in the deucravacitinib group with 3 or more comorbidities achieved sPGA 0/1. CI, confidence interval; PASI 75, ≥75% reduction from baseline in the Psoriasis Area and Severity Index; sPGA 0/1, static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline.

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Abstract N°: 4328

Use of Patient Reported Outcomes (PROMs) information in clinical practice in Spain for clinical management of psoriasis patients – SUMMER Project

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Introduction & Objectives:

Psoriasis is a chronic condition that may seriously affect patient's health-related quality of life (HRQoL). It is important to assess and monitor the effectiveness of treatments and clinical management of psoriasis patients in a global way. Routine collection of patient's point of view about psoriasis and its treatment through standardized Patient Reported Outcome Measurements (PROMs), additionally to Clinician Reported Outcome Measurements (CROMs), could improve symptom management, clinical outcomes and patient satisfaction and facilitate shared decision making. The objective of the study was to test whether PROMs are used by dermatologists to guide treatment decision in clinical practice.

Materials & Methods:

The SUMMER Project is an ambispective, non-interventional, multicenter study aimed at knowing the impact and management of moderate to severe psoriasis in clinical practice in the Spanish NHS. In the prospective phase, primary data (PROMs) were collected as a 6–9-month follow-up period. Adult patients with moderate to severe psoriasis with at least one-year of clinical records were included and followed up in routine clinical practice between January 1st 2022 and April 5th 2023. An interim analysis has been conducted to evaluate the baseline characteristics, the results of PROMs and its impact on disease management.

Extraction of parameterized and non-parameterized data from the medical records was performed through natural language recognition processing (NLP), analysing demographics and CROMs: Psoriasis Area Severity Index (PASI) and Body Surface area (BSA). PROMs were collected through a web-based platform every 3 months: Dermatology life quality index (DLQI) to assess HRQoL (score from 0 to 30 points), a 10-point Visual Analogic Scale (VAS) to assess psoriasis global impact, and the Treatment Satisfaction Questionnaire for Medication (TSQM-9) (score from 0 to 100). Higher scores of PROMs indicate worse HRQoL in DLQI and VAS and better patient satisfaction in TSQM-9. **

Results:

To date, 222 patients have been included in the prospective phase. A total of 60 patients from 4 hospitals have been included in this interim analysis. At baseline, mean age (SD) was 47.89 years (11.85), 58.3% were male, 91.67% were receiving biologic and 5% systemic treatment for psoriasis. According to CROMs at baseline, 6.7% (3/60) had PASI ≥ 5 and/or BSA ≥ 3. Any patient had PASI or BSA ≥ 10. Mean scores in TSQM-9 were 83.44 (22.41) for "effectiveness", 82.93 (14.32) for "convenience" and 85.42 (14.28) for "global satisfaction". Median baseline DLQI was 2.00 (3.50) and 10% (6/60) had ≥ 5 points. Mean VAS score was 2.23 (2.91) and 10% (6/60) had ≥ 7 points. Of all patients, 11.67% (7/60) changed their treatment during the follow-up. At the moment of changing: 28,57% (2/7) had PASI ≤3 and 48,85% (3/7) PASI ≥ 5, and 85,71% (6/7) had DLQI ≥ 5 and/or VAS≥ 7.

These patients who changed of treatment showed a median improvement of 5 points in DQLI, 4 points in VAS, indicating an improvement in their HRQoL, and in “effectiveness” dimension of TSQM-9.

Conclusion:

Most patients with psoriasis remained stable in their treatment during follow-up, showing stable and fairly good level of HRQoL. Only few patients showed moderate to extreme impact on HRQoL and were changed of treatment during follow-up. PROs can help decide treatment change in almost a third of patients in routine clinical practice, even with PASI<3.

	Patients who did not change of treatment				Patients who changed of treatment (n=7)*	
	Basal (n=53)	1st follow-up (n=44)	2nd follow-up (n=37)	3rd follow-up (n=22)	Before change	After change
DLQI, median (Pc25-Pc75)	1.0 (0.0-2.0)	1.0 (0.0-2.0)	1.0 (0.0-2.0)	1.0 (0.0-3.0)	8.50 (1.5-16.3)	3.5 (0.0-16.3)
VAS, median (Pc25-Pc75)	1.0 (0.0-2.0)	1.0 (0.0-2.5)	1.0 (0.0-2.0)	1.0 (0.0-3.0)	7.5 (5.0-8.3)	3.5 (1.0-7.3)
TSQM - Effectiveness, mean (SD)	84.67 (23.06)	79.27 (25.69)	74.70 (33.07)	72.00 (34.58)	52.57 (32.10)	60.86 (27.29)
TSQM - Convenience, mean (SD)	83.67 (14.34)	80.95 (16.08)	84.65 (15.63)	82.55 (14.91)	78.57 (16.78)	78.57 (19.51)
TSQM - Global satisfaction, mean (SD)	86.96 (13.74)	83.23 (16.69)	83.89 (19.55)	79.59 (17.18)	62.43 (30.09)	53.14 (25.50)
	* 1 patient changed twice					

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Abstract N°: 4332

Polymorphism study as biomarkers of response to tildrakizumab

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Introduction & Objectives:

Tildrakizumab is a monoclonal antibody that targets IL23p19 used for the treatment of moderate to severe plaque psoriasis. To date, no published studies have investigated the use of polymorphisms as predictors of the efficacy of tildrakizumab.

The aim of this study was to identify the possible association of single nucleotide polymorphisms (SNPs) with the response to tildrakizumab in patients with psoriasis in real clinical practice.

Materials & Methods:

A total of 180 SNPs were analyzed in patients with psoriasis from 15 spanish hospitals. Efficacy was evaluated at 3, 6, and 12 months using absolute PASI £3, £2 and £1. Genotype analysis will be performed using a QuantStudio 12K Flex qPCR instrument with an OpenArray termal block (Applied Biosystems, Thermofisher, USA). The last observation carried forward method was used for imputing missing data. A multivariable logistic regression analysis was performed including variables with a p-value <0.01 in the univariate analysis and confounding variables. SNPs and subjects with a genotyping error rate above 10% were excluded.

Results:

A total of 81 patients, 44 males and 37 females, with a mean age of 52 years, were genotyped, of which 20% were biologic-naïve patients.

After 3 months of treatment, 77% achieved PASI ≤3, 65% PASI ≤ 2, and 45% PASI ≤1. At 6 months, 77% achieved PASI ≤3, 65% PASI ≤2, and 62% PASI ≤1, while at 12 months, 81% achieved PASI ≤3, 77% PASI ≤2, and 67% PASI ≤1. The multivariable logistic regression analysis identified the association between different SNPs and treatment efficacy independently of whether patients had received prior biological treatments or not. The rs2787094 (ADAM33) and rs1800469 (TGFB1) were associated with achieving PASI ≤3 at 3 months of treatment, while the rs4645983 (CASP9), rs1050152 (SLC22A4), and rs4796681 (KRT17) were associated with achieving PASI≤2. The analysis at 6 months showed the association of rs766748 (IL17F), rs9373839 (ATG5), and rs1012656 (CCR6) with the possibility of achieving PASI ≤3, and rs12191877 (HLA-Cw6) and rs11591741 (CHUK) with PASI ≤2. Finally, an association was observed between rs3006433 (S100A7), rs1800974 (ITGA7), and rs62190005 (CCL20) with achieving PASI ≤3 at 12 months of treatment, and rs62190005 (CCL20), rs3006433 (S100A7), and rs1800974 (ITGA7) with achieving PASI ≤2 at 12 months.

Conclusion:

Our results suggest an association between SNPs and response to tildrakizumab. Further larger-scale studies are needed to confirm the association of the identified polymorphisms in this study with the response to tildrakizumab.

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Abstract N°: 4362

Anti-IL23 for nail psoriasis in real life: results of efficacy and safety during a 52-week period

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Introduction & Objectives:

Nail psoriasis (NP) is often considered disfiguring for patients with a relevant impact on quality of life (QoL). It is also difficult to treat for dermatologists who are often frustrated by the scarcity of effective therapeutic alternatives in this particular location. Topical therapies are often used as first-line treatment for mild NP, but efficacy is modest. Conventional disease-modifying antirheumatic drugs (cDMARDs) (e.g., cyclosporine, methotrexate, acitretin, and dimethyl fumarate) are generally avoided in NP without general cutaneous involvement. Biologics represent, to date, a concrete possibility for the management of these patients. The data from the cinical trials are encouraging, although there are still few data in real-life.

Materials & Methods:

Here we report a study conducted on 20 patients with nail psoriasis on both hands and feet treated with anti-IL23 for 52 weeks.

Results:

No differences were evaluated from baseline to week 4 of anti IL-23 treatment. NAPSI greatly improved at week 24 with almost 60% of patients reaching NAPSI75 and 40% NAPSI50. At week 52, almost 75% of patients reached NAPSI90. No adverse effects were reported in the patients in the study.

Conclusion:

The clinical response observed in these patients suggests that treatments that target interleukin-23 may be an effective option for NP, especially when refractory to conventional therapies.

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Abstract N°: 4367

A challenging case of Generalized Pustular Psoriasis- what lies underneath?

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Introduction: Generalised pustular psoriasis (GPP) is an unusual, severe form of pustular psoriasis. It is characterised by recurrent flares of widespread sterile pustules on erythematous, painful skin. GPP can be associated with systemic inflammation including fevers and gastrointestinal, hepatic, musculoskeletal, renal, or pulmonary involvement. The pathophysiology is multifactorial and is thought to be due to a combination of immunological, genetic and environmental factors. Furthermore, GPP can be caused by an underlying condition that requires specific interventions in addition to the conventional management of the skin disease. Reports show a strong relationship between hypocalcemia as a trigger for GPP highlighting the necessity of appropriate workup of the patient and possible treatment modifications in emergency conditions.

Here, we report a case of a 61-year-old woman with life threatening GPP and Fahr's syndrome related to hypocalcemia.

Case report: A 61 year old woman was admitted to our department for generalized pustular eruption, with fever, malaise and peripheral oedema. She is a well-known patient to the dermatology department, since she is a psoriasis patient for more than 40 years, and a histopathologicaly verified pustular psoriasis for the last 15 years, for which she is on therapy with MTX. She has a history of hypothireosis, adverse reactions to clindamycin and occasional tremor. Initial lab findings showed leukocytosis with neutrophilia, high sedimentation rate (110), CRP (365) and d-dimers (10.440) and severe hypocalcemia (1,2) and hypoalbuminemia (28). Therapy with prednisolone, acitretin, ceftriaxone and low molecular weight heparin was initiated, as well as substitution therapy with albumins and Ca Gluconate. On the 7th day of hospitalization, because of persistent high inflammatory markers and signs of urinary infection, ciprofloxacin was added to the therapeutic regimen. The next day the patient presented with worsening of the general state of health, facial oedema, generalized macular exanthema, elevated hepatic enzymes and peripheral eosinophilia, from which DRESS syndrome was diagnosed. The antibiotic was discontinued and the dose of prednisolone was tapered to fit. After the stabilization of the skin condition, despite the daily substitution, hypocalcemia was still evident, and we still observed neurological outbursts and occasional psoriasiform flares. Additional clinical and paraclinical examinations reveled idiopathic chronic hypoparathyroidism (pth- 1,4) and MRI changes to the brain in the form of bilateral symmetrical calcifications of basal ganglia and nucleus dentatus. This lead us to the diagnosis of Fahr's Syndrome secondary to chronic idiopathic parathyroidsm. With proper calcium, calcitrol and vitamin D supplementation all of the skin and neurological symptoms regressed.

Conclusion: We presented the 5th case of GPP associated with Fahr's Syndrome secondary to chronic hypoparathyroidism. Although we are privileged as dermatologists to always see the disease first, we should never undermine non-skin manifestations, as skin diseases are often associated with other disorders. Rare syndromes are a major challenge for clinicians, but aaccurate diagnosis directs us to the correct treatment.

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Abstract N°: 4409

Knuckling down on knuckle pads: atypical psoriasis.

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Introduction & Objectives:

Psoriasis is a common chronic inflammatory skin condition characterized by distinct clinical and dermoscopic features. However, it is essential to acknowledge that psoriasis can sometimes manifest with atypical presentations further compounded by the koebner phenomon, which may pose challenges for accurate diagnosis and management.

Materials & Methods:

We report a case of solitary plaque psoriasis masquerading as knuckle pads, and we highlight the significant role of dermoscopy in redressing the diagnosis.

Results:

A 23-year-old man presented to our department with a well-defined, smooth, firm thickenings over the third metacarpophalengeal joint of the right hand, evolving for 9 years. He did not report any pain or pruritus, but only an aesthetic discomfort. According to the patient, he did not suffer from any other symptoms, including articular ones, nor any other lesions. The medical history did not reveal any particulars habits, such as bulimia, sucking/chewing, or boxing. Also, no other family members had similar lesions.

The overall clinical presentation was highly suggestive of knuckle pads also known as Garrod’s nodes.

Surprisingly, application of dermoscopy revealed a regularly distributed dotted vessels on a light red background and white scales. Dermoscopy raised the suspicion of psoriasis and prompted us to proceed to a skin biopsy which confirmed the diagnosis. Histology revealed epidermis hyperplasia of psoriasiform architecture surmounted by a very thickened hyperkeratotic stratum corneum, dotted with areas of parakeratosis and focal microabscesses. A discrete exocytosis of neutrophils was seen. The dermal papillae were edematous and congestive with a discrete perivascular infiltrate, mainly lymphocytic.

In addition, systemic examination revealed scalp and nail involvement which supported the diagnosis of psoriasis.

A metabolic assessment was performed, and the patient was put on a combination of dermocorticoids and a keratolytic agent.

Conclusion:

In the current case the atypical clinical manifestations of psoriasis resulted in late diagnosis. Dermoscopic recognition of the characteristic vascular pattern raised the possibility of psoriasis and contributed significantly to the final diagnosis. This case also emphasizes the value of a systematic examination in dermatology patients. It will be interesting to highlight that in the literature this aspect of psoriasis was associated with rheumatologic involvement.

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Abstract N°: 4410

Efficacy and safety of the use of Risankizumab in real clinical practice: a multicenter study of the Spanish Psoriasis Group

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Introduction & Objectives:

Risankizumab is a novel and effective drug for the treatment of patients with psoriasis, although its speed of action is questioned and presumed to be lower than other latest-generation biologic drugs. Our objective is to assess the efficacy of risankizumab in routine clinical practice.

Materials & Methods:

Retrospective multicenter study including all patients who have received risankizumab in some spain hospitals. Efficacy was evaluated in relative terms using PASI90 and in absolute terms.

Results:

A total of 510 patients were included, with 61.2% being males and 38.8% females, with a mean age of 51.7 years. The most frequent comorbidity was overweight-obesity in 61.2% of patients, with 35.7% of them being obese (BMI > 30). A total of 21.9% (109) of patients were naive to biologic drugs. The mean initial PASI of patients was 11.2, which decreased to 4 at week 4 of treatment (n = 298; data not available for the remaining patients in that week), 1.6 at week 16 (n = 395), 1.2 at week 24 (n = 336), 0.8 at week 40 (n = 231), and 1.1 at one year (n = 296). In an analysis per protocol, PASI less than 1 was achieved by 68.1%-75.3%-80%-73.6% at week 16-24-40 and one

year of treatment, respectively, while in an intention-to-treat analysis, PASI less than 1 was achieved by 52.7%-49.6%-36.3%-42.7% at week 16-24-40 and one year of treatment, respectively. There were no statistically significant differences in efficacy in terms of PASI less than 1 at different follow-up weeks and the presence of overweight/obesity. Naive patients responded better at week 16 and one year of treatment than non-naive patients in terms of PASI less than 1 (82.6% vs 63.6%, p = 0.003; 84.5% vs 69.5%, p = 0.02, respectively). There were no significant differences in efficacy if the patient had previously failed another IL-23 inhibitor (including ustekinumab). Thirty-eight patients (7.4%) discontinued treatment before one year of follow-up, with 2 discontinuations due to drug-related adverse effects.

Conclusion:

The study reflects the real-world clinical experience with risankizumab in our setting, showing it to be an effective and fast-acting drug for the treatment of psoriasis.

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Abstract N°: 4439

The peripheral MAIT cell transcriptome is enriched in cytotoxic and memory-effector markers, and associated with differences in cell lineage, not psoriasis vulgaris.

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Introduction & Objectives: Psoriasis vulgaris (PV) is a chronic autoimmune skin disease driven mostly by autoreactive T-cells. Adaptive αβT cells are typically involved, but a role for innate-like, mucosal-associated (MAIT) cells has been also proposed. These unconventional αβT cells are commonly found in human skin and express semi-invariant TCRVα7.2 receptor that binds MR1-restricted, non-peptide microbial antigens. Distorted proportions of MAIT cell subpopulations have been reported in blood and skin lesions of PV patients, but the molecular events behind their numerical aberrations remain a puzzle.

Materials & Methods: We used a targeted RNASeq approach to examine immunotranscriptome (359 genes, AmpliSeq Immune Response Panel, Illumina Miniseq) of flow-sorted, bulk MAIT cells (CD3ε, MR1-5-OP-RU-tet, TCRVα7.2, FACS Canto II/BioRadS3e) in peripheral blood of 11 affected (type I PV, median PASI 5.4, max 24) and 10 age- and gender-matched control individuals. Flow cytometry of CD4+, CD8+, double negative (DN, CD4-CD8-), and double positive (CD4+CD8+) MAIT cell subsets was performed in parallel. The BaseSpace RNA Amplicon software and limma-voom were used for differential gene expression analysis (false discovery rate $q<0.1$).

Results: Cases and controls did not differ by MAIT cell numbers (Mann-Whitney test). Overall, MAIT cells were highly enriched for KLRB1 (CD161), stem-like (TCF7, IL7R, CD28) and cytotoxic, effector-memory markers (ID2, GNLY, GZMK/A, IFNG, CCL4/5). PV, disease severity, and gender (5F vs. 16M) did not significantly affect target gene expression. Instead, a moderate relationship was observed with the CD4:CD8 partition of MAIT cells (Pearson correlations, $p<0.05$, regularized log-counts). Higher

CD8+MAIT cell numbers (63-89% of all MAIT cells, min-max) were associated with PI3K-AKT signaling (PIK3CD, AKT, MAPK1), IL-2 pathway (IL2RB, STAT3, STAT5A), immunoregulatory molecules (PDCD1, ADORA2A), gut-homing integrins (ITGB7), and two distinct metabolic checkpoints (the mitochondrial complex II component SDHA, and G6PD, a rate-limiting enzyme in the pentose phosphate pathway). CD8-CD4-MAIT cells (5-35%) largely recapitulated those results, but higher CD4+MAIT cell numbers (0.7-12% of all MAIT cells) coincided with a distinct set of up-regulated genes. Among them, we found

IL23A (the p19 subunit of the heterodimeric cytokine IL-23), interferon response genes (STAT1, ISG15, IFI35), co-stimulatory receptors from the TNFRSF family, and skin-homing cytokines such as CCL20 (a CCR6 ligand).

Conclusion: Bulk transcriptome analysis of circulating MAIT cells may not be strongly informative in mild type I PV. Most likely, CD4+ and CD8+/DN MAIT cells exhibit different gene expression profiles. MAIT cells are enriched in druggable molecules increasing the likelihood of off-target effects in patients receiving biological agents. Further evaluation of their skin counterparts, preferably by single-cell techniques, is warranted.

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Abstract N°: 4463

Pustular psoriasis successfully treated with Brodalumab: a case series

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Pustular psoriasis successfully treated with Brodalumab: a case series

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Introduction & Objectives: Pustular psoriasis (PP) represents a rare subtype of psoriasis, and its treatment may be very challenging. Recent evidence supports the Interleukin (IL)-17/T-helper 17 (Th17) axis involvement in the pathophysiology of PP. Moreover, biologicals targeting IL-17A have demonstrated to be effective and safe in treating PP. Herein, we present a case series of three patients diagnosed with PP successfully treated with Brodalumab.

Materials & Methods:

Three patients presented at our outpatient clinic with the following variants of PP: one with Generalized Pustular Psoriasis (GPP) and two with Acrodermatitis Continua of Hallopeau (ACH). PP severity was assessed using GPPASI and DLQI. At baseline GPPASI was 45 and the mean DLQI was 15. The two patients with ACH had involvement of 5 and 7 fingers, respectively. Two out of three patients were naïve to biological therapy, while one patient had received a previous biological agent. One patient had concomitant Psoriatic Arthritis (PsA). Brodalumab was administered to all patients at the recommended dosage of 210 mg at weeks 0, 1, and 2, followed by 210 mg every 2 weeks.

Results: Within the first 4 weeks of treatment, all patients showed significant clinical improvement. Complete clearance of GPP was noted 3 months after starting Brodalumab. An important reduction in fingers involvement as well as in DLQI was observed in both patients with ACH. At 12 months follow-up all patients achieved complete clinical remission, with a dramatic impact on quality of life.

Conclusion: Brodalumab may be an effective and safe therapeutic option for PP and other clinical variants of PP. Nevertheless, this observation needs to be further investigated on a larger number of PP patients.

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Abstract N°: 4506

A Phase 2, Randomized, Placebo-controlled, Dose-ranging Study of Oral JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis: Efficacy of Overall and Scalp Psoriasis Responses from FRONTIER 1

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Introduction & Objectives: FRONTIER 1 (NCT05223868) was a randomized, double-blind, placebo (PBO)-controlled, phase 2 study of JNJ-77242113 in adults with moderate-to-severe plaque psoriasis. JNJ-77242113 is a competitive oral peptide antagonist that binds with high affinity to the interleukin-23 receptor (IL-23R), and selectively inhibits IL-23 proximal and downstream cytokine production. The objective of this analysis was to evaluate the efficacy and safety of orally administered JNJ-77242113 in the treatment of moderate-to-severe plaque psoriasis.

Materials & Methods: In this phase 2 study, patients were randomized 1:1:1:1:1:1 to receive JNJ-77242113 25 mg daily (QD), 50 mg QD, 25 mg twice daily (BID), 100 mg QD, 100 mg BID, or PBO through Week (W) 16. The primary endpoint was the proportion of patients achieving ≥75% improvement in Psoriasis Area and Severity Index (PASI 75) at W16. PASI 90, PASI 100, Investigator's Global Assessment (IGA) score of cleared or minimal (0/1), IGA score 0, and scalp-specific (ss)-IGA score of 0/1 with ≥2-grade improvement from baseline at W16 were also evaluated. Patients with intercurrent events (ICEs), including discontinuation of study agent due to lack of efficacy, worsening of psoriasis, or use of a prohibited psoriasis treatment, were considered non-responders at W16. Observed data were used for patients who discontinued study agent for other reasons. After accounting for ICEs, patients with missing data were considered non-responders.

Results: A significant dose response was observed for the primary endpoint of PASI 75. Response rates (PASI 75, PASI 90, PASI 100, IGA score 0/1, IGA score 0, and ss-IGA score 0/1 with ≥2-grade improvement from baseline) for all JNJ-77242113 doses were significantly higher than PBO (nominal $p < 0.05$ for all comparisons) at W16 (Table 1). The proportions of patients with adverse events (AEs) were comparable between JNJ-77242113 groups and the PBO group. Most frequently reported AEs were COVID-19 and nasopharyngitis with no dose-dependent trends.

Conclusion: JNJ-77242113 is a first-in-class oral IL-23R antagonist peptide that demonstrated significantly greater efficacy compared with PBO in patients with moderate-to-severe plaque psoriasis, including scalp psoriasis, and was well-tolerated in all treatment groups.

Table 1. Proportions of Patients Achieving Overall and Scalp Psoriasis Efficacy Endpoints at Week 16 by Treatment Group

	PBO (N=43)	JNJ-77242113				
		25 mg QD (N=43)	50 mg QD (N=43)	25 mg BID (N=41)	100 mg QD (N=43)	100 mg BID (N=42)
PASI 75, n (%)	4 (9.3)	16 (37.2)	25 (58.1)	21 (51.2)	28 (65.1)	33 (78.6)
PASI 90, n (%)	1 (2.3)	11 (25.6)	22 (51.2)	11 (26.8)	20 (46.5)	25 (59.5)
PASI 100, n (%)	0	5 (11.6)	11 (25.6)	4 (9.8)	10 (23.3)	17 (40.5)
IGA score 0/1, n (%)	5 (11.6)	17 (39.5)	25 (58.1)	21 (51.2)	27 (62.8)	27 (64.3)
IGA score 0, n (%)	0	7 (16.3)	15 (34.9)	6 (14.6)	12 (27.9)	19 (45.2)
Baseline ss-IGA score ≥2, n	35	37	40	32	40	36
ss-IGA score 0/1 and ≥2-grade improvement from baseline, n (%)	4 (11.4)	12 (32.4)	28 (70.0)	21 (65.6)	27 (67.5)	27 (75.0)

IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; ss-IGA=Scalp-specific Investigator's Global Assessment

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Abstract N°: 4509

Dupilumab-induced psoriasis in a patient with atopic dermatitis successfully treated with Upadacitinib

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Introduction & Objectives: Dupilumab, a monoclonal antibody that targets IL-4 and IL-13, is an approved biologic treatment for moderate-to-severe atopic dermatitis (AD). While extremely well tolerated with low rates of adverse events, there have been reports of patients with AD managed on Dupilumab developing new-onset psoriasis. Development of psoriasis in patients with AD on Dupilumab is believed to occur due to a decrease in Th2 activity and resultant disinhibition of the Th1 and Th17 pathways involved in psoriasis pathogenesis. Upadacitinib, an oral, selective Janus Kinase 1 (JAK1) inhibitor, is approved for use in moderate-to-severe AD as well as psoriatic arthritis. Our objective is to present evidence to support the use of Upadacitinib for treatment of patients with AD who develop psoriasis on IL4/13 inhibitors.

Materials & Methods: This is a case report of a 66-year-old female with long-standing AD and allergic rhinitis, successfully treated with Dupilumab. After 3 years of almost-clear skin on Dupilumab, she presented with new onset widespread psoriasiform plaques, confirmed to be psoriasis on histopathology. Following this new clinical presentation, Dupilumab was discontinued, and she was treated with topical therapy and oral Apremilast, without benefit. Subsequently, she initiated treatment with Upadacitinib with excellent response, and has had clear skin with no adverse effects for over 1 year.

Results: We present a case of new-onset psoriasis that developed in the setting of Dupilumab treatment of AD, successfully treated with Upadacitinib. Dupilumab inhibits Th2-mediated inflammation, which in this patient's case, may have driven an immunologic shift towards the Th1/Th17 pathway involved in psoriasis pathogenesis and the resultant clinical presentation. Upadacitinib's target of inhibition – JAK1 – is known to be involved in signalling through Interferon alpha/beta, IL6, IL10 and IL22 receptors, and therefore, has broader immunomodulatory properties than Dupilumab. A case series of concomitant psoriasis and AD, successfully treated with Upadacitinib, demonstrated that JAK1 inhibition was of benefit in cases with clinical overlap.

Conclusion: The uncommon occurrence of AD to psoriasis "switches" on Dupilumab therapy is relatively well described, however, pathogenesis and management is not. A previous case report and literature review of patients who developed psoriasis in the setting of Dupilumab therapy indicated the majority of patients benefitted from topical monotherapy. In the case presented here, the patient did not respond adequately to topical therapy and systemic treatment was warranted. The dilemma was whether to target therapy towards the psoriasis or AD pathway and ultimately, use of Upadacitinib was of benefit. This case contributes to the current knowledge base for JAK inhibitors and suggests that patients who develop psoriasis on IL4/13 biologic therapy for AD can be treated safely and effectively with JAK inhibitors.

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Abstract N°: 4511

Evaluation of the effects of biological agents used in the treatment of psoriasis on the systemic immune inflammation index

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Introduction & Objectives: Psoriasis is a chronic, inflammatory disease associated with a wide range of comorbidities, characterized by skin involvement as well as increased pro-inflammatory cytokines in the systemic circulation. Systemic Immune Inflammation Index (SII) is a novel inflammation based biomarker that has become increasingly used in systemic inflammatory diseases in recent years. Studies have shown that SII levels are elevated in patients with psoriasis and may be used for predicting psoriasis activity. The anti-inflammatory effects of biological agents targeting cytokines that play a key role in the pathogenesis of psoriasis have been demonstrated in various studies. Our study aimed to compare the effects of biological therapies used in psoriasis on SII levels and to assess their association with disease severity.

Materials & Methods: The study retrospectively examined the data of 168 patients who had received the same biological agent treatment for at least 12 months for psoriasis. Patients were evaluated for demographic characteristics, disease duration, family history, joint, hair, nail, genital area involvement, and comorbidities. Patients were divided into four groups according to the biological therapy they received (TNF-α, IL-12/23, IL-17, IL-23 inhibitors). For each group; PASI, CRP, ESR levels; at baseline, 4, 12, 24, and 52 weeks were recorded, and the SII index was calculated using the formula platelet count x (neutrophil / lymphocyte). Between the biological therapy groups, amounts and rates of change in SII values at 4,12,24 and 52 weeks are compared to baseline values using Kruskal Wallis and Wilcoxon tests. The correlation between SII and PASI among groups was examined using the Spearman Correlation test. $P \leq 0.05$ value was considered statistically significant.

Results: Of the patients, 45 (26.8%) were using a TNF-α inhibitor, 45 (26.8%) an IL-12/23 inhibitor, 45 (26.8%) an IL-17 inhibitor, and 33 (19.6%) an IL-23 inhibitor. All biological treatment groups showed a significant reduction in SII compared to baseline. Significant reductions were observed starting from the 4th week using TNF-α and IL-17 inhibitors, and from the 12th week using IL-12/23 and IL-23 inhibitors. The amount of decrease and the decrease ratios were higher in those using TNF-α and IL-17 inhibitors compared to those using IL-12/23 and IL-23 inhibitors. While no correlation was found between PASI and SII at weeks 0, 4, and 12; positive correlation was observed at weeks 24 and 52. Only in those who recieved TNF-a inhibitors, a positive correlation was found between SII and PASI. A positive correlation was found between CRP, ESR levels and SII. A significant association was found between SII levels measured in the fourth week and the presence of hypertension-cardiovascular disease and between SII levels measured in all weeks and body mass index and the presence of hepatosteatosis.

Conclusion: SII may be a useful marker in monitoring the anti-inflammatory effects of biological agents used in psoriasis. Considering SII values, TNF-α and IL-17 inhibitors might demonstrate faster and stronger outcomes in suppressing systemic inflammation compared to other biologic agents. To our knowledge, our study is the first to compare the effects of four different groups of biological therapies used in psoriasis on SII. Further prospective studies with more patients are needed comparing the effects of biological agents on systemic inflammation markers and comorbid diseases.

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Abstract N°: 4523

Safety and efficacy of Secukinumab 300mg single device in Real World Evidence: a prospective, multicentric cohort study in psoriatic patients from Andalusia

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Introduction & Objectives:

Psoriasis is a systemic, chronic inflammatory disease where the effect of Il-17 on the development of lesions and comorbidities is well described. Secukinumab is an Il-17 inhibitor monoclonal antibody that has shown safety and efficacy in patients with moderate to severe psoriasis at 300mg dose. However, there is limited Real World Evidence on the efficacy and safety of this treatment since its use in a single 300mg pen. The main goal of this study is to assess the safety and efficacy of Secukinumab 300mg in a single device injection in patients with moderate to severe psoriasis

Materials & Methods:

A multicentric, prospective, cohort study was conducted. The included patients were moderate to severe psoriatic patients that were going to start treatment with Secukinumab 300mg with a single pen according to the technical data sheet. The patients were followed up for 52 weeks. Epidemiological variables such as age, sex, association with psoriatic arthritis and other comorbidities, disease duration and number of previous biologic drugs were included. Efficacy was assessed by employing PASI, BSA and IGA. Moreover, the effect on patients´ quality of life was also evaluated through the DLQI questionnaire. The study was approved by the Ethics Committee of the Hospital Universitario Virgen del Rocío (Seville, Spain).

Results:

75 patients were included. Mean age was 54.44+/-14.23 years, with a 61.33% of male patients. Mean body mass index (BMI) was 29.55+/-5.57 and the average time of evolution of the disease was of 14.88+/-10.89 years. Moreover, a 57.33% of patients presented with scalp psoriasis and 34.67% with nail psoriasis. 40% of patients had positive PURE 4 scores and 41.33% were diagnosed of psoriatic arthritis by a Rheumatologist. The most prevalent comorbidity was high blood pressure, with up to 30.67% of patients presenting with non-alcoholic fatty liver disease. At week 0, mean PASI was 12.39+/-7.24 and mean DLQI was 12.97+/-4.88, while mean pruritus measured by visual analog scale was 4.73+/-2.65. At week 4, PASI and DLQI mean scores were reduced by half, with 24.53% with IGA 0/1. At week 12, PASI and DLQI mean scores were under 2 points, and, at week 24, these scores were under 1. These results were consistent at week 52, with a 94.52% of patients with IGA 0/1. Only 4 patients stopped the treatment during the follow-up period due to a lack of efficacy. No severe adverse events were diagnosed during the 52-week follow-up period.

Conclusion:

Nowadays, multiple therapies are available for the treatment of severe psoriasis. In this prospective, multicenter

study, the single pen of Secukinumab 300mg has shown safety and efficacy during the 52-week follow-up period, with up to 80% of patients achieving PASI<3. These results reassert the importance of the Th17 pathway and the blockade of its main effector molecule, Il-17, in achieving rapid a sustained improvements in patients with moderate to severe psoriasis.

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Abstract N°: 4555

Patient-reported Benefits and Clinical Improvements of Switching to Apremilast from Fumaric Acid Esters for the Treatment of Psoriasis in Germany: Findings from the APART Real-World Study

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Introduction & Objectives: The multicenter, 2-part, prospective, observational APART (NCT02954081) study assessed the benefits of switching from fumaric acid esters (FAE) to apremilast (APR) in patients with moderate to severe plaque psoriasis (PsO) treated in German clinical practice.1,2

Materials & Methods: In part 1, adults with moderate to severe PsO, and no prior biologic, FAE, or APR treatment, received FAE and were followed for 24 weeks. In part 2, patients who switched from FAE to APR due to lack of efficacy, AEs, or other reasons were observed for a further 32 weeks. The primary outcome was patient-reported satisfaction with APR treatment, measured using the Treatment Satisfaction Questionnaire for Medication (TSQM) total score (4 domains; each 0-100, higher scores indicate higher satisfaction) at week 24. The APR efficacy population included all patients initiating APR with available data in part 2. Secondary outcomes included Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), Patient Preference Questionnaire (PPQ), Patient Benefit Index (PBI), reasons for FAE discontinuation, reasons for switching to APR, and adverse events (AEs). Subgroup analyses assessed 1) the TSQM side effects subscale in patients who switched due to AEs and 2) the TSQM effectiveness subscale and PASI-50, -75, and -90 in patients who switched due to lack of efficacy.

Results: Of 681 patients enrolled, 527 (77%) discontinued FAE and 267 (39%) switched to APR. Approximately half (256/527 [49%]) of patients discontinuing FAE did so in the first 8 weeks of treatment. Among 255 patients in the APR efficacy population, most switched to APR due to AEs or lack of efficacy on FAE (154/255 [61%] and 76/255 [30%], respectively). Mean (SD) treatment duration was higher for APR versus FAE (187.2 [84.76] vs 113.7 [73.67] days). Table 1 summarises patient characteristics at switch. In the APR efficacy population, improvements in total TSQM score were observed as early as week 8 of APR treatment and sustained through week 24 (Figure 1a). Improvements in the TSQM side effects and effectiveness subscales were observed in patients switching due to AEs and lack of efficacy, respectively (Figures 1b,c); 69% (42/61), 44% (27/61) and 30% (18/61) of patients switching due to lack of efficacy achieved PASI-50, -75 and -90, respectively. Among patients completing the PPQ at week 24, most (116/137 [85%]) preferred APR over their prior FAE treatment, considering it to be better tolerated (108/137 [79%]) and more effective (106/137 [77%]). At APR initiation, patients reported a mean (SD) DLQI score of 9.4 (7.32). At week 24 of APR treatment, mean (SD) DLQI was 4.6 (5.09) and over one-third (78/205 [38%]) reported PsO had no/little effect on their QoL (DLQI 0/1). Among patients completing the PBI, most (68/84 [81%]) reported clinically meaningful improvements on APR treatment (Figure 1d; PBI 3 or 4). Adverse events were consistent with the known safety profiles of FAE and APR (Table 2).

Conclusion: In our study of patients switching to APR from FAE, we observed increased treatment satisfaction and clinically meaningful improvements in patient- and physician-reported outcomes as early as week 8, sustained until week 24. In addition, most patients had strong preference for APR over previous FAE treatment.

\1. Mrowietz U et al., APART study 1st interim analysis, EADV congress 2019, Madrid/Spain, Poster P1642.

\2. Mrowietz U et al., APART study 2nd interim analysis, EADV congress 2020, virtual, Poster P1313.

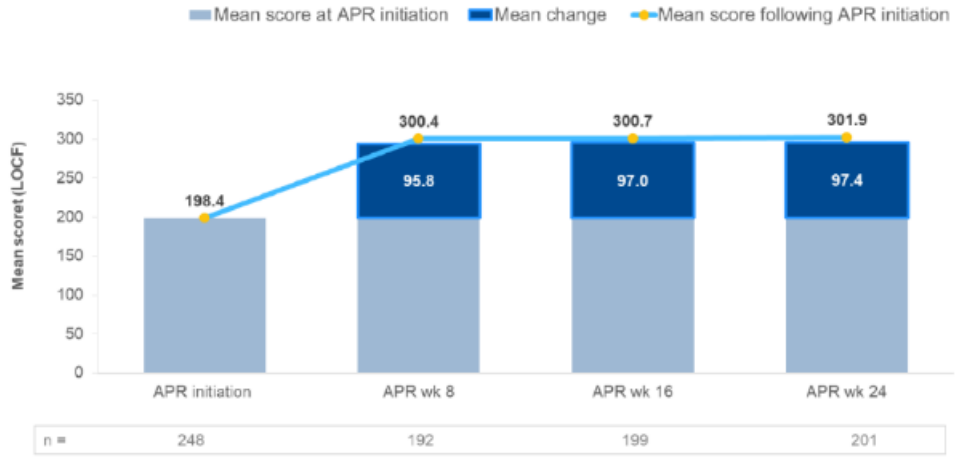
Table 1: Baseline characteristics at APR initiation

Parameter	Patients switching from FAE to APR (N=267)
TSQM, mean (SD)	198.4 (81.73)
DLQI, mean (SD)	9.4 (7.32)
PASI, mean (SD)	12.2 (11.53)
Scalp involvement, n (%)	194 (72.7)
Nail involvement, n (%)	86 (32.2)
Palmoplantar involvement, n (%)	80 (30.0)
Pruritus, n (%)	228 (85.4)
Pruritus VAS, mean (SD), mm	37.9 (29.46)

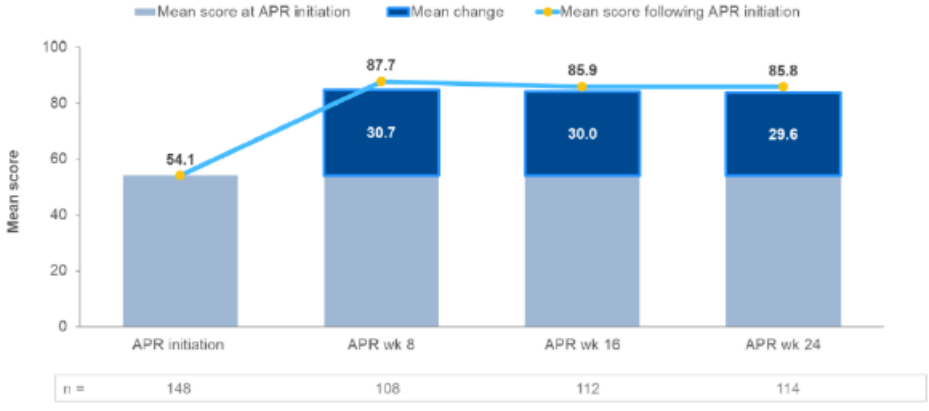
APR, apremilast; DLQI, Dermatology Quality of Life Index (0-30, higher values indicate greater quality of life impairment); FAE, Fumaric Acid Ester; PASI, Psoriasis Area Severity Index (0-72, higher values indicate greater severity); TSQM, Treatment Satisfaction Questionnaire for Medication (4 domains with 0-100 each; higher values indicate higher satisfaction); VAS, Visual Analogues Scale (0-100 mm).

Figure 1. Patient-reported outcomes on APR treatment (APR efficacy population)

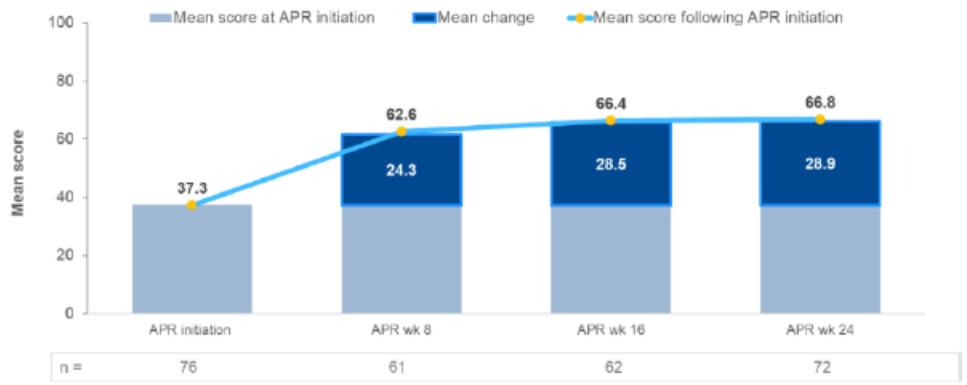
a. TSQM total score



b. TSQM side effects sub-score in patients switching from FAE to APR due to AEs



c. TSQM effectiveness sub-score in patients switching from FAE to APR due to lack of efficacy



d. Patient Benefit Index at Week 24 of APR Treatment (Efficacy Population; n=84 patients with non-missing data)

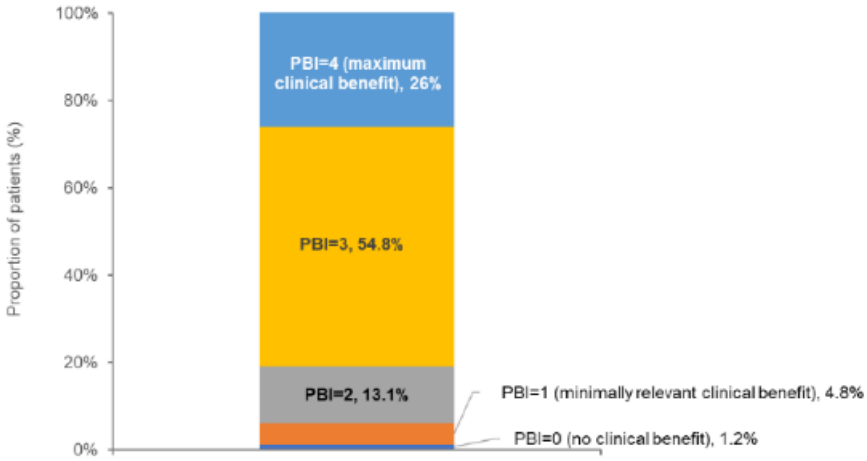


Table 2: Adverse events reported in at least 5% of patients during FAE and APR treatment

	FAE (N=675)	APR (N=267)
Gastrointestinal disorders, % of pts	44.1	16.1
Vascular disorders, % of pts	27.1	4.9
General disorders and administration site conditions, % of pts	9.0	13.1
Blood and lymphatic system disorders, % of pts	8.0	1.1
Skin and subcutaneous tissue disorders, % of pts	5.8	4.5
Infections/infestations, % of pts	5.5	3.4
Nervous system disorders, % of pts	4.7	7.1

AEs, Adverse Events; APR, apremilast; FAE, Fumeric Acid Ester; pts, patients.

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Abstract N°: 4560

Nail involvement is associated with higher cardiovascular risk in patients with psoriasis: A cross-sectional study

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Introduction & Objectives:

Psoriasis is an inflammatory skin disease that can be associated with increased cardiovascular risk. This risk can be assessed by non-invasive techniques such as carotid intima-media thickness (IMT) or pulse wave velocity (PWV). The objective of this study is to explore which clinical factors are associated with increased

cardiovascular risk measured through IMT and PWY, as well as to evaluate the usefulness of blood count indices for the evaluation of cardiovascular risk in patients with psoriasis.

Materials & Methods:

A cross-sectional study was carried out in patients with psoriasis who were candidates for systemic treatment. Carotid IMT and PWV were measured as cardiovascular risk markers and Systemic Immune-Inflammatory Index (SIII) was calculated. Clinical and disease activity data, were collected prior to the start of systemic treatments.

Results:

Thirty-four patients with psoriasis were included, with a mean age of 47,6 years and a male:female ratio of 1,62. Mean PASI index was 9,68 and 29% patients met criteria for metabolic syndrome. Male sex ($p<0,01$), nail involvement ($p=0,01$), older age ($p=0,07$) and greater SIII ($p=0,07$) were associated with greater subclinical atherosclerosis (IMT). On the other hand, older age, higher blood pressure, higher tobacco consumption, nail involvement ($p<0,01$), as well as a higher body mass index and lower SIII ($p=0,08$) were associated with greater arterial stiffness (PWV).

Conclusion:

Nail psoriasis, as well as SII and NLR seem to be markers of psoriasis patients with higher cardiovascular risk. The detection of these features may be of benefit for identifying psoriasis patients with higher risk of high blood pressure, insulin resistance or metabolic syndrome.

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Abstract N°: 4589

Real-world evidence of effectiveness and safety of Tildrakizumab in patients with moderate to severe psoriasis from 8 hospitals

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Introduction & Objectives:

Tildrakizumab is a humanized IgG1κ monoclonal antibody targeting the p19 subunit of IL-23 for the treatment of moderate-to-severe plaque psoriasis with demonstrated efficacy and safety on long-term clinical trials. We provide real-world data on the effectiveness and safety of tildrakizumab in our patients.

Materials & Methods:

Multicentric retrospective study including patients with moderate-to-severe psoriasis receiving tildrakizumab in routine clinical practice between November 2019 and January 2023 in 8 hospitals from Catalunya (Spain) with a minimum follow-up of 12 weeks. All variables were assessed using descriptive statistics. Psoriasis was assessed using Psoriasis Area and Severity Index (PASI), Body Suface Area (BSA) and Dermatology Life Quality Index (DLQI). Adverse events were analysed as incidence per person-year.

Results:

A total of 104 patients were included, 54 females (51.92%) and 50 males (48.07%), with a mean age of 51.29±15.01 years and a mean BMI of 27.53±5.61 kg/m2. The most common comorbidities were hypertension (32.6%), dyslipidemia (29.8%), psychiatric diseases (18.2%), non-alcoholic fatty liver disease (17.3%), metabolic syndrome (17.3%) and diabetes (16.3%). Patients with psoriatic arthritis were 6.7%. Latent tuberculosis was detected in 23 cases (22.1%). The most common form of psoriasis was plaque psoriasis (93.2%) and the mean disease duration was 20.22±13.26 years. Ninety-eight patients (94.2%) had received previous classic systemic therapy and 28 (26.9%) had never been treated with biologic drugs before. The most common previous biologics were adalimumab and ustekinumab. The mean follow up with tildrakizumab was 63.03±42.37 weeks. Administration frequencies other than every 12 weeks were prescribed in 10.58% of the patients. The mean baseline PASI was 8.78±5.27, BSA 11.22±11.90 and DLQI 10.08±6.22. At 12-16 weeks treatment, mean PASI was 1.96±2.80 and 75/104 (72.11%) patients achieved PASI ≤2, mean BSA was 2.82±6.41 and 74.03% achieved BSA ≤2, and mean DLQI was 2.41±4.29. At 6 months, 69/85 (81.17%) patients achieved PASI ≤2, 74/85 (87.05%) achieved BSA ≤2 and 64/78 (82.05%) achieved DLQI 0/1. At 12 months, PASI ≤2 was achieved in 49/56 (87.5%), BSA ≤2 in 51/56 (91.07%) and DLQI 0/1 in 42/52 (80.76%). At 24 months, 17/17 (100%) patients achieved PASI ≤2, 16/17 (94.11%) achieved BSA ≤2 and 13/17 (76.47%) achieved DLQI 0/1. Discontinuation of therapy occurred in 26 patients (25.0%). The main causes for discontinuation were ineffectiveness (primary failure in 10 patients and secondary failure in 5) and loss of follow-up in 5 patients. No severe adverse events were observed.

Conclusion:

Tildrakizumab was effective and well tolerated in patients with moderate to severe psoriasis in our series when used in real-life practice. No severe adverse events were reported during the follow-up period.

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Abstract N°: 4593

2-Week Low-Salt Diet Improves Overall Vascular Reactivity and Endothelium-Dependent Vasodilation in Psoriasis Patients

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Introduction & Objectives: Psoriasis presents an independent cardiovascular risk factor, characterized by chronic low-grade systemic inflammation and oxidative stress which altogether might lead to endothelial dysfunction. It has been reported that increased oxidative stress has a pivotal role in high dietary sodium-induced endothelial dysfunction. Recent studies on sodium accumulation in psoriatic skin lesions and the sodium-induced augmentation in Th17 immune response, raise the question on the complex interplay between sodium and psoriasis, especially in the context of cardiovascular morbidity. We aimed to investigate the effect of a 2-week low-salt diet on endothelium-dependent and endothelium-independent cutaneous microvascular vasodilation in patients with psoriasis vulgaris.

Materials & Methods: The study was designed as an interventional study in which patients with psoriasis were assigned to same study protocol. The participants were instructed to maintain a low-salt diet (LS diet) according to DASH eating plan, with sodium intake of 1500 mg (3.75 g of salt), within the period of 14 days. Adherence to the diet has been assessed by 24-hour sodium urine excretion. Cutaneous microvascular reactivity in response to vascular occlusion (post-occlusive reactive hyperemia, PORH), iontophoresis of acetylcholine (ACh induced dilation, AChID) and sodium nitroprusside (SNP induces dilation, SNPID), and local thermal heating (local thermal hyperemia, LTH) were assessed using laser Doppler flowmetry (LDF).

Results: Twenty psoriasis patients with baseline PASI > 5 completed the study protocol. 24-hour natriuresis confirmed that participant conformed to the LS diet. Both PORH and AChID (considered endothelium-dependent vasodilation) significantly increased after the 2-week LS diet compared with baseline measurements (PORH: baseline 100.1 ± 2.1 vs. LS diet 120.9 ± 34.1; p=0.048; AChID: baseline 12.6 (7.1 -15.4) vs. 12.1 (9.1 - 20.9), p=0.048). SNPID and LTH did not significantly change following LS diet compared to baseline.**

Conclusion: A 2-week LS diet led to an increase in endothelium-dependent vascular reactivity in psoriasis patients, as seen in significantly increased PORH and AChID. According to LTH results, it seems that LS diet affects vascular endothelium potentially via modulating endothelium derived vasoactive mediators other than nitric oxide.

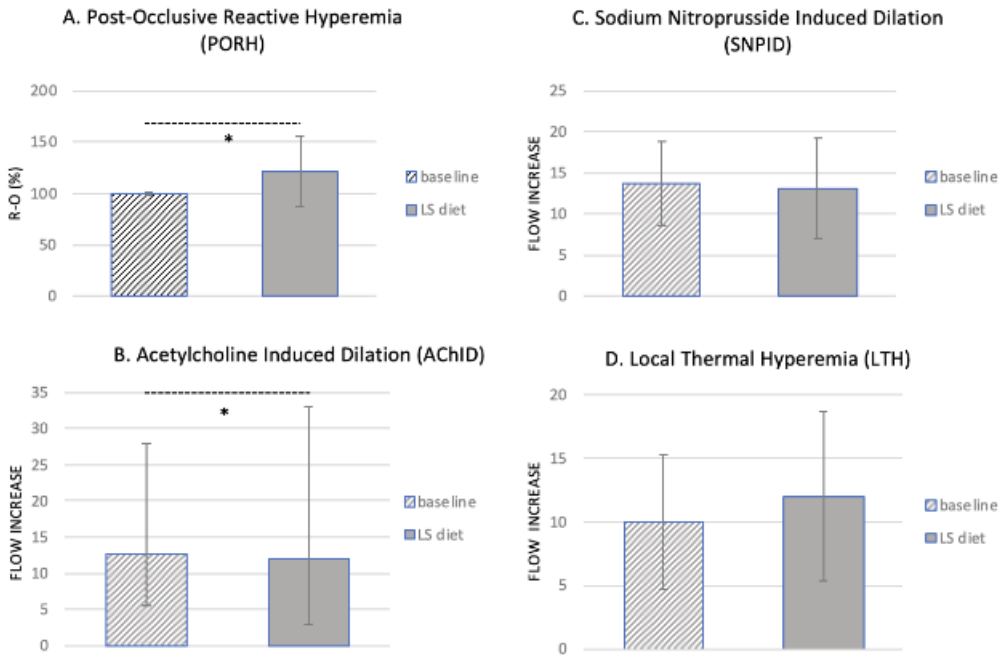

Figure 1. The effect of 2-week low-salt diet on vascular reactivity and endothelial function in subjects suffering from psoriasis. (A) Post-occlusive reactive hyperemia (PORH), (B) Acetylcholine-induced dilation (AChID), (C) Sodium nitroprusside induced dilation (SNPID), and (D) Local thermal hyperemia (LTH). PORH measurement is expressed as the difference between percentage of change of flow during reperfusion after occlusion compared with baseline (R-O%). AChID and SNPID are expressed as flow increase following ACh or SNP iontophoresis compared to baseline flow. Data are presented as average ± SD. LS- low-salt; AChID- acetylcholine induced dilation; SNPID- sodium nitroprusside induced dilation. *p<0.05, baseline vs. after 2 weeks of low-salt diet.

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Abstract N°: 4689

Psoriasis and quality of life About 103 cases

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Introduction & Objectives:

Psoriasis is a frequent chronic inflammatory dermatosis which alters the quality of life of patients; the stigma is huge, often leading to social exclusion. However, the experience of the disease differs from one patient to another. The objective of our study is to evaluate the impact of psoriasis on the quality of life in our patients.

Materials & Methods:

This is a prospective descriptive observational study of cases of psoriasis vulgaris in adults treated at the Regional University Military Hospital of Oran during the period between 2019 and 2021. We used the score DLQI (Dermatology Life Quality Index) to assess quality of life in all patients. Statistical analysis was performed using Epi info version 7 software. Qualitative and quantitative variables were described by percentages and means respectively.

Results:

In total, we collected 103 cases of psoriasis vulgaris during the study period. The average age was 35.2 years with a clear male predominance with a sex ratio of 19.4. A family history of psoriasis was found in 24.3% of cases. The triggering factor was psychological in 86.4% of cases. A summer remission was observed in 59.2% of cases. Classic plaque psoriasis was found in 86.4% of patients. Scalp involvement was observed in 71% of cases and the nail involvement in 19.4% of cases. Only 6.8% of cases have arthropathic psoriasis. The extent of the affected surface was 1 to 15.5%. The attack was described as very severe in 19.4% of cases. The DLQI score was greater than 10 in 17.5% of patients, showing a severe to very severe impact on quality of life. All patients received personal therapeutic education.

Conclusion:

The quality of life of patients with psoriasis, measured by the DLQI score, must be systematically assessed at each consultation and should be taken into account in the various therapeutic strategies.

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Abstract N°: 4774

Psoriasis Affecting the Lips and Perioral Region: An Uncommon Presentation of a Common Disease

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Introduction & Objectives: Psoriasis is a chronic and relapsing dermatosis affecting 1-3% of the world's population. While the classical skin lesions generally enable accurate diagnosis, psoriasis involving the perioral and oral region is rarely documented and may precede the appearance of typical psoriasis lesions by several years, posing a diagnostic challenge. This case report aims to emphasize the diagnostic and therapeutic complexities of perioral psoriasis.

Materials & Methods: We present a case of a patient with psoriasis exclusively affecting the perioral region and lips, which exhibited successful response to methotrexate.

Results: A 39-year-old woman reported a three-year history of erythematous and desquamative cheilitis with pustules extending beyond the vermillion border. She experienced a burning sensation on her lips and discomfort while eating. Clinical examination revealed diffuse erythema with fissures, desquamation, and white-yellowish scales accompanied by pustules over her lips and perioral region. Additionally, she exhibited geographic tongue, while her skin and nails were uninvolved. The patient had been treated with doxycycline and topical corticosteroids for 5 months, with the initial diagnosis of perioral dermatitis, without response. A biopsy performed on a pustular lesion revealed the presence of parakeratosis, acanthosis, accumulation of neutrophils within the stratum corneum and beneath the keratin layer, and a lymphocytic inflammatory infiltrate in the dermis. Based on the clinicopathological correlation, a diagnosis of psoriasis was established. Isotretinoin 20mg per day was introduced, considering her age and childbearing potential. Due to the lack of response after six months, isotretinoin was replaced by oral methotrexate at a dosage of 15mg weekly. Significant improvement was observed after 12 weeks of treatment.

Conclusion: Psoriasis affecting the lips is more commonly seen in women, and presents a significant cosmetic and psychological concern for patients. Since neither the clinical nor the histopathological changes are entirely specific to psoriasis, especially in the absence of cutaneous lesions, diagnosis may be challenging. Clinical differential diagnoses include actinic dermatitis, irritative cheilitis, chronic candidiasis, chronic eczema, leukoplakia, and perioral dermatitis. Treatment refractoriness is often observed, likely due to the constant friction of the lips and frequent contact with food products. Therefore, in cases of chronic and recurrent erythematous and desquamative lesions with pustules on the lips, psoriasis should be considered in the differential diagnosis.

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Abstract N°: 4782

Long-Term Real-world Data of SB5 (Adalimumab Biosimilar) Treatment in Patients with Moderate-to-Severe Psoriasis from the British Association of Dermatologists Biologic and Immunomodulators Register (BADBIR)

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Introduction & Objectives:

SB5 is an adalimumab biosimilar that is approved in the EU and US for inflammatory diseases including psoriasis and psoriatic arthritis. However, long-term real-world data on the effectiveness and safety of SB5 in psoriasis is limited. We analysed 4-year follow-up data of SB5 from BADBIR, a prospective observational registry of patients with moderate to severe psoriasis in the UK and the Republic of Ireland.

Materials & Methods:

Patients receiving SB5 between Jun 01, 2019 and Aug 31, 2022 were identified from BADBIR. Demographics, disease characteristics and severity (Psoriasis Area and Severity Index, PASI and Dermatology Life Quality Index, DLQI) were assessed upon registry enrolment or at the start of SB5 treatment. We also assessed change in PASI and DLQI from baseline score, change in therapy, and persistence rate. The persistence rate was assessed with Kaplan-Meier analysis. Any gap in treatment for more than 90 days was considered a discontinuation; therefore, patients who discontinued SB5 for more than 90 days and restarted were considered separate treatment series.

Results:

1,195 patients with psoriasis received SB5 between Jun 01, 2019 and Aug 31, 2022. Mean (± SD) age was 45.7 ± 13.32 years, 750 patients (62.8%) were male, 445 (37.2%) were female and mean body mass index was 31.8 ± 7.24 kg/m2. Other than psoriasis, 80 patients (6.7%) also had psoriatic arthritis. Mean disease duration was 22.3 ± 14.34 years. Mean PASI at registry enrolment and SB5 start were 11.5 ± 7.9 and 9.1 ± 8.32, respectively. Mean DLQI at registry enrolment and SB5 start were 14.7 ± 8.5 and 14.6 ± 8.59, respectively. 23 patients (1.9%) were previously exposed to biologics; 16 patients (1.3%) were switched from reference adalimumab to SB5.

PASI and DLQI were recorded both at baseline measured at SB5 start and at 1 year for 122 patients and 59 patients, respectively. For 122 patients with baseline PASI < 10 (median PASI: 1.8, IQR: 2.4), disease activity was maintained at 1 year (median PASI: 1.2, IQR: 2.0) with median PASI change of -0.6 (IQR: 2.0). For 67 patients with baseline PASI ≥ 10 (median PASI: 14.6, IQR: 8.5), median PASI at 1 year was 1.8 (IQR: 5.7) with median PASI reduction of -11.6 (IQR: 9.8). For 59 patients with baseline DLQI < 10 (median DLQI: 6.0, IQR: 6.0), disease activity was improved at 1 year (median DLQI: 0.0, IQR: 4.0) with median DLQI change of -3.0 (IQR: 3.0). For 48 patients with baseline DLQI ≥ 10 (median DLQI: 19.5, IQR: 8.0), median DLQI at 1 year was 0.5 (IQR: 4.5) with median DLQI reduction of -15.0 (IQR: 7.5).

Out of 1,195 patients, 64 patients discontinued SB5 for more than 90 days and restarted. 62 patients were counted as two and 2 patients as three separate treatment observations, respectively. SB5 treatment was discontinued in

490 out of 1,195 treatments (41.0%) and mean (± SD) SB5 treatment duration was 12.2 months ± 8.74.

Common reasons for SB5 discontinuation were inefficacy in 177 patients (14.8%) and adverse events in 145 patients (12.1%). Among 16 patients who switched from reference adalimumab, 3 patients (18.8%) discontinued treatment due to adverse events, 2 patients (12.5%) as per patient choice, 1 patient (6.3%) due to inefficacy, 1 patient (6.3%) due to a contraindication, and 1 patient (6.4%) due to financial consierations.

Conclusion:

This BADBIR data indicates that SB5 can be successfully started or transitioned to from reference adalimumab in patients with moderate-to-severe psoriasis.

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Abstract N°: 4808

Psoriasis epidemiology screening tool (PEST) is useful for the detection of psoriatic arthritis in daily dermatology practise

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Introduction & Objectives:

Psoriatic arthritis (PsA) affects up to one-third of patients with psoriasis. It is the major comorbidity of psoriasis because of the likelihood that loss of function and permanent disability will develop if initiation of treatment is delayed. Dermatologists are uniquely positioned to recognize early signs of PsA and be the first-line healthcare practitioners to detect PsA in patients with psoriasis. PsA can affect six clinical domains: peripheral arthritis, dactylitis, enthesitis, psoriasis, psoriatic nail disease, and axial disease. However, not every patient will have involvement of all domains and the domains affected can change over time.

Materials & Methods:

In this study, we investigated the utility of a representative tool, the psoriasis epidemiology screening tool (PEST) questionnaire, to identify risk of PsA among our patients with psoriasis. PEST questionnaire is a simple and fast method for the screening of PsA. A total of 100 patients with psoriasis were enrolled in this study.

Results:

Among them, 31 patients had PEST ≥ 3. The frequency of PEST ≥ 3 was increased in patients with nail and scalp psoriasis. Lower back and knee were the most common sites of joint pain.

Conclusion:

Taken together, our study suggests that the PEST questionnaire is a useful tool to identify risk of PsA among our patients with psoriasis.

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Abstract N°: 4832

Simple Scoring Model Stratifies Risk for Psoriatic Arthritis among patients with Psoriasis

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Introduction & Objectives:

Psoriatic Arthritis (PsA) is the most common and debilitating complication of psoriasis (Pso), affecting up to 30% of patients. the evolution of PsA among Pso patients is thought to reflect progression of the inflammatory process from the skin to joints and other organs. However, identifying groups of Pso patients with high risk for developing PsA remains problematic, and impedes early intervention and management of these patients.

Materials & Methods:

Using computed medical registry analysis tools, all patients diagnosed with Pso in Dermatology who had not been previously diagnosed with PsA were retrieved. Data collected included cohorts' epidemiological characteristics, psychiatric illness/therapy (Tx), arthralgia, metabolic syndrome- associated conditions and Txs, Txs for Pso, clinical features of psoriatic disorder, and concurrent medical conditions. PsA cases were diagnosed in Dermatology or Rheumatology wards. Cases whom diagnosis of PsA was given < 90 days after initial Pso diagnosis were excluded from initial analysis. Uni- and multivariable logistic regression models were fitted to evaluate contribution of variables to the risk of developing PsA.

Results:

3590 Pso patients were included in the final cohort, of which 170 (4.74%) developed PsA in times ranging between 91 and 4847 days (Median: 650). PsA Patients were diagnosed with Pso at older age (49 Vs. 45 years, p=0.01) and received more Tx lines (1.26 Vs. 0.77, p < .001) than those who did not develop PsA.

Univariate models found muculoskeletal (MSK) pain (OR = 1.16), biologic therapy (Tx) (OR = 1.15), smoking (OR = 1.1), systemic non-biological Tx (OR=1.09), psychiatric condition or Tx (OR = 1.08), IBD (OR = 1.05), age > 40 (OR = 1.03), metabolic syndrome or associated Tx (OR = 1.04), Diabetes Mellitus (OR = 1.03) Hypertension (OR = 1.027) and hyperuricemia (OR= 1.03) significantly associated with higher risk of developing PsA.

a multivariate logistic regression model found MSK pain (OR = 1.13), biological Tx (OR=1.11), systemic non-biological Tx (OR=1.06), smoking (OR = 1.04), psychiatric illness or Tx (OR = 1.05), and metabolic syndrome or associated Tx (OR = 1.03) as significant risk factors for progression to PsA.

Based on the multivariate model we built a scoring model to predict progression to PsA, which stratifies patients to distinct risk groups: <5 points have 2.4% (N=2725), 5-14 points have 8.7% (N=641), 15-24 points have 18.7% (N=187) and patients with ≥ 25 points have 32.4% (N=35) of developing PsA.

To exclude suspected cases of undiagnosed PsA, regression models were fitted also for the study's cohort without patients that reported MSK pain. All significant predictors found in the main models were also verified in these models, and IBD was found an additional independent risk factor (OR = 1.06).

Conclusion:

Using a simple scoring model can stratify risk of progression to PsA among Pso patients and direct clinician's management preferences.

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Abstract N°: 4844

Circulating 25-OH vitamin D and Th17 cytokines levels in patients with plaque psoriasis

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Introduction & Objectives:

Psoriasis is a chronic immune-mediated inflammatory skin disorder commonly complicated by various comorbidities. The IL-23/IL-17 pathogenic axis plays a key role in the pathogenesis of psoriasis. Vitamin D is also thought to be involved in the pathogenesis of the disease.

The present study aims to assess vitamin D status and the serum concentrations of pro-inflammatory cytokines IL-17 and Il-23 in patients with chronic plaque psoriasis and their association with various demographic and clinical characteristics.

Materials & Methods:

The study was conducted during the autumn/winter period on 48 patients with chronic plaque psoriasis and 48 controls. Total serum 25(OH)D level was determined with Roche Elecsys® 2010 Vitamin D total assay. Vitamin D status was defined according to the level of 25(OH)D as deficiency (≤ 20 ng/ml), insufficiency (21-29 ng/ml), and sufficiency (≥ 30 ng/ml). Commercial ELISA kits were used for quantifying the serum levels of IL-17A and IL-23. Descriptive statistics were conducted to analyze data. Categorical variables are presented as numbers and percentages. Continuous data are presented as mean and standard deviation or as the median and interquartile range (IQR). Comparisons between groups were made using the Chi-square ($\chi 2$) test and the Mann-Whitney U test. Spearman's rank correlation was used to assess the association between serum cytokine levels, 25(OH)D, and various clinical parameters.

Results:

Serum 25(OH)D had a median value of 16.95 ng/ml (IQR 10.8-23.50) for patients with psoriasis and 18.80ng/ml (IQR 15.45-25.85) for the control group ($p=0.09$). A moderate negative correlation was found between the PASI score and 25(OH)D levels ($rs= -0.34$; $p=0.02$). No statistical differences in 25(OH)D serum concentrations were detected in psoriatic patients with cardio-metabolic (CMDs) compared to patients with no CMDs ($p=0.14$). The serum levels of IL-17 ($p=0.001$), and IL-23 ($p=0.01$) were significantly higher in the patient group compared to controls. IL-17 concentrations were higher in patients with moderate to severe psoriasis compared to patients with mild psoriasis ($p=0.003$). Among psoriatic patients, the presence of concomitant systemic disease (cardiovascular and/or metabolic) was not associated with significant differences in the serum levels of IL-17 ($p=0.24$) and IL-23 ($p=0.32$) although the median levels were higher in psoriasis patients with CMDs. No significant correlations were detected between the serum concentrations of 25(OH)D and IL-17 and IL-23.

Conclusion:

It was confirmed that IL-17 serum level is associated with psoriasis severity. Measurement of 25(OH)D serum

concentration can be useful in patients with moderate to severe psoriasis with or without comorbidities. This study did not identify a direct association between 25(OH)D serum concentration and the serum concentrations of IL-17 or IL-23.

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Abstract N°: 4877

Evaluating patient benefit from topical treatment: Development and pilot validation of a patient-reported outcomes tool, the PBI-TOP

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Introduction & Objectives:

Topical treatment plays a crucial role in the treatment of skin diseases, including psoriasis. However, their use can come with substantial time effort and inconvenience and patients often report non-satisfactory treatment outcomes. As both can affect treatment adherence, it is of particular importance to consider patient preferences and benefit in therapy planning. However, available patient-reported outcomes measures (PROMs) for the evaluation of topical treatment cover either characteristics of topicals (such as absorption) or treatment benefit regarding effectiveness, but not both combined allowing for calculation of an overall benefit score. Therefore, we aimed to develop a new version of the established PROM "Patient Benefit Index" (PBI) that assesses patient-relevant treatment goals and benefits in topical psoriasis treatment ("PBI-TOP").

Materials & Methods:

Patients described their needs in topical treatment in semi-structured interviews, focus groups, and free-text questionnaires. Data were analyzed with qualitative content analysis, based on which treatment goal items for the PBI-TOP were developed by a consensus group. The PROM was then refined based on cognitive debriefing interviews with patients. In a pilot validation, data on the PBI-TOP as well as convergent criteria (Dermatology Life Quality Index, DLQI; Psoriasis Area and Severity Index, PASI; affected Body Surface Area, BSA) were collected.

Results:

Thirty patients (26-72 years, mean 47, 60% male) described various treatment goals which could be assigned to the themes "effectiveness" and "product characteristics". Twenty patients took part in the cognitive debriefings (22-84 years, mean 50.6, 50% male). Eighty-six patients participated in the pilot validation (18-81 years, mean 47, 62% male). In addition to an importance-weighted score on overall effectiveness, three subscales were defined based on exploratory factor analysis: effectiveness on symptoms; effectiveness on quality of life; product characteristics. All four scores showed good (Cronbach's alpha > 0.8) to excellent (alpha > 0.9) internal consistency. The PBI-TOP effectiveness score correlated significantly with DLQI (r = -0.41), PASI (r = -0.32), and BSA (r = -0.22). The two effectiveness subscales correlated with DLQI (r = -0.41; -0.32) and PASI (r = -0.27; -0.33). The PBI-TOP product characteristics score correlated significantly with the DLQI (r = -0.34).

Conclusion:

PBI-TOP assesses treatment needs and benefits from topical treatment of psoriasis, covering goals with regard to both treatment effectiveness and product characteristics. The pilot validation indicated favourable psychometric characteristics of the PBI-TOP. A longitudinal validation study is currently being conducted.

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Abstract N°: 4887

Early Oligoarticular Psoriatic Arthritis Responds to Treatment With Apremilast: Week 16 Results From FOREMOST – a Phase 4 Randomized Controlled Trial

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Introduction & Objectives:

Psoriatic arthritis (PsA) is underdiagnosed in dermatology practice, typically presenting 10 years after skin symptoms. Dermatologists may encounter early PsA since up to 30% of patients (pts) with psoriasis have PsA. Oligoarticular PsA affects ≤4 joints, is very common, and is underrepresented in clinical trials as most pivotal studies exclude pts with <3 swollen and tender joints. Here we report the efficacy and safety of apremilast (APR) vs placebo (PBO) for the treatment of early oligoarticular PsA.

Materials & Methods:

FOREMOST (NCT03747939), a randomized controlled trial, compared APR 30 mg BID + standard of care (SOC) vs PBO + SOC in pts with oligoarticular PsA (>1 but ≤4 tender joint and ≤4 swollen joint count [TJC and SJC], of 66-68 joints assessed) and early disease (PsA duration ≤5 years). A stable dose of oral glucocorticosteroids, NSAIDs, or 1 csDMARD (MTX or SSZ) were allowed. Pts were randomized 2:1 to APR or PBO for 24 weeks, stratified based on concomitant medication use, with an early escape at Week 16. The primary endpoint was the proportion of pts at Week 16 who achieved modified Minimal Disease Activity (MDA-Joints1), a composite of TJC ≤1 and SJC ≤1 plus achieving 3 of the following: psoriasis Body Surface Area (BSA) ≤3%, pt pain visual analog scale on a 100-mm scale ≤15, Pt Global Assessment (PtGA) on a 100-mm scale ≤20, physical function (HAQ-DI) ≤0.5, and enthesitis count ≤1 based on the Leeds Enthesitis Index. Secondary endpoints, Clinical Disease Activity in PsA (cDAPSA) remission (REM ≤4) or low disease activity (LDA >4 to ≤13) score, Pt Assessment of Pain, PtGA, PsA Impact of Disease (PsAID-12), PsA Disease Activity Score (PASDAS), safety, and exploratory endpoints (nail evaluation; BSA of 0%) were assessed. Primary and secondary analyses were based on sentinel joints, those affected at baseline. Exploratory analyses were performed for all joints. Pts who discontinued prior to week 16 due to AEs or lack of efficacy were imputed as non-responders. The remaining missing values at week 16 were imputed by multiple imputation.

Results:

Of 308 pts randomized (APR: n=203; PBO: n=105), mean PsA duration was 9.9 (SD 10.2) months, mean age was 50.9 (SD 12.5) years, and 39.9% of pts were using csDMARD (**Table 1**). MDA-Joints response was achieved in 33.9% vs 16.0% for pts treated with APR vs PBO (primary endpoint, p=0.0008; **Table 2**). At Week 16, a greater proportion, 70.2%, of pts treated with APR achieved cDAPSA REM/LDA vs 51.8% with PBO (p=0.0017; **Table 2**). Greater proportions of pts achieved a good/ moderate response in PASDAS score with APR (61.0%) vs PBO

(41.8%). Consistently higher MDA-joints, cDAPSA REM/LDA, TJC ≤1, and PASDAS responses were observed with APR vs PBO when evaluated by sentinel vs all joints impacted (**Table 2**). Pts treated with APR also achieved greater improvements in nail psoriasis score and quality-of-life measures (Pt Pain, PsAID-12, and PtGA) when compared to PBO (**Table 2**). No new safety signals were identified.

Conclusion:

FOREMOST is the first global randomized controlled trial, exclusively studying early oligoarticular PsA. We report the first results of FOREMOST, the primary outcome, and show better disease control is achievable with APR+SOC, with twice the MDA-Joint response compared with PBO+SOC at 16 weeks. These findings show APR treatment of early oligoarticular PsA improves clinical and quality-of-life outcomes and may inform optimal management of these pts.

References: 1. Coates LC, et al. J Rheumatol. 2016;43:371–5.

Table 1. FOREMOST Baseline Characteristics

Characteristic	PBO N=105	APR N=203	Total (N=308)
Age, years	50.2 (13.0)	51.3 (12.3)	50.9 (12.5)
Female, n (%)	51 (48.6)	118 (58.1)	169 (54.9)
BMI, kg/m^2	31.4 (7.5)	30.2 (6.8)	30.6 (7.1)
PsA duration, months	10.0 (10.6)	9.8 (10.0)	9.9 (10.2)
SJC[a]	2.6 (0.7)	2.7 (0.7)	2.6 (0.7)
TJC[a]	3.2 (0.8)	3.2 (0.8)	3.2 (0.8)
BSA (%)	6.3 (10.9)	6.9 (12.3)	6.7 (11.8)
≤3%	63 (60.0)	120 (59.1)	183 (59.4)
Pt pain VAS (0-100 mm)[b]	51.1 (22.7)	52.3 (22.0)	51.9 (22.2)
PtGA VAS (0-100 mm) [b]	50.5 (20.7)	51.6 (22.0)	51.3 (21.5)
HAQ-DI[b]	1.1 (0.6)	1.0 (0.6)	1.0 (0.6)
PsAID-12[b]	4.8 (2.2)	4.7 (2.0)	4.7 (2.1)
cDAPSA[b]	15.9 (4.5)	16.3 (4.3)	16.2 (4.4)
cDAPSA, n (%)			
REM	0 (0.0)	0 (0.0)	0 (0.0)
LDA	30 (28.6)	45 (22.2)	75 (24.4)

Data are presented as mean (SD), unless otherwise specified.
[a] Sentinel joints are defined as joints affected at baseline. [b] Higher scores indicate greater burden/worse status.
APR, apremilast; BMI, body mass index; BSA, body surface area; cDAPSA, Clinical Disease Activity in Psoriatic Arthritis; HAQ-DI, Health Assessment Questionnaire Disability Index; LDA, low disease activity (cDAPSA >4–≤13); PBO, placebo; PsA, psoriatic arthritis; PsAID-12 (0–10), Psoriatic Arthritis Impact of Disease; Pt, patient; PtGA, Patient Global Assessment of Disease Activity; REM, remission (cDAPSA ≤4); SD, standard deviation; SJC, swollen joint count; TJC, tender joint count; VAS, visual analog scale.

Table 2. FOREMOST Week 16 Results

Endpoints	Sentinel* Joints			All Joints		
	PBO N=105 n (%)	APR N=203 n (%)	Difference (95% CI)	PBO N=105 n (%)	APR N=203 n (%)	Difference (95% CI)
Primary Endpoint						
MDA-Joints	16.8 (16.0)	68.8 (33.9)	18.5% (8.9, 28.1) p=0.0008	8.3 (7.9)	43.2 (21.3)	13.6% (5.9, 21.4) p=0.0028
Secondary Endpoints						
cDAPSA REM/LDA	54.4 (51.8)	142.6 (70.2)	18.6% (7.0, 30.2) p=0.0017	40.0 (38.0)	122.5 (60.3)	22.5% (10.7, 34.3) p=0.0004†
SJC ≤1‡	72.4 (69.0)	150.2 (74.0)	5.1% (-5.8, 16.0) p=0.3539†	43.5 (41.5)	117.5 (57.9)	16.4% (4.7, 28.0) p=0.0068†
TJC ≤1‡	46.7 (44.4)	134.4 (66.2)	22.1% (10.4, 33.7) p=0.0003†	17.5 (16.7)	77.2 (38.0)	21.4% (11.6, 31.2) p=0.0002†
PtGA VAS ≤20‡	–	–	–	20.1 (19.1)	61.7 (30.4)	11.8% (1.7, 22.0) p=0.0286†
Pt Pain VAS ≤15‡	–	–	–	13.8 (13.1)	59.6 (29.4)	16.3% (6.9, 25.8) p=0.0022†
PsAID-12, LS Mean (SE) Change From Baseline‡	–	–	–	-0.42 (0.216)	-1.45 (0.178)	-1.03 (-1.48, -0.59) p<0.0001†
PASDAS Good/ Moderate Response‡	43.9 (41.8)	123.8 (61.0)	19.7% (7.7, 31.8) p=0.0016†	42.8 (40.8)	120.3 (59.3)	19.0% (7.0, 31.1) p=0.0023†
Exploratory Endpoints				**PBO N=69**	**APR N=143**	**Difference (95% CI)**
Nail Psoriasis Score, LS Mean (SE) Change From Baseline	–	–	–	-6.8 (2.6)	-13.9 (2.1)	-7.1 (-12.4, -1.8) p=0.0094†
BSA 0%, n (%)¥	–	–	–	17.7 (16.9)	63.3 (31.2)	14.4 (4.6, 24.2) p=0.0073†

Non-responder and multiple imputation methods were used for handling missing data. All the secondary endpoints were tested sequentially in the pre-specified order as presented in the table.

For binary outcomes (MDA-Joints, cDAPSA REM/LDA, SJC ≤1, TJC ≤, Pt Pain ≤15, PtGA ≤20, PASDAS response, and BSA 0%), the adjusted difference in proportions was the weighted average of the treatment differences across strata formed by two stratification factors, prior/concomitant use of csDMARD, and baseline glucocorticoid use per IWRS data, using CMH weights. Two-sided 95% CI was based on a normal approximation to the weighted average. P-value was based on the CMH test, adjusting for prior/concomitant use of csDMARD and baseline glucocorticoid use that was normalized via the Wilson-Hilferty transformation.

For continuous outcomes (Nail Psoriasis Score and PsAID-12), the LS mean treatment difference and p-value were based on MMRM model including treatment group, time, treatment group by time interaction, prior/concomitant use of csDMARD, and baseline glucocorticoids use per IWRS data as factors, and baseline value of the measure as a covariate.

*Sentinel joints are defined as joints affected at baseline. †Nominal p-value. ‡The following secondary endpoints did not achieve statistical significance according to the pre-specified sequential testing for the purpose of multiplicity adjustment, however, the p-values are all less than 0.05and numerical improvement was observed. ¥Proportion of pts with pre-existing skin involvement (BSA >3%) whose BSA improves to 0%.

APR, apremilast; BSA, body surface area; cDAPSA, Clinical Disease Activity in Psoriatic Arthritis; CI, confidence interval; CMH, Cochran-Mantel-Haenszel; csDMARD, conventional synthetic disease-modifying antirheumatic drug; IWRS, Interactive Web Response System; LDA, low disease activity (cDAPSA >4–≤13); LS, least- squares; MDA, Minimal Disease Activity; MMRM, mixed-effects model for repeated measures; PASDAS, Psoriatic Arthritis Disease Activity Score; PBO, placebo; PsAID-12 (0–10), Psoriatic Arthritis Impact of Disease; PtGA, Patient Global Assessment of Disease Activity; REM, remission (cDAPSA ≤4); SE, standard error; SJC, swollen joint count; TJC, tender joint count; VAS, visual analog scale.

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Abstract N°: 4892

Prediction of psoriatic arthritis at onset of psoriasis

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Introduction & Objectives:

Early intervention in PsA (PsA) is disease modifying and a delay in diagnosis by as little as six months is associated with substantially lower treatment response. Nevertheless, diagnosis is frequently delayed and the median time from onset of symptoms to diagnosis has been estimated at 2.5 years. Therefore we obtained data from the Stockholm Psoriasis Cohort (SPC), an inception cohort study with long-term follow-up, to identify predictors of PsA present already at onset of skin manifestations of psoriasis.

Materials & Methods:

The SPC enrolled patients with psoriasis within one year of first disease onset in the Stockholm area, Sweden. Patients were followed-up clinically at 5 and 10 years. The study started in 2000 and enrolled 753 patients. Data on patient history, life-style factors, genotype, phenotype, systemics inflammation, and metabolomics were obtained. The study was also linked to Swedish administrative registers to complement data from the examinations. Reflecting the substantial number of potential predictors, traditional statistical methods requiring pre-specification were complemented with statistical learning techniques to derive a predictive algorithm.

Results:

In total, the SPC enrolled 721 patients. Among the 686 patients alive after 10 years; 509 (74%) were followed-up clinically and are included in these analyses. Patient characteristics of the 509 patients are presented in Table 1.

In total 120/509 patients (24%) had PsA at ten years. We estimated associations between PsA at ten years and 121 potential predictors using logistic regression models controlling for sex and age. Table 2 presents variables with p-values that were smaller than their Benjamini and Hochberg critical values assuming a false discovery rate of 10%. The ten variables with the lowest p-values were all directly related to joint pain. However, the variable with ranks 11-20 comprised three markers of systemic inflammation (CRP, IL-6, and SAA), one lipid marker (LHDL-p), family history of rheumatic disease, and three variables related to general health and energy. Furthermore, variables related to sleep, heavy lifting, a genetic variant associated with IL23R, GlycA, lipid metabolism, and history of eye infection all had p-values below the threshold.

To derive a preliminary prediction algorithm, we combined data using a recursive partitioning algorithm using with conditional inference framework. The algorithm identified three subgroups with distinct risks for developing PsA: The first group comprised patients with peripheral enthesitis and a genetic polymorphism in an IL23-R coding gene (6% of all patients; 10-year PsA risk: 81%). The second group were patients with peripheral enthesitis without the polymorphism in the IL23-R coding gene (13% of all patients; 10-year PsA risk: 47%). The third group comprised patients without arthralgia, no history of neck pain, and normal range low density lipoprotein size (26% of all patients; 10-year PsA risk: 3%). The remaining 55% of patients had 10-year a PsA risk of 22%. The classification model had a c-statistic of 0.745.

Conclusion:

These results derived indicate the importance of several -omics for PsA prediction but also underline the value of

anamnestic data to estimate the risk of PsA. To improve calibration and discrimination of the predictive algorithm, future analyses will include more detailed joint-related data and genetic polymorphisms specific to PsA.

Table1. Baseline patient characteristics at enrollment examination

Factor	Value
Participants	509
Male sex, n (%)	224 (44.0%)
Age, mean (SD)	40 (16)
BMI, median (IQR)	24.7 (22.1, 27.5
Current smoking, n (%)	190 (37.4%)
Frequency of alcohol consumption	
Never	25 (5.6%)
Once per month	100 (22.5%)
Two to four times per month	186 (41.8%)
Two to three times per week	113 (25.4%)
Four time per week or more	21 (4.7%)
Onset phenotype	
Guttate	116 (22.8%)
Plaque	389 (76.4%)
Other	4 (0.8%)
Psoriasis disease severity*, n (%)	
Remission	21 (4.1%)
Mild disease	280 (55.0%)
Moderate disease	155 (30.5%)
Severe disease	53 (10.4%)
Scalp lesions, n (%)	280 (55.0%)
Nail lesions, n (%)	85 (16.7%)
Inflammatory bowel disease	5 (1.1%)
Thyroid disease	22 (5.1%)
Recurrent eye infection	14 (3.2%)
Arthralgia	204 (40.1%)
Peripheral enthesitis	82 (17.0%)
Heavy lifts at work	120 (31.6%)
Self-reported general health	
Excellent	44 (9.9%)
Very good	139 (31.4%)
Good	158 (35.7%)
Neither good nor bad	88 (19.9%)
Bad	14 (3.2%)

*Defined using combination of treatment and Psoriasis Area and Severity Index at the enrolment examination.

Table 2. Clinical factors associated with number of biologics

Variable	Odd ratio	P-value
Peripheral enthesis	7.75	<0.001
Arthrosynovitis	14.42	<0.001
Arthralgia	4.79	<0.001
History of wrist pain	5.55	<0.001
Inflammatory back pain	14.55	<0.001
History of fee pain	3.83	<0.001
History of hip and knee pain	3.56	<0.001
Tenosynovitis	10.88	<0.001
History of neck pain	3.91	<0.001
History of shoulder pain	3.61	<0.001
C-reactive protein	1.45	<0.001
General health	1.65	<0.001
Energy during the day	1.70	<0.001
History of lower back pain	2.56	<0.001
Serum Amyloid A (SAA)	1.40	<0.001
Physically tired	1.46	0.001
Upper back pain	2.25	0.001
Family history of rheumatic disease	1.96	0.004
Circulating IL-6	1.37	0.004
Large HDL particle count	0.90	0.005
Dactylitis	10.43	0.005
Plaque onset	2.33	0.005
Difficult to wake-up	1.32	0.005
Difficult to fall asleep	1.32	0.007
Physically exhausted during the date	1.11	0.008
High-density lipoprotein concentration	0.98	0.008
Heavy lifting	1.98	0.009
GlycA	1.00	0.010
IL23R SNP rs7530511	1.78	0.011
Wake up during night	1.30	0.013
Lipoprotein Insulin Resistance Score	1.01	0.021
LDL particle count	1.00	0.022
Mean size HDL particles	0.66	0.025
Small LDL particle count	1.00	0.026
Recurrent eye infections	3.35	0.028

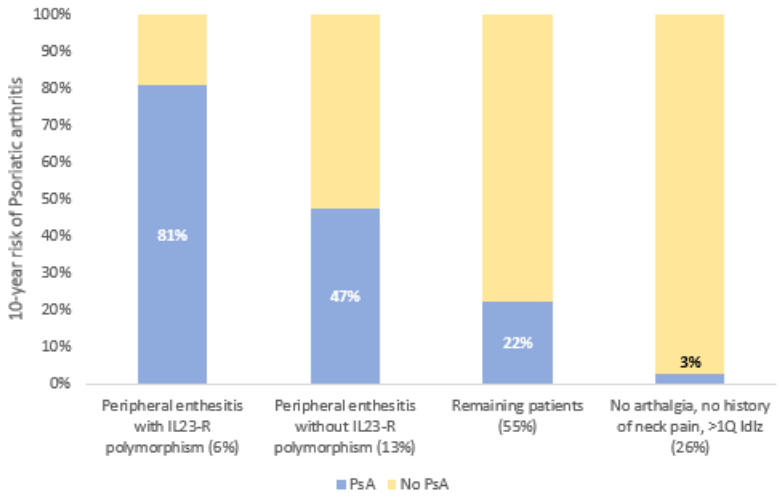

Figure 1 Subgroups distinct 10 year risks of developing PsA in patients with recent onset psoriasis. The groups were developed using recursive partitioning with conditional inference.

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Abstract N°: 4912

Risankizumab shows effectiveness regardless of the involvement of difficult-to-treat areas in plaque psoriasis: long-term results from a multicenter real-world experience – IL PSO (ITALIAN LANDSCAPE PSORIASIS)

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Risankizumab shows effectiveness regardless of the involvement of difficult-to-treat areas in plaque psoriasis: long-term results from a multicenter real-world experience – IL PSO (ITALIAN LANDSCAPE PSORIASIS)

Introduction & Objectives:

Risankizumab is a humanized monoclonal antibody that selectively targets interleukin-23, currently approved for the treatment of moderate-to-severe plaque psoriasis and psoriatic arthritis. Despite several clinical trials and real-life experiences being published, only limited data are available regarding the effectiveness of risankizumab on difficult-to-treat areas (i.e., scalp/face, palms/soles, genitalia and nails).

Materials & Methods:

We analyzed data from the psoriasis database of 17 Italian Dermatology Units. Nine hundred and sixteen patients were enrolled, all treated with risankizumab for at least one year. We compared the decrease in Psoriasis Area and Severity Index (PASI) after one, two and three years between patients with and without the involvement of difficult-to-treat areas. Moreover, we assessed the percentage of patients who achieved a site-specific Physicians Global Assessment (PGA) of 0 or 1 (clear or almost clear) at the same time points.

Results:

At baseline, 539 patients (58.84%) had the involvement of at least one difficult-to-treat area. Two hundred and ninety patients were affected by psoriatic onychopathy, 129 had palmoplantar psoriasis, 216 had scalp involvement, and 111 suffered from genital psoriasis. At baseline, the mean PASI was 15.57 and 16.41 among patients with and without the involvement of difficult-to-treat areas, respectively. At week 52, a reduction of at

least 90% in PASI compared with baseline (PASI 90) was achieved by 80.33% and 83.02% of patients in the two groups. Comparable PASI 90 responses were also observed after two and three years of treatment. Moreover, after one year, a site-specific PGA of 0 or 1 was achieved by 79.17%, 75.19%, 82.88%, and 80.34% of patients with the involvement of scalp, palms/soles, genitalia, and fingernails, respectively.

Conclusion:

In our experience, risankizumab showed comparable effectiveness in terms of PASI 90 in patients with and without the involvement of difficult sites. Furthermore, the effectiveness of risankizumab was maintained throughout three years of treatment in both subpopulations without any severe adverse events.

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Abstract N°: 4924

Serum level of neutrophil gelatinase-associated lipocalin (NGAL) and proprotein convertase subtilisin/kexin type 9 (PCSK9) in patients with psoriasis receiving cyclosporine therapy.

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Introduction & Objectives:

Neutrophil gelatinase-associated lipocalin (NGAL) may promote development of inflammation in psoriasis, whereas proprotein convertase subtilisin/kexin type 9 (PCSK9) may account for dyslipidemia in some of patients with psoriasis. The aim of the study was to analyze an influence of cyclosporine therapy on serum levels of NGAL and PCSK9 in patients with psoriasis vulgaris.

Materials & Methods:

Serum samples were obtained before and after 3-months cyclosporine therapy. Patients were grouped into responders and non-responders to cyclosporine depending whether they achieved at least 50% reduction of Psoriatic Activity Score Index (PASI) or not. Serum levels of PCSK9 and NGAL were assayed using commercially available ELISA tests. Levels lipids were measured with enzymatic method.

Results:

There were enrolled 40 patients. A significant decrease in the NGAL level in serum was seen in subjects who responded to cyclosporine. No similar dependance was seen for PCSK9 level in serum. Serum level of NGAL correlated with BSA and PASI, whereas serum level of PCSK9 correlated with total cholesterol (TChol) and low-density lipoprotein (LDL) at the baseline and after 3-month of the treatment.

Conclusion:

The level of NGAL in serum may serve as a marker of the response to cyclosporine therapy since it shows moderate to strong correlation with BSA and PASI, respectively. Correlation between serum level of PCSK9 and TChol as well as LDL concentration may help to understand a drug induced dyslipidemia after cyclosporine.

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Abstract N°: 4973

Short-term IL-23 neutralization reduces IL-23 transcription and number of activated pro-inflammatory mononuclear phagocyte (MNPs) in psoriasis skin ex vivo

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Introduction & Objectives:

In psoriasis, inflammatory signaling in the skin is primarily driven by the interleukin (IL)-23/Th17 axis. Systemic blockade of IL-23 in psoriasis patients has led to high levels of clinical response, accompanied by reduced frequencies of pro-inflammatory CD11c+CD14brightCD64bright monocyte-like cells, the main producers of IL-23 within mononuclear phagocyte (MNP) infiltrates in psoriatic lesions. Yet, how IL-23 blockade regulates MNPs remains unclear.

Materials & Methods:

To study this, we treated full-thickness human lesional and peri-lesional psoriatic skin with an anti-IL23p19 subunit mAb for up to 72h *ex vivo*.

Results:

The psoriatic phenotype was maintained during organ culture, as confirmed by demonstrating significantly higher numbers of CD3+IL-17A+, CD14+CD11c+, and CD14-CD11c+ cells in lesional versus peri-lesional skin, and release of IL-17A, CCL20, IL-1β, and β-defensin-2 into the medium. RNAseq analysis confirmed expression of the psoriatic transcriptomic signature in lesional compared to peri-lesional skin; this was partially corrected by IL-23 blockade in lesional skin, as demonstrated by a trend towards down-regulation of select genes (e.g. *IL17A*, *CCL20, IL1B*, and *IL36G)*. IL-23 blockade also led to a trend in reduction of IL-17A and significant reduction of the keratinocyte or myeloid cell-derived cytokines CCL20 and IL-1β. Importantly, neutralization of IL-23 in lesional skin resulted in decreased mRNA expression of *IL23A*, *FCGR1A* (CD64)*, CD40* and *CD80,* and* reduction in the proportions of CD40+ and CD64+ cells among CD14-CD11c+ and CD14+CD11c+, but not CD14+CD11c- cells.

Conclusion:

In conclusion, short-term IL-23 blockade affects inflammatory MNP activities in a psoriasis skin explant model.

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Abstract N°: 4983

Ethniciy affects pruritus and unpleasant skin symptoms among patients living with psoriasis :Data from the All Skins-All Colors-All Dermatoses: the ALL PROJECT:

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Introduction & Objectives

Pruritus [PrT] is the most frequently reported subjective sensation of psoriasis, it is considered the most bothersome symptom of the disease. leading to a deterioration in quality of life.

In addition to PrT that creates the urge to scratch, patients with psoriasis can suffer from other skin unpleasant sensations (SUS), such as tingling, pain, burning and tightness, which are rarely mentioned in studies. Ethnic differences in the prevalence and clinical characteristics of PrT and other unpleasant sensations have rarely been studied. The aim of the present study was to evaluate and compare the prevalence of PrT associated with psoriasis among different ethnic populations.

Material and methods

ALL PROJECT involves 50,552 individuals, representative of the adult populations of 20 countries spread over 5 all five continents. Among the 50552 individuals, patients who reported psoriasis, confirmed by a physician, were identified.

Four groups of patient respondents (PRs) were identified from self-reports: African descent (AD), Caucasian descent (CD), East Asian cohort from South Korea and Japan (EA) and Indian cohort (IC) from India.

Results

Among the 50552 individuals, 1759 patients who reported psoriasis were identified: including 924 (52.5%) males and 835 (47.5%) females. There were 73 (4.2%) AD respondents, 1086 (79.9%) CD respondents, 415 (61.7%) EA respondents and 185 (10.5%) IC respondents.

A total of 1470 PR (83.6%) reported subjective skin symptoms with 1146 (65.2%) PrT and 324 (18.4%) SUS without PrT. A total of 543 (30.9%) PR patients exclusively had PrT, while 603 (34.3%) suffered from PrT associated with the presence of unpleasant skin sensations. A total of 324 (18.4%) PR patients had unpleasant skin sensations without PrT. Only 289 (16.4%) PR had no symptoms. The absence of skin symptoms was more common in CD patients than in EA respondents (21.4% vs 8.9%, p 5,64E-06) and in IC respondents (21.4% vs 4.9%, $p<0.0001$). The prevalence of PrT (76.1% vs 61.7%, $p<0.0001$) was higher in EA respondents than in CD respondents (91.1% vs 78.6%, $p<0.0001$). The prevalence of SUS is higher in AD than in EA (37.0% vs 14.9%. $p<0.0004$) and CD (37.0% vs 16.9%, $p<0.0008$). The intensity of PrT was greater in Indian respondents than in EA (3.89 vs 3.09, p 1.54e-14), AD (3.89 Vs 3.21, $p<0.0001$) and CD (3.89 vs 3.15, , $p<0.0001$). CD respondents reported significantly more days with itching than EA respondents (4.05 vs 3.21, $p<0.0001$), AD respondents (4.05 vs 2.88 p 0.0006) and IC respondents (4.05 vs 3.54, $p< 0.007$).

Discussion

This is the first study to provide a comprehensive description of the frequency of Prurit and SUS in patients with

psoriasis according to ethnicity. Among psoriatic patients, the prevalence of PrT in our study, which is 65.2%, is in the range of that reported in other studies, which is estimated to range from 60 to 90% of patients with psoriasis. We found that there are also differences in the prevalence of subjective symptoms among racial/ethnic groups, with a higher prevalence of subjective symptoms in psoriasis among IC and EA, which may be explained by differences in skin permeability and barrier function. Our study also reported an increased prevalence of PrT with or without SUS in EA compared with CD.

EA DV CONGRESS
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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 5006

A changed life: The life experiences of patients with psoriasis receiving biological treatment

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Introduction & Objectives:

Psoriasis has a large negative impact on quality of life and is associated with both depression and anxiety. The introduction of biologics has improved treatment outcome but the ways in which patients perceive these improvements are not well characterized. Thus, the aim of this study was to investigate the everyday life experiences of patients with psoriasis receiving biological treatment in order to gain an understanding of their needs and to improve the quality of care.

Materials & Methods:

A qualitative narrative methodology was utilised. A total of 48 hours of participant observations during consultations, and 15 semi-structured interviews, were conducted with patients receiving biological treatment. Data were analysed according to Ricoeur's theory of interpretation.

Results:

Receiving biological treatment was experienced as a turning point, with a significant impact on physical, psychological and emotional levels. However, psychological consequences, such as isolation and social withdrawal, seemed to be a part of the patient's identity; the negative perceptions of psoriasis left marks behind that affected the patient's self-image. Perceived fear of discontinuance of the biological treatment resulted in insecurity, and patients were reluctant to initiate discussion about these concerns with health care professionals.

Conclusion:

Providing assistance when patients enter the transition of receiving biological treatment may be important. Patients' fear of biological treatment being discontinued is an ongoing issue that health care professionals could address.

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Abstract N°: 5014

Ocular findings in psoriasis: comparison with controls and association with demographic factors, occupation, comorbidities, and medical treatment

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Introduction & Objectives:

Extra-dermatological presentations are common in psoriasis, among which eye involvement has recently come to attention. Considering the uncertainty and conflicting report about this co-occurrence, the present study aims to compare the frequency of

ophthalmic presentations in psoriatic patients with non-psoriatic individuals.

Materials & Methods:

A case-control study was performed on 116 subjects with psoriasis and 116 age- and sex-matched controls. For every participant, the severity of psoriasis, presence of eye diseases, demographic information, comorbidities, and medication use were recorded. Comparisons were made between the two groups to assess differences in the rates of various common eye disorders and their associated factors using descriptive statistics and logistic regression modelling.

Results:

The occurrence of ophthalmic presentations was 82.8% in psoriatic cases compared with 67% in the control group ($p=0.002$). Meibomian gland dysfunction (73.28% vs. 50.86%, $p<0.001$) and blepharitis (23.28% Vs 8.62%, $p=0.009$) were the most differentially

distributed eye diseases. Ocular manifestations were also independently associated with age, comorbidities (diabetes, hypertension, and hyperlipidaemia), and outdoor occupations.

Among psoriatic patients, those receiving systemic treatment showed higher rates of eye diseases (95.1% vs. 76.0%, $p=0.009$), with most presentations seen among Retinoid and Cyclosporine users. After consideration of confounding factors, the chance of ocular disease in individuals with psoriasis was estimated to be 5.77-fold higher than in controls ($p=0.001$).

No association was found between psoriasis and cataract, uveitis, or corneal disease.

Conclusion:

These findings highlight the importance of ophthalmological examinations in psoriatic patients for preventative care and modification of the treatment plan.

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Abstract N°: 5031

Bimekizumab efficacy through 144 weeks in moderate to severe plaque psoriasis: Patient-reported outcomes from BE RADIANT

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Introduction & Objectives

Psoriasis is a chronic disease requiring long-term control; objective severity measures may not fully capture the impact of psoriasis on patients' lives.1 Here, the impact of bimekizumab (BKZ) on patientreported outcomes (PROs) in patients with moderate to severe plaque psoriasis is reported over 144 weeks of the BE RADIANT phase 3b trial.

Materials & Methods

Patients were randomised 1:1 to: BKZ 320 mg every 4 weeks (Q4W) to Week 16, then Q4W or Q8W to Week 48; or secukinumab (SEC) 300 mg weekly to Week 4, then Q4W to Week 48.2,3 The ongoing openlabel extension (OLE) began at Week 48; all patients received BKZ Q4W or Q8W based on Week 48 Psoriasis Area and Severity Index response and Week 16–48 treatment. Following protocol amendment, patients receiving BKZ Q4W switched to Q8W at Week 64 or the next scheduled visit.

Mean proportions of patients (referred to as rates) scoring 0 in the itching, skin pain, and scaling Psoriasis Symptoms and Impacts Measure items (P-SIM=0; no symptom, range 0–10) and 0 or 1 in the Dermatology Life Quality Index (DLQI 0/1; no effect of skin disease on patient's life, range 0–30) are reported to Week 144.

Data are reported for patients initially randomised to BKZ or SEC who later entered the OLE and received open-label BKZ (BKZ/BKZ and SEC/BKZ patients), and the subset of BKZ/BKZ patients who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE). Patients who discontinued due to lack of efficacy or treatmentrelated adverse events were considered nonresponders at subsequent timepoints; multiple imputation was used for all other missing data (modified non-responder imputation; mNRI).

Results

336 BKZ and 318 SEC-randomised patients entered the OLE. Of the 336 BKZ/BKZ patients, 177 received BKZ Q4W/Q8W/Q8W.

Proportions of patients with P-SIM=0 at baseline were largely similar for BKZ/BKZ vs SEC/BKZ patients (**Table**), as

were baseline mean scores: itching, 6.6 vs 6.6; skin pain, 4.5 vs 4.6; scaling, 6.7 vs 6.7. Week 48 PSIM=0 rates were numerically higher with BKZ vs SEC (BKZ/BKZ and SEC/BKZ patients, respectively) for each item (**Table**). BKZ/BKZ patients maintained high PSIM=0 rates from Week 48–144, as did the BKZ Q4W/Q8W/Q8W subgroup (**Table**). SEC/BKZ patients reported increased P-SIM=0 rates for itching and scaling and maintained rates for skin pain after switching to BKZ at Week 48. Week 144 PSIM=0 rates for BKZ/BKZ vs SEC/BKZ patients were: itching, 62.4% vs 60.0%; skin pain, 80.0% vs 78.9%, scaling, 67.4% vs 67.5%.

Proportions of patients with DLQI 0/1 at baseline were similar for BKZ/BKZ vs SEC/BKZ (**Table**), as was mean baseline total DLQI: 10.9 vs 11.2. Week 48 DLQI 0/1 rates were numerically higher with BKZ vs SEC. High rates were maintained through Week 48–144 in the BKZ/BKZ arm and the BKZ Q4W/Q8W/Q8W subgroup (**Table**). Rates in SEC/BKZ patients increased after switching to BKZ at Week 48 and remained high to Week 144 (**Table**). At Week 144, 80.3% BKZ/BKZ vs 79.6% SEC/BKZ patients achieved DLQI 0/1.

Conclusion

BKZ/BKZ patients reported improvements in PROs at Week 48 that were durable through Week 144. SEC/BKZ patients reported increased rates of PRO achievement after switching to BKZ at Week 48, which remained high to Week 144 and were similar to rates in BKZ/BKZ patients.

References

1. Augustin M & Radtke MA. Expert Rev Pharmacoecon Outcomes Res 2014;14:559–68; **2.** Kokolakis G. Presented at EADV 2022, P1595; **3.** Reich K. N Engl J Med 2021;385:142–52, NCT03536884.

Funding

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Table. P-SIM=0 and DLQI 0/1 rates through Weeks 0–144 of BE RADIANT (mNRI)

	P-SIM=0 % [95% CI]									DLQI 0/1 % [95% CI]		
	Itching			Skin Pain			Scaling					
	BKZ/BKZ N=336	SEC/BKZ N=318	BKZ Q4W/Q8W /Q8W N=177	BKZ/BKZ N=336	SEC/BKZ N=318	BKZ Q4W/Q8W /Q8W N=177	BKZ/BKZ N=336	SEC/BKZ N=318	BKZ Q4W/Q8W /Q8W N=177	BKZ/BKZ N=336	SEC/BKZ N=318	BKZ Q4W/Q8W /Q8W N=177
Double-blinded study period (patients receiving BKZ or SEC)												
Baseline[a]	3.6	3.5	4.5	19.3	12.9	20.9	1.5	1.3	1.7	5.7	5.0	7.9
Week 48	68.3 [63.3, 73.4]	55.5 [50.0, 61.0]	71.4 [64.6, 78.1]	88.2 [84.7, 91.7]	81.6 [77.2, 85.9]	92.6 [88.7, 96.5]	79.1 [74.7, 83.5]	57.1 [51.6, 62.6]	82.5 [76.9, 88.2]	87.4 [83.9, 91.0]	80.7 [76.4, 85.1]	88.9 [84.1, 93.6]
Open-label extension (all patients receiving BKZ)												
Week 72	63.9 [58.7, 69.1]	67.5 [62.3, 72.8]	64.6 [57.5, 71.8]	85.4 [81.5, 89.3]	84.2 [80.1, 88.4]	87.2 [82.1, 92.3]	72.7 [67.9, 77.6]	75.6 [70.8, 80.5]	74.5 [68.0, 81.0]	86.3 [82.5, 90.1]	86.3 [82.3, 90.3]	87.9 [83.0, 92.9]
Week 96	63.2 [57.9, 68.4]	63.0 [57.6, 68.5]	65.6 [58.4, 72.8]	82.8 [78.5, 87.0]	81.5 [77.0, 85.9]	83.9 [78.2, 89.5]	74.7 [70.0, 79.5]	73.5 [68.5, 78.6]	76.8 [70.4, 83.2]	86.0 [82.1, 89.9]	81.5 [77.1, 86.0]	86.8 [81.5, 92.0]
Week 120	63.2 [57.9, 68.5]	61.8 [56.3, 67.3]	66.1 [59.0, 73.2]	81.0 [76.7, 85.4]	80.4 [75.9, 85.0]	84.2 [78.6, 89.8]	67.6 [62.5, 72.8]	69.8 [64.6, 75.1]	70.8 [63.9, 77.7]	83.9 [79.8, 88.0]	83.3 [78.9, 87.7]	86.3 [81.0, 91.6]
Week 144	62.4 [57.0, 67.9]	60.0 [54.4, 65.6]	65.0 [57.3, 72.6]	80.0 [75.4, 84.6]	78.9 [74.2, 83.6]	83.1 [77.3, 89.0]	67.4 [62.1, 72.7]	67.5 [62.1, 72.8]	70.2 [63.1, 77.3]	80.3 [75.8, 84.8]	79.6 [74.8, 84.4]	81.8 [75.8, 87.8]

Data were imputed using mNRI; patients who discontinued due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. The BKZ/BKZ group includes all patients who received BKZ in both the double-blinded treatment period and OLE, regardless of dosing frequency. The SEC/BKZ group includes patients initially randomised to SEC who switched to BKZ upon entering the OLE at Week 48. The BKZ Q4W/Q8W/Q8W group includes patients who received BKZ 320 mg Q4W to Week 16, Q8W to Week 48, and continued to receive BKZ Q8W from the start of the OLE. Baseline data and rates for BKZ/BKZ and SEC/BKZ patients at baseline, Week 48, Week 72, and Week 96 have been reported previously using an alternative mNRI analysis and data cut.[2] [a] Presented in the table are P-SIM=0 and DLQI 0/1 rates at baseline. Mean baseline P-SIM scores for the BKZ/BKZ, SEC/BKZ, and BKZ Q4W/Q8W/Q8W groups were: itching, 6.6, 6.6, 6.2; skin pain, 4.5, 4.6, 4.2; scaling, 6.7, 6.7, 6.4. Mean baseline DLQI scores for the BKZ/BKZ, SEC/BKZ, and BKZ Q4W/Q8W/Q8W groups were: 10.9, 11.2, 10.5. BKZ: bimekizumab; CI: confidence interval; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; P-SIM: Psoriasis Symptoms and Impacts Measure; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab.

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Abstract N°: 5033

Implementing Value-Based Healthcare in Psoriasis management: baseline findings of the Value in Psoriasis (IRIS) trial

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease and is associated with a high disease burden, a negative impact on quality of life and multiple associated comorbidities. However, the current psoriasis management often remains siloed, inappropriate and does not always fulfill patients' needs. With the high economic burden of psoriasis and the rising healthcare expenditures, the healthcare sector is under financial pressure which is why a shift towards a sustainable system is required. The conceptual framework known as value-based healthcare (VBHC) is further explored in psoriasis management with 'value' being defined as 'the achieved patient-relevant outcomes, divided by the costs needed to achieve these outcomes'. We applied the VBHC approach to psoriasis, in the dedicated setting of PsoPlus, and the trial presented here documents the value we bring for the investments we make. The first baseline findings are presented.

Materials & Methods:

The Value in Psoriasis (IRIS) trial (NCT05480917) is a prospective clinical study in which new patients attending the psoriasis clinic (PsoPlus) of the Ghent University Hospital, Belgium, are followed up during a period of 1 year. We aim for a sample size of 350 patients. The primary outcome is to determine the value created for psoriasis patients through data envelopment analysis, which obtains a value score. Secondary outcomes are related to comorbidity control, outcome evolution and treatment costs. In addition, a bundled payment scheme will be determined as well as potential improvements in the treatment process. A value-based outcome set was defined earlier resulting in 21 outcomes, including provider-reported (n = 5) and patient-reported outcomes (n = 16).

Results:

A total of 49 new psoriasis patients are currently (January 12, 2023 till April 24, 2023) included in the trial with a mean Psoriasis Area and Severity Index (PASI) of 6,6 (SD 4.65). A baseline PASI from 6 to 10 was observed in 26,5% and 11 or higher in 20,4%. The higher the PASI, the more severe their symptoms ($r = .638$; $p < ,001$), with redness, scaling, and flaking being reported as most disturbing. Only 4,1% was treated with systemic therapy, 77,6% with topical agents and 16,3% was not treated at all. The overall treatment satisfaction among patients who were treated within the last year was low. Treatment convenience and treatment efficacy were scored as 56,3% (SD 20,83) and 37,0% (SD 17,44). Communication with the previous healthcare professional was scored poorly (31,9%; SD 24.93). Finally, dyslipidaemia (52,2%), anxiety and depression (48,9%) and overweight or obesity (46,9%) were the three most observed comorbidities in our patients. A sample size of 100 patients and 3 and 6 month outcome evolution are expected in the final quarter of 2023.

Conclusion:

At baseline, mild and severe psoriasis was associated with high symptom burden. Patients were still undertreated for their skin disease and comorbidities and reported low satisfaction scores regarding treatment convenience, treatment efficacy and communication. These findings show that an integrated approach around psoriasis patients is highly needed. By introducing VBHC in psoriasis management such an approach can be achieved. Measuring

both the outcomes and costs simultaneously, creates insights in cost drivers, and enables continuous improvement in efficiency of clinical practice and patient-relevant outcomes, which will lead to higher value in psoriasis patients.

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Abstract N°: 5039

The complexity of the treatment journey has no impact on subsequent drug survival of first-time biologics in patients with psoriasis – a nationwide cohort study.

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Introduction & Objectives:

The treatment journey prior to initiating biologics in patients with psoriasis can be lengthy and intricate as treatments are typically prescribed by a successive approach. Limited evidence exists regarding the putative effects of the treatment journey before starting biologics on subsequent drug survival. The objective of this study was thus to examine the potential impact of a complex treatment journey on subsequent biologic drug survival in patients with psoriasis.

Materials & Methods:

The study utilised longitudinal data from Danish national registries and included all adult patients who, for the first time, initiated a biologic for. The maximum follow-up period was set at 5 years. Patients were followed from first prescription of a biologic, between January 1 2010 and June 30 2021, to allow for a minimum follow-up period of 6 months. The study used three proxies for complexity as well as the following conventional treatments: acitretin, cyclosporine, dimethyl fumarate, and methotrexate. The first proxy was the cumulative number of treatment series of all conventional treatments. The second proxy was the number of unique conventional treatments prior to the initiation of biologics. The third proxy was time from first conventional treatment to first biological therapy. The proxies were stratified into quartiles. The drug survival for the three different proxies were illustrated using Kaplan–Meier curves and compared using a multivariate log rank test. The Bonferroni correction was applied, and a p-value of < 0.003 was considered statistically significant. A sensitivity analysis was conducted by grouping patients according to their biological treatment.

Results:

A total of 2,496 patients were included in the study with 1,380 (55.3%) receiving adalimumab, 608 (24.4%) receiving ustekinumab, 271 (10.9%) receiving secukinumab, 166 (6.7%) receiving etanercept, and 71 (2.8%) receiving infliximab. The mean age at initiation of biologics was 43.6 years (Standard Deviation (SD) 15.2 years) and most patients were male (62.9%). During the follow-up of 5,477 patient-years, 1,953 patients (78.2%) reached the main endpoint of discontinuation. The probability of remaining on the therapy after the first 12 months was 56.4% for adalimumab, 46.2% for etanercept, 49.3% for infliximab, 53.5% for secukinumab, and 76.2% for ustekinumab. Using a multivariate log rank test, the probability of remaining on treatment was unaffected by the three proxies used for the complexity of the treatment journey.

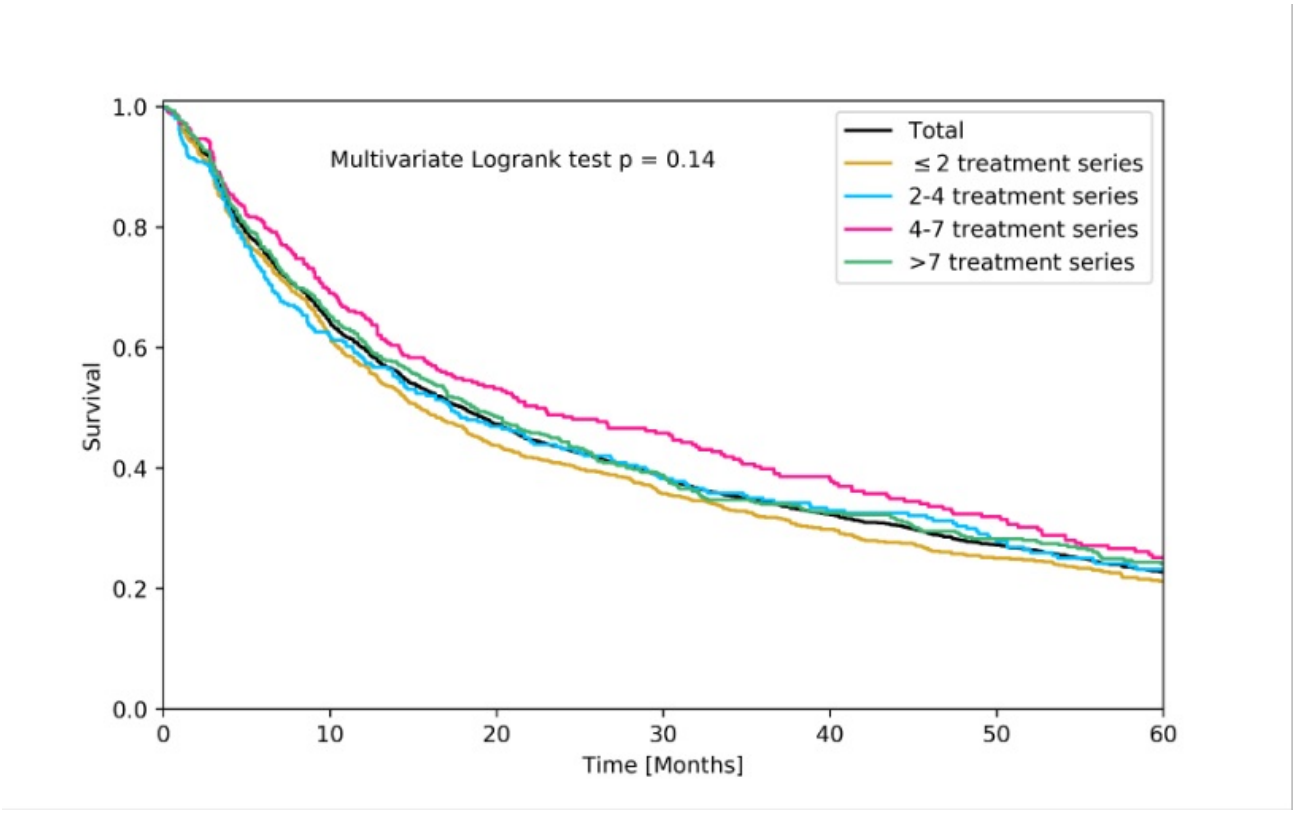
Conclusion:

Neither of the three proxies used to assess the complexity of the treatment journey appeared to impact drug survival for patients with psoriasis initiating first-time biological treatment. As long as patients experience adequate disease control, these results suggest that conventional systemic treatment still holds value in the management of psoriasis without negatively impacting drug survival of biologics if biologics were to be initiated

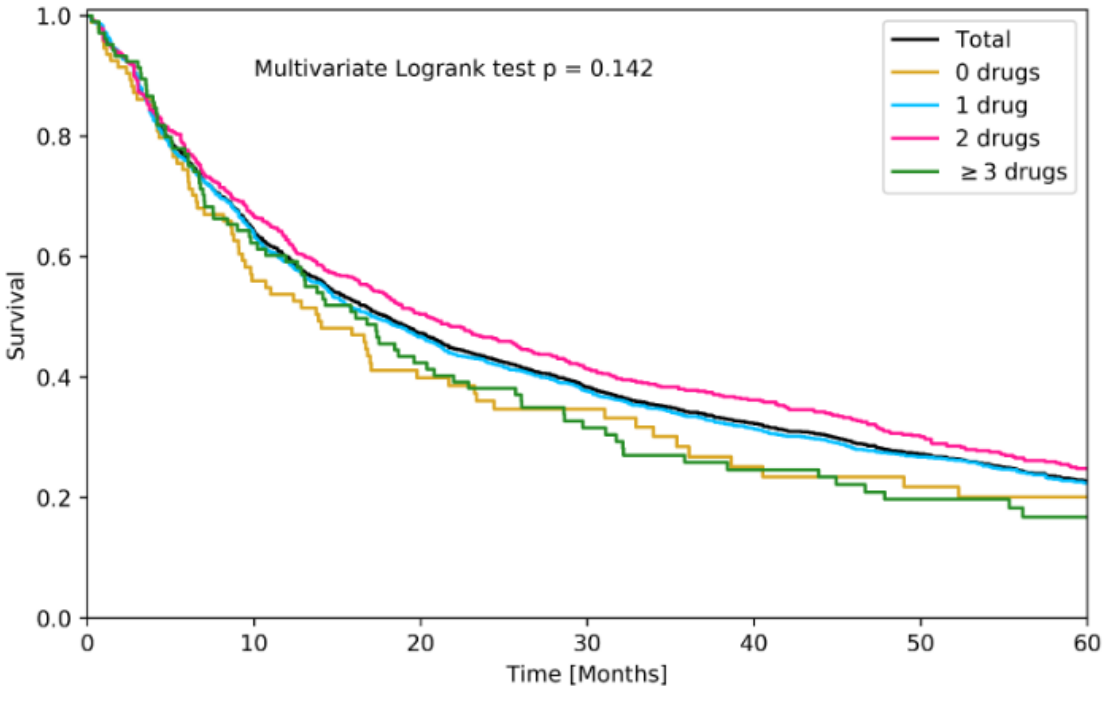
at a later stage. However, this finding does not account for the impact of the time from disease onset to systemic treatment, whether biological or not, which may hold potential for disease modification.

FIGURE 1a Kaplan–Meier curve illustrating drug survival for all biologics stratified on:

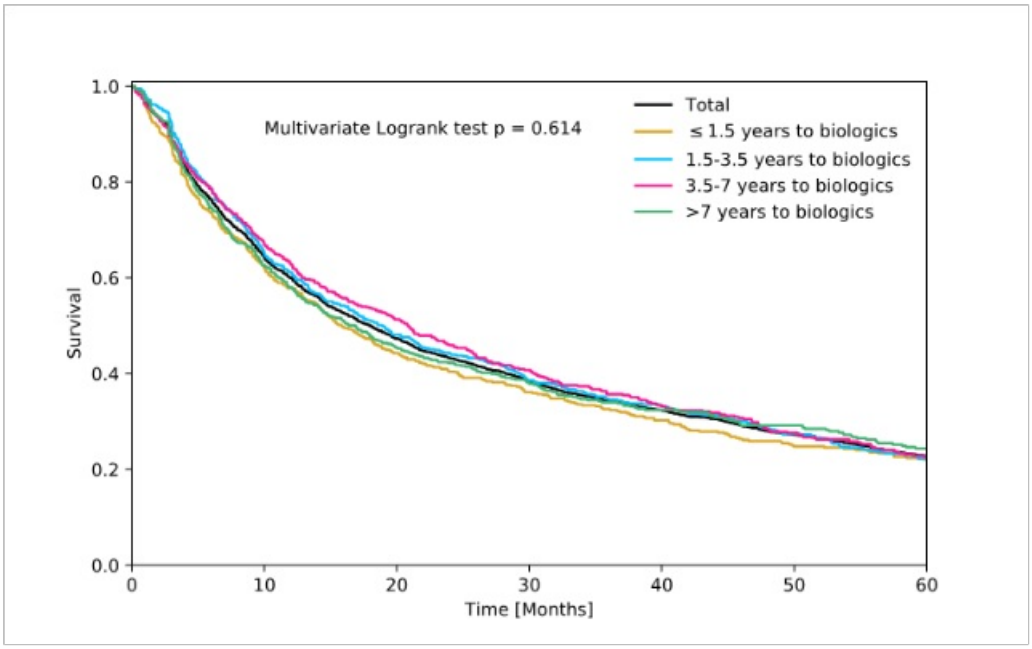
A) number of treatment series with conventional treatments.



b) number of unique conventional treatments.



c) time from first systemic treatment to biologic.


Multivariate Logrank test p = 0.614
Total
≤ 1.5 years to biologics
1.5-3.5 years to biologics
3.5-7 years to biologics
>7 years to biologics
Survival
Time [Months]
1.0
0.8
0.6
0.4
0.2
0.0
0
10
20
30
40
50
60

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Abstract N°: 5070

Childhood and adult-onset psoriasis: do metabolic and cardiovascular comorbidities differ?

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Introduction & Objectives:

Cardiovascular comorbidities including hypertension, coronary diseases, major cardiovascular events (MACE), and metabolic comorbidities such as obesity, abnormal lipid metabolism and insulin resistance have been associated with psoriasis, however the relationship of those comorbidities with age at onset is not clear.

In our study, we aimed to evaluate the frequency of cardiovascular and metabolic comorbidities in adult patients aged 30 to 50 years, and compare of the frequency of those in patients with childhood-onset of psoriasis (COP) - onset between the ages of 0 and 18 -, with patients with adult-onset psoriasis (AOP) - onset after the age of 18 -.

Materials & Methods:

This cross-sectional, multicenter study of adults with psoriasis was conducted in 12 dermatology centers in 12 different regions of Turkey. Data on patient and disease characteristics, presence of cardiovascular risk factors and cardiovascular diseases, metabolic diseases, and other comorbidities were evaluated. Metabolic laboratory parameters including fasting blood glucose, insulin, total cholesterol, fasting triglyceride, HDL-Cholesterol, LDL-cholesterol, HOMA-IR, and inflammation markers including C-reactive protein and sedimentation rate, the levels of liver enzymes and creatinine were systematically recorded.

Results:

A total of 1955 patients with psoriasis (female 47.8%, male 52.2%, and 34.5% with COP) were consecutively included in the study. While women were affected more frequently in COP group, men were in the majority in AOP group. The mean disease duration was 28.28 ± 53.42 years. First-degree relatives had a history of psoriasis in 30.7% of the patients. Female COP patients had a higher rate of psoriasis history in the family compared to male COP patients. Arthritis was present in 16% of the patients. While the onset of the disease in childhood did not increase the incidence of arthritis, the age at diagnosis of arthritis was significantly lower in COP. While generalised plaque and erythrodermic type of psoriasis were significantly more common in COP group, localized

plaque, inverse, palmoplantar and pustular type of psoriasis were more common in AOP group. The mean age of onset of cardiovascular diseases was significantly lower in women. While the frequencies of dyslipidemia and metabolic syndrome were found to be higher in those with AOP, the mean age of onset of dyslipidemia and obesity was lower in those with COP. While there were no differences between the groups regarding the frequency of cardiovascular events, such as myocardial infarction, stroke, etc., only history of angiography was more common in AOP group. Total cholesterol, LDL-cholesterol, HOMA-IR levels were found to be higher in those with AOP.

Conclusion: Our results showed that COP does not seem to be an additional risk factor for higher frequencies of cardiovascular and metabolic comorbidities during adulthood.

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Abstract N°: 5092

ERAP2 Gene Variants as a Potential Clinical Biomarker of Anti-IL-17A Response in Psoriasis Vulgaris

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Introduction & Objectives:

Interleukin 17A (IL-17A) is a proinflammatory cytokine, that plays an essential role in the development of psoriasis. While treatment with anti-IL-17A monoclonal antibodies treatments has demonstrated efficacy in psoriasis patients, not all patients respond equally well, highlighting the need for biomarkers to predict treatment response. A specific polymorphism in the *ERAP2* gene has been associated with psoriasis and other immune-mediated diseases. In this study, we aimed to investigate the association between the *ERAP2* rs2248374 genotype and response to secukinumab treatment in psoriasis patients.

Materials & Methods:

A total of 75 patients with plaque psoriasis were included. All patients were genotyped for the*ERAP2* rs2248374 single-nucleotide polymorphism (SNP) and *HLA-C*06:02* status.

Results:

Our results showed that the *ERAP2* G/G genotype was associated with a significantly lower response rate to secukinumab treatment. Stratifying for *HLA-C*06:02* status pointed towards an increased risk of treatment failure among *HLA-C*06:02*-positive patients, although this was not statistically significant.

Conclusion:

Our findings suggest that *ERAP2* gene variants may serve as a potential clinical biomarker of secukinumab treatment response in psoriasis vulgaris.

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Abstract N°: 5109

Calcipotriol Plus Betamethasone Dipropionate Foam as a treatment for Psoriasis: a systematic review and meta-analysis

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Introduction & Objectives:

Psoriasis Vulgaris (PV) is an immune-mediated skin condition characterized by well-demarcated erythematous plaques covered with silvery scales, commonly over the extensor surfaces of the skin, scalp and lumbosacral region. When treating mild to moderate cases, topical medications are often the preferred long-term solution. Calcipotriene and Betamethasone Dipropionate (Cal/BD) gel and ointment are commonly used and considered effective. However, the latest Cal/BD foam formulation has shown better patient adherence, potentially improving maintenance treatment. Recent studies suggest that Cal/BD foam has higher absorption rates and targets different pathological points of psoriasis, making it a viable treatment option. However, there is still a need for high-quality evidence to support Cal/BD foam for PV treatment, warranting a systematic review and meta-analysis.

Materials & Methods:

We searched PubMed, Embase, and Cochrane Central for randomized controlled trials (RCTs). A total of 5 randomized studies were included, with 1215 patients. The primary outcomes were effectiveness and adverse events (AEs), which were reported as odds ratio (OR). To assess effectiveness, we considered Psoriasis Global Assessment (PGA), Physician's Global Assessment (PaGa) scores, and patient-reported improvement. Statistical analysis was performed by Review Manager 5.4, and heterogeneity was assessed with I^2 statistics. The protocol was prospectively registered in PROSPERO (ID: CRD42023397407).

Results:

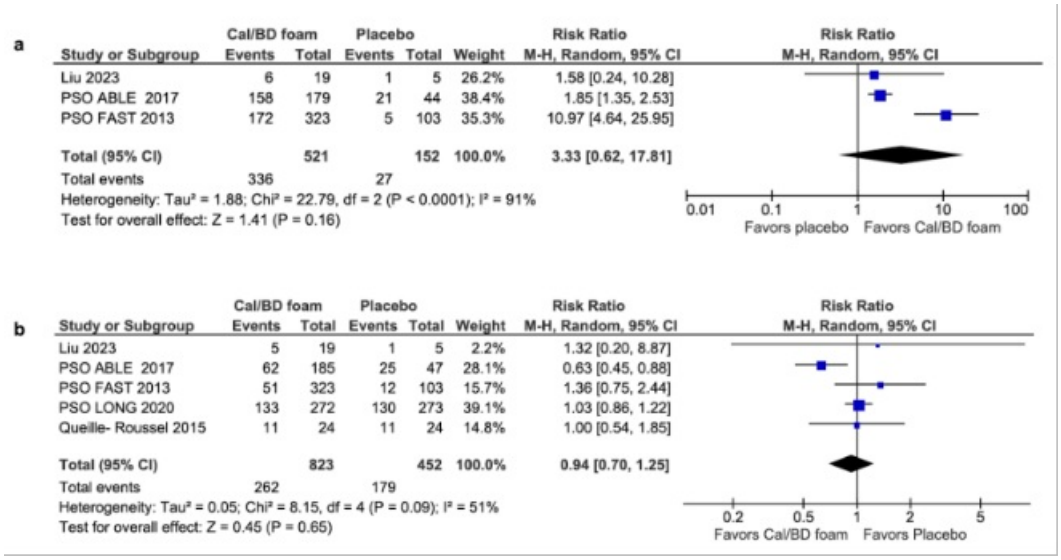
This Meta-analysis included 5 RCTs. We found no significant differences in the incidence of adverse events (AEs) between Cal/BD foam and placebo, including pain in the application site, diarrhea, and headache (RR 0.94; 95% CI 0.7-1.25; $p = 0.65$). Similarly, there were no significant differences in effectiveness between Cal/BD foam and placebo (RR 3.33; 95% CI 0.62-17.81; $p = 0.16$).

Conclusion:

Our analysis found no significant differences in adverse events and effectiveness between Cal/BD foam and placebo. However, we acknowledge that limited available clinical trials, as well as the use of different measurement scales and a small number of included patients, may have led to underpowered results. While most studies suggest improved patient adherence and tolerability, further high-quality studies are necessary to evaluate optimal dosages, protocol combinations, and vehicles. To strengthen our findings, future studies should include larger samples sizes which ensure accurate comparisons.

Fig 1 Cal/BD foam and placebo did not show significant differences in effectiveness**(a)** and in the incidence of

adverse events (AEs) **(b).**



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Abstract N°: 5120

Relationship between obesity, waist circumference, and psoriasis severity in patients in Rizal Medical Center: A cross-sectional study

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Introduction & Objectives:

Psoriasis is considered to be one of the most common chronic, noncommunicable, immunologically-mediated papulosquamous skin inflammation seen in dermatological out patient clinics affecting patients of all ages, although it is more commonly found in the middle-aged population. The most common type is chronic plaque psoriasis and was deemed to have a bidirectional relationship with obesity as well as an above normal waist circumference. This study aimed to assess the relationship between obesity, waist circumference, and psoriasis severity in patients in Rizal Medical Center, a tertiary hospital in the Philippines.

Materials & Methods:

This was a cross-sectional research wherein the study population involved psoriasis patients in Rizal Medical Center aged 18 and above. Participants were asked for their weight and height as well as their waist circumference measured at the level of the umbilicus. Asia-pacific metrics was used to categorize participants' body mass index. Meanwhile, waist circumference was classified according to the WHO cutoff per sex.

Results:

A total of 186 participants were enrolled in this study: 62.37% were obese, 23.66% were normal, 11.83% were overweight and 2.15% were underweight. 79.57% participants also presented with normal waist circumference. 70.43% of the patients enrolled have moderate to severe psoriasis severity and 59.54% were females. Statistical analysis was performed using cramer's V.

Conclusion:

In conclusion, both body mass index and an above normal waist circumference has shown weak association to the psoriatic severity.

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Abstract N°: 5126

Ixekizumab provides high PASI response for both shorter and longer psoriasis disease durations: results from six randomized clinical trials

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Introduction & Objectives:

Ixekizumab (IXE) is a high-affinity, monoclonal antibody targeting IL-17A approved for the treatment of moderate-to-severe psoriasis (PsO). Clinical response to biologic treatment can vary according to patient demographics and disease characteristics. Although studies indicate that longer disease duration does not impact the response to IXE treatment1,2, these analyses have not examined the response of patients with a shorter disease duration. This study aims to assess the efficacy of IXE in different disease duration subgroups.

Materials & Methods:

An integrated post hoc analysis consisting of patients treated with on-label IXE from the intent to treat populations of six pooled randomised clinical trials (UNCOVER-1, UNCOVER-2, UNCOVER-3, IXORA-S, IXORA-R and SPIRIT-H2H) was used to assess the efficacy of IXE in disease duration subgroups (<2 or ≥2 years and <5 or ≥5 years). The response rates of patients in each subgroup achieving 90% and 100% improvement from baseline in Psoriasis Area and Severity Index (PASI90 and PASI100) through week 12 was evaluated. Another outcome evaluated was the mean PASI percent improvement from baseline through week 12. For missing data, non-responder imputation was applied for categorical responses and modified baseline observation carried forward was applied for continuous results. PASI response rates with 95% confidence intervals (CI) and mean PASI percent improvement with 95% CI were summarized. Descriptive data compared the baseline disease and demographics characteristics across subgroups.

Results:

Baseline demographics and disease characteristics were similar among most of the selected patient subgroups (Table 1). A higher proportion of patients had nail psoriasis in the longer disease subgroups (≥2 years: 60.3%; ≥5 years: 61.1 %) compared to patients in the shorter disease subgroups (<2 years: 36.7 %; <5 years: 46.6 %); a similar trend was observed for psoriatic arthritis (PsA) (Table 1). All subgroups of patients treated with IXE showed rapid skin clearance with PASI90 and PASI100 response rates increasing over time (Figure 1). Overall, PASI response rates and treatment efficacy at week 12 were similar across the subgroups (Figure 1). Mean percentage improvements in PASI scores were similar for the shorter and longer disease duration subgroups (Figure 2).

Conclusion:

The response rates and mean PASI percent improvement were similar for the shorter and longer disease duration

subgroups (<2, ≥2 years and <5, ≥5 years). IXE consistently showed high efficacy at 12 weeks, and early onset of skin clearance at 4 weeks, for patients with moderate-to-severe PsO irrespective of disease duration in these subgroup analysis from 6 clinical studies through week 12.

References:

1. Lynde, C., et al. Comparative Effectiveness of Biologics Across Subgroups of Patients with Moderate-to-Severe Plaque Psoriasis: Results at Week 12 from the PSoHO Study in a Real-World Setting. Adv Ther. 2023; 40(3):869-886.
2. Torres, T., et al. Drug survival of IL-12/23, IL-17 and IL-23 inhibitors for psoriasis treatment: a retrospective multi-country, multicentric cohort study. Am J Clin Dermatol. 2021; 22:567–579.

Data are mean (standard deviation) unless otherwise stated.

Abbreviations: Body surface area (BSA); Dermatology Life Quality Index (DLQI); Psoriasis Area and Severity Index (PASI); Psoriatic arthritis (PsA); Psoriasis (PsO); Static Physician Global Assessment (sPGA).

*Pooled data from 6 clinical trials: UNCOVER-1, UNCOVER-2, UNCOVER-3, IXORA-R, IXORA-S and SPIRIT-H2H (PsO population).

[a]Nail psoriasis is summarized as collected for each study: Baseline Fingernail Involvement (UNCOVER-1, UNCOVER-2, UNCOVER-3, IXORA-S), Physician's Global Assessment of Fingernails score>0 (IXORA-R), Nail Psoriasis Severity Index score>0 (SPIRIT-H2H).

[b]Pooled data from 5 studies (IXORA-S excluded, as no PsA data collected at baseline).

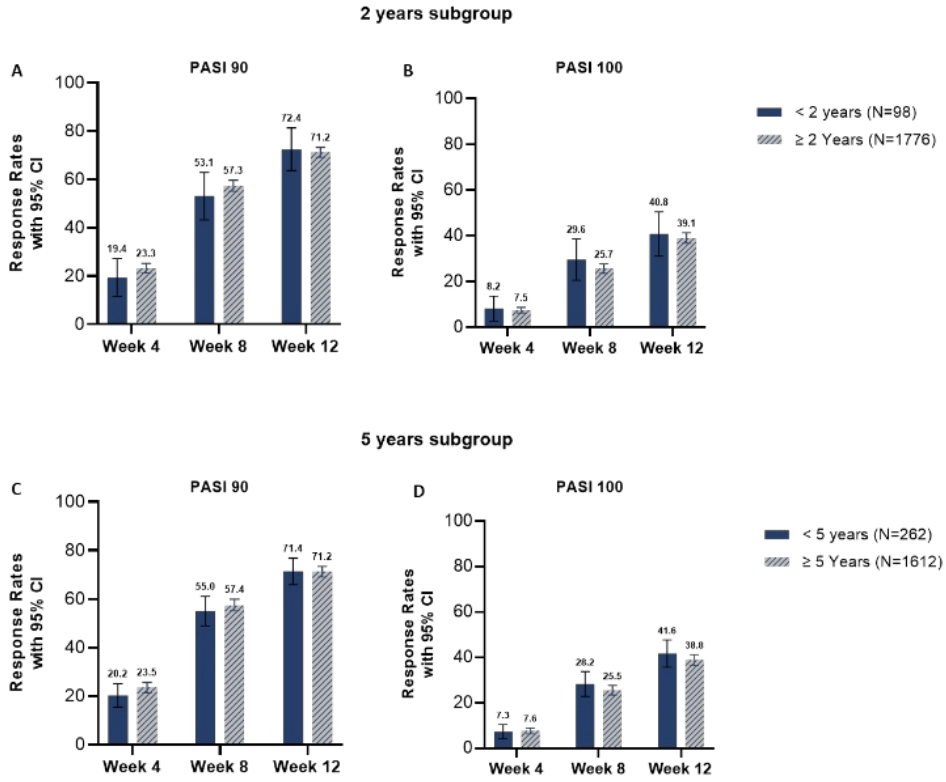
[c]Pooled data from 4 studies (SPIRIT-H2H and IXORA-R excluded, as no scalp PsO data collected at baseline).

	Duration of PsO symptoms (N=1874)			
	2 years subgroup		**5 years subgroup**	
	< 2 years (N=98)	**≥ 2 years (N=1776)**	**< 5 years (N=262)**	**≥ 5 years (N=1612)**
Age, years	44.4 (16.1)	46.1 (13.1)	43 (15.3)	46.5 (12.9)
Male, n (%)	54 (55.1)	1170 (65.9)	162 (61.8)	1062 (65.9)
Weight, kg	89 (23.4)	92 (23.4)	93.2 (27.2)	91.6 (22.7)
Duration of psoriasis (PsO), years	1.2 (0.4)	19.1 (12.2)	2.6 (1.3)	20.7 (11.7)
Percentage of Body surface area (BSA)	26.4 (16.8)	26.7 (17.2)	25.1 (16)	26.9 (17.4)
PASI score	19.6 (7.2)	20 (8)	19.8 (7.9)	20 (8)
sPGA	3.4 (0.5)	3.6 (0.6)	3.5 (0.6)	3.6 (0.6)
Nail Psoriasis[a], n (%)	36 (36.7)	1071 (60.3)	122 (46.6)	985 (61.1)
PsA[b], n (%)	12 (13.2)	442 (26.9)	49 (20.2)	405 (27.1)
Scalp Psoriasis[c]	45 (86.5)	1137 (90.7)	134 (89.3)	1048 (90.7)
DLQI score	14.1 (6.4)	12.7 (7)	13.8 (6.8)	12.6 (7)

Tables and Figures

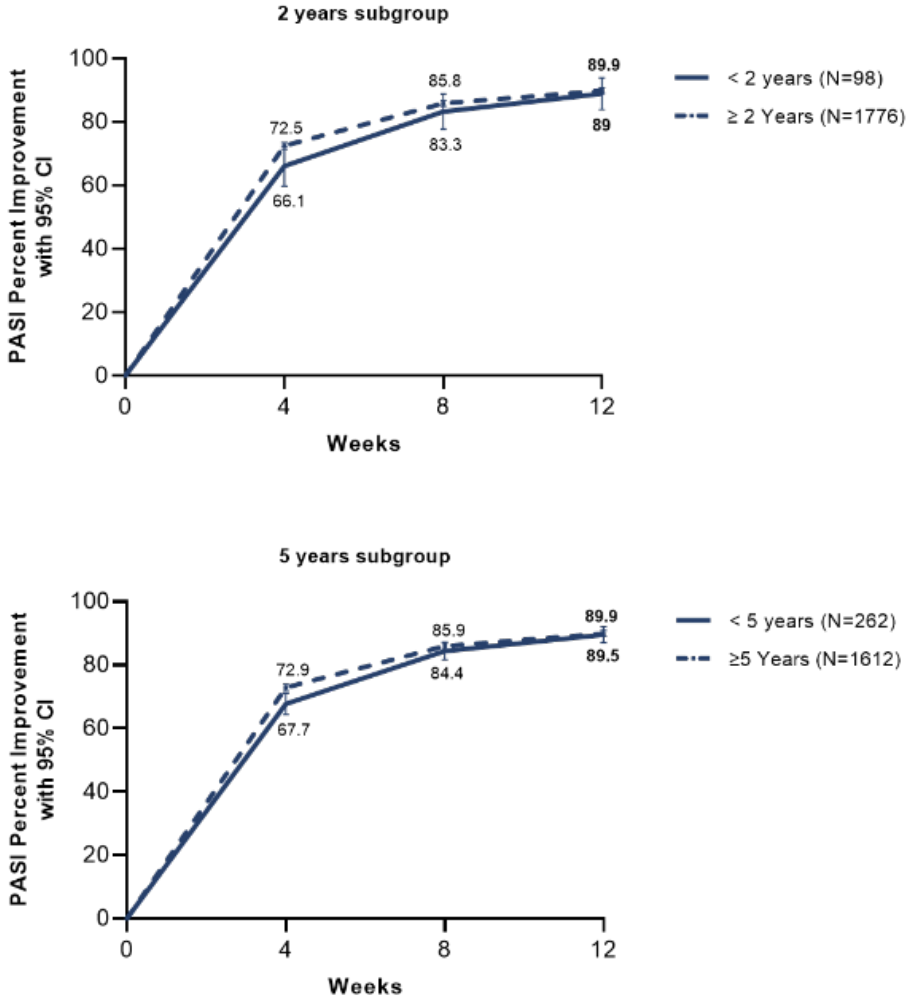
Table 1. Baseline demographics and disease characteristics of pooled data from six clinical trials* by PsO disease duration subgroups

Figure 1. PASI90 and PASI100 response rates of patients treated with IXE by duration of PsO



Abbreviations: Confidence intervals (CI); IXE (Ixekizumab); Psoriasis Area and Severity Index (PASI); Psoriasis (PsO).

Figure 2. PASI percent improvement (%) from baseline of patients treated with IXE by duration of PsO



CI for weeks 4, 8 and 12 are smaller than the width of the line for the ≥ 2 and ≥ 5 years subgroups.

Mean values represented (above line: the ≥ 2 and ≥ 5 years subgroups; below line: the < 2 and < 5 years subgroups).

Abbreviations: Confidence intervals (CI); IXE (Ixekizumab); Psoriasis Area and Severity Index (PASI); Psoriasis (PsO).

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Abstract N°: 5145

Real-world data on the use of certolizumab pegol for the treatment of moderate-to-severe plaque psoriasis: 1-year results from a prospective non-interventional cohort study

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Introduction & Objectives:

Certolizumab pegol (CZP) is a PEGylated, fragment crystallisable (Fc)-free anti-tumour necrosis alpha (TNFα) with an established efficacy and safety profile in moderate-to-severe plaque psoriasis (PsO).1,2 This study aimed to assess the clinical outcomes (skin and quality of life [QoL] improvements) and safety at 3-months and 1-year after CZP treatment start in routine practice in patients (pts) with moderate-to-severe PsO from the observational study CIMREAL (NCT04053881).

Materials & Methods:

Adult pts with PsO who had been newly and independently prescribed CZP as per local prescribing information were eligible for enrolment, with sites in Belgium, Canada, Czech Republic, France, Germany, Greece, Italy, Spain and the United Kingdom. Pts were followed for 1 year, receiving 400 mg CZP every 2 weeks (Q2W) or CZP 200 mg Q2W with 400 mg initial doses at Weeks 0, 2, 4. There were four observational points (OPs; OP1- Baseline; OP2- Month 3 [Week 10–18]; OP3- Month 6 [Week 19–37]; OP4- Month 12 [Week 38–56]). The primary outcome was the percentage of pts achieving a Psoriasis Area and Severity Index improvement of 75% (PASI75) at OP2; secondary outcomes pertain to effectiveness, and safety. Data are presented from Safety Analysis Set (SAS, pts receiving ≥1 dose CZP) and Full Analysis Set (FAS, pts with baseline and ≥1 post-baseline PASI assessment) as multiple imputation (MI) and observed cases (OC) at OP2 and OP4.

Results:

Overall 399 (SAS) and 371 (FAS) pts with PsO were included. Mean (standard deviation [SD]) age was 42.9 (13.5) years and BMI was 28.5 (6.8); 68.2% of the pts were female. 93.7% (374/399) and 77.9% (311/399) of pts completed OP2 and OP4 of the study. PASI75 response rate (OC) was reached by 45.0% of pts at OP2 and improved further to 77.0% at OP4. Likewise, PASI90 response rates improved from 23.4% (OP2) to 56.5% (OP4) (**Table 1**). PASI75 and PASI90 responses achieved at OP2 were maintained by 89.3% (108/121) and 75.9% (44/58) pts at OP4, respectively. Pts achieving Dermatology Life Quality Index (DLQI) 0/1 was improved over time up to

OP4. PASI75, PASI90 and DLQI improvements were seen across treatment subgroups -presence of comorbidities and previous exposure to biologics (**Table 1**). Overall, 30.6 %, 9.3%, and 9.0% of pts experienced any treatment-emergent adverse events (TEAEs), serious TEAEs, or treatment-emergent adverse drug reactions (ADRs), respectively (**Table 2**). Total 22.1% (88/399) pts discontinued the study treatment; of which 2.8% (11/399) discontinued due to AEs. There were no incidences of serious cardiovascular events, haematopoietic cytopenias, bleeding events, hypersensitivity reactions and anaphylactic reactions or demyelinating-like disorders. There was one death, unrelated to treatment. The safety profile was consistent with that known for CZP.

Conclusion:

CIMREAL study is the largest observation of safety and effectiveness of CZP in PsO pts in routine practice. Improved skin clearance and quality of life was observed in the overall cohort and across subgroups after CZP treatment. No new safety signal was identified for CZP. This suggests CZP improves PsO-specific outcomes in a real-world clinical setting.

References:

- i. EMA, June 2022, Summary of Product Characteristics, available at: https://www.ema.europa.eu/documents/product-information/cimzia-epar-product-information_en.pdf. Last accessed March 2023.
- i. Lebwohl M, et al. *J Am Acad Dermatol.* 2018;79(2):266-276.

Funding statement: This study was funded by UCB Pharma. Medical writing support was provided by Enago Life Sciences

Table 1: PASI and DLQI outcomes at OP2 (Week 10-18) and OP4 (Week 38-56) for patients with PsO treated with CZP stratified by previous biologic treatment and by comorbidities (FAS)

PASI Outcomes – FAS												
		OP	n	Overall	n	Biologic Pre-treatment Naïve	n	Biologic Pre-treatment	n	With Comorbidity	n	Without Comorbidity
PASI75 response % (95% CI)	OC	OP 2	333	45.0 (39.6-50.6)	214	47.7 (40.8-54.6)	119	40.3 (31.4-49.7)	145	49.0 (40.6-57.4)	188	42.0 (34.9-49.4)
		OP 4	283	77.0 (71.7-81.8)	180	79.4 (72.8-85.1)	103	72.8 (63.2-81.1)	120	79.2 (70.8-86.0)	163	75.5 (68.1-81.9)
	MI	OP 2	371	45.0 (39.7-50.2)	235	48.1 (41.5-54.6)	136	39.6 (30.9-48.3)	162	48.5 (40.6-56.5)	209	42.2 (35.3-49.2)
		OP 4	371	70.2 (65.1-75.3)	235	73.8 (67.6-79.9)	136	64.0 (55.1-72.9)	162	70.3 (62.6-78.0)	209	70.1 (63.4-76.8)
PASI90 response % (95% CI)	OC	OP 2	333	23.4 (19.0-28.3)	214	24.8 (19.1-31.1)	119	21.0 (14.1-29.4)	145	26.2 (19.3-34.2)	188	21.3 (15.7-27.8)
		OP 4	2832	56.5 (50.5-62.4)	180	57.8 (50.2-65.1)	103	54.4 (44.3-64.2)	120	54.2 (44.8-63.3)	163	58.3 (50.3-65.9)
	MI	OP 2	371	23.7 (19.2-28.2)	235	25.0 (19.2-30.8)	136	21.4 (14.0-28.8)	162	26.3 (19.3-33.4)	209	21.7 (15.8-27.5)
		OP 4	371	50.0 (44.5-55.6)	235	52.3 (45.2-59.3)	136	46.2 (37.2-55.1)	162	47.1 (38.8-55.4)	209	52.3 (45.0-59.7)
DLQI Outcomes – FAS												
DLQI 0/1 % (95% CI)	OC	OP 2	322	28.6 (23.7-33.8)	207	30.0 (23.8-36.7)	115	26.1 (18.3-35.1)	138	23.9 (17.1-31.9)	184	32.1 (25.4-39.3)
		OP 4	271	59.4 (53.3-65.3)	174	56.9 (49.2-64.4)	97	63.9 (53.5-73.4)	114	56.1 (46.5-65.4)	157	61.8 (53.7-69.4)

CI, confidence interval; CZP, Certolizumab pegol; DLQI, Dermatology Life Quality Index; FAS, full analysis set; MI, multiple imputation; OC, observed case; OP, observational point; PASI, Psoriasis Area and Severity Index; PsO; plaque psoriasis; SD, standard deviation.

Table 2: Safety outcomes at OP4 (Week 38-56) for patients with PsO treated with CZP. Observed Cases (SAS)

	Overall (N=399)
Any TEAEs	122 (30.6)
Serious TEAEs	37 (9.3)
Opportunistic infections	1 (0.3)
Malignant or unspecified tumours	2 (0.5)
Treatment-emergent ADRs	36 (9.0)
Serious treatment-emergent ADRs	9 (2.3)
Deaths (TEAEs leading to death)	1 (0.3)

ADR, adverse drug reaction; CZP, Certolizumab pegol; OP, observational point; PsO; plaque psoriasis; SAS, safety analysis set; TEAE, treatment-emergent adverse event.

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Abstract N°: 5189

Nail psoriasis and its relationship with disease activity, functional status, and quality of life in patients with psoriatic arthritis

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Introduction & Objectives: Nail changes are observed in about 40% of psoriasis (PsO) patient (pts), a percentage that increasers to about 80% in pts with psoriatic arthritis (PsA). Nail PsO is considered as one of the six core PsA domains by GRAPPA and can predict enthesopaty. It can considerably impair health-related quality of life (HRQoL) beyond the impairments due to other PsO symptoms. The aim of study to assess the relationship nail PsO with disease activity, clinical symptoms, functional status and HRQoL in pts with PsA.

Materials & Methods: 172 (M/F=90 (52.3%)/ 82(47.7%) PsA pts fulfilling the CASPAR criteria were included. Mean age 45.1±11.8 years (yrs), DAPSA 28±22.2 median (Me). All pts underwent standard clinical examinations and PROs (VAS global assessments, VAS global pain, BASDAI, PsAID-12, FACIT and HAQ).

Results: When 93 (53,7%) pts with nail PsO and 79 pts (46,2 %) without nail PsO were compared, patients with nail PsO had more disease activity 32.5±23.6 vs 22.8±19.2 respectively. SJC, dactylitis, modified Leeds Enthesitis Index (LEI and plantar fascia), VAS global assessments, VAS global pain, HAQ, BASDAI, FACIT were signifcantly better in pts without nail PsO ($p < 0.05$ for all). The comparison of clinical parameters of pts with and without nail PsO is given in Table 1. PsAID-12 showed (Figure 1) that pts with nail PsO had statistically significant impairments of almost all scales compared with pts without nail PsO ($p < 0.05$). It is noteworthy that the scale of “Sleep disturbance” was comparable in both groups (p=0,23).

Conclusion: In PsA pts reported that with nail PsO is associated with greater PsA disease activity and worse functional status and QoL.

Table 1. Comparison of groups with and without nail PsO regarding physical examination and clinical evaluation (n=172).

|**Parameters**|
Nail PsO

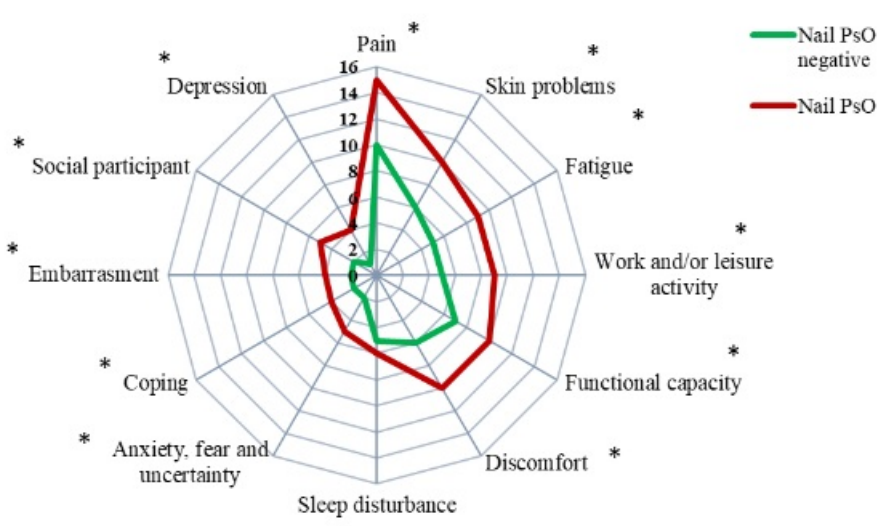
(n=93)

|
Nail PsO negative

(n=79)

p			
TJC (mean±SD)	12.3±10.8	9.05±8.4	0.01
SJC (mean±SD)	9.46±9.39	6.02±5.18	0.006
Dactylitis, n (%)	43(25)	23 (13.3)	0.04
Modified LEI (mean±SD)	1.78±1.37	0.88±0.53	0.01
DAPSA (mean±SD)	32.5±23.6	22.8±19.2	0.007
BSA, n(%)			
BSA ≤ 3% n(%)	43 (25)	59 (34.3)	0.67
BSA > 3% n(%)	50 (29)	20 (11.6)	<0.001
BASDAI (mean±SD)	4.47±2.65	3.10±2.24	0.0006
VAS global pain (mean±SD)	48.2±26.7	38.1±26.7	0.01
VAS global assessments (mean±SD)	43.9±24.9	35.8±24.6	0.03
HAQ (mean±SD)	1.1±0.74	0.88±0.81	0.03
FACIT-F (mean±SD)	37.9±11.1	32.06±10.3	0.0004

Figure.1 Impact of nail PsO on HRQoL (PsAID-12)



EA DV CONGRESS
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 5203

Real world data on the 1-year treatment of psoriasis with the use of certolizumab pegol in women of child-bearing potential

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Introduction & Objectives:

Certolizumab pegol (CZP), an anti-tumour necrosis factor alpha (TNFα) approved for the treatment of moderate-to-severe plaque psoriasis (PsO),1 has demonstrated no-to-minimal levels of transplacental and breastmilk transfer2,3 due to the absence of fragment crystallisable (Fc) region. Dermatology guidelines suggest the use of CZP in the "female pregnancy wish" population with moderate-to-severe PsO4, if clinically needed. This analysis aims to present effectiveness outcomes of CZP in patients with moderate-to-severe PsO in clinical practice, with women of child-bearing potential (WoCBP) as main subpopulation.

Materials & Methods:

CIMREAL (NCT04053881) is a multicenter, international, non-interventional, prospective study that observed clinical response to the CZP treatment and safety over 1 year in a real-world PsO cohort of pts newly prescribed CZP (400 mg CZP every 2 weeks (Q2W) or CZP 200 mg Q2W with 400 mg initial doses at Weeks 0, 2, 4) as per local practice from sites in 8 European countries and Canada. There were four observational points (OPs; OP1-Baseline; OP2- Month 3 [Week 10–18]; OP3- Month 6 [Week 19–37]; OP4- Month 12 [Week 38–56]). The primary outcome was the percentage of pts achieving Psoriasis Area and Severity Index improvement of 75% (PASI75) response at OP2. Secondary outcomes pertain to effectiveness (PASI response, improvement in Dermatology Life Quality Index [DLQI]) and safety of CZP. Demographics and safety data are presented from the Safety Analysis Set (SAS; pts received ≥1 dose of CZP) and clinical outcomes as observed cases (OC) from the Full Analysis Set (FAS; SAS pts with valid Baseline and ≥1 valid post-Baseline PASI measurement).

Results:

Of the 399 PsO pts enrolled (SAS) in the study, 272 (68.2%) were female and out of them 193 (71%) were WoCBP. At baseline, 8 women (4.1%) were pregnant, 14 (7.3%) were breastfeeding. The mean age (standard deviation [SD]) was 33.8 (7.3) years in WoCBP and 42.9 (13.5) years in overall population; mean PASI, and DLQI total scores

were 13.0 (8.6) and 13.2 (8.7), and 13.2 (7.3) and 12.3 (7.5) in WoCBP and overall populations, respectively (**Table 1**). 93.8% and 79.8% WoCBP pts completed the OP2 and OP4, respectively. Response rates in PASI75 (49.3% [OP2] to 77.0% [OP4]) and PASI90 (27.3% [OP2] to 60.0% [OP4]) were observed in WoCBP. This is consistent to the improvement in the overall population. Pts achieving DLQI 0/1 increased over time up to OP4 (**Table 2**). There was one death, unrelated to treatment. There were no new safety signals.

Conclusion:

Treatment with CZP for up to 1-year improved skin clearance and quality of life in the overall study population as well as WoCBP pts, the predominant PsO subpopulation in this study. The safety profile was consistent with that known for CZP. This suggests CZP offers a valuable option for disease control in WoCBP in a real-world clinical setting.

References:

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Table 1. Baseline characteristics (SAS)

Characteristic, mean (SD)/median (min, max)/n[a], unless otherwise stated	Overall n=399	Male n=127	Female n=272	WoCBP n=193
Age (years), mean (SD)	42.9 (13.5)	48.2 (12.4)	40.4 (13.2)	33.8 (7.3)
BMI, mean (SD)	28.5 (6.8)	29.3 (6.2)	28.1 (7.1)	27.7 (7.2)
PASI score, mean (SD)	13.2 (8.7)	13.6 (8.3)	13.0 (8.9)	13.0 (8.6)
PASI ≤10, n (%)	139 (34.8)	44 (34.6)	95 (34.9)	65 (33.7)
DLQI score, mean (SD)	12.3 (7.5)	10.8 (7.6)	13.1 (7.3)	13.2 (7.3)
DLQI ≤10, n (%)	164 (41.1)	64 (50.4)	100 (36.8)	65 (33.7)
Any PsO medication history, n (%)	369 (92.5)	113 (89.0)	256 (94.1)	190 (98.4)
Prior systemic treatment with a non-biologic, n (%)	272 (68.2)	83 (65.4)	189 (69.5)	139 (72.0)
Prior treatment with biologic therapies[b,c], n (%)				
1	85 (21.3)	32 (25.2)	53 (19.5)	33 (17.1)
≥2	59 (14.8)	20 (15.7)	39 (14.3)	26 (13.5)
Comorbidities, n (%)	186 (46.6)	61 (48.0)	125 (46.0)	81 (42.0)
Vascular disorders, n (%)	53 (13.3)	27 (21.3)	26 (9.6)	6 (3.1)
Musculoskeletal and connective tissue disorders, n (%)	58 (14.5)	21 (16.5)	37 (13.6)	23 (11.9)
Metabolism and nutrition disorders, n (%)	59 (14.8)	29 (22.8)	30 (11.0)	9 (4.7)
Psychiatric disorders, n (%)	35 (8.8)	8 (6.3)	27 (9.9)	16 (8.3)

From safety set. [a]For characteristics without n values in cell, see column heading. [b]Only pts with prior biologic therapy are included in calculations. [c]Only biologic agents with potential impact on Psoriasis.
BMI, body mass index; DLQI, Dermatology Life Quality Index (scores: 0–30; higher score: greater impact of PsO on pt's life); PASI, Psoriasis Area and Severity Index; PsO, psoriasis; pts, patients; SAS, safety analysis set; SD, standard deviation; WoCBP, women of child-bearing potential.

Table 2. PASI75/90 (FAS-OC) & DLQI remission (SAS-OC) at OP2 and OP4

PASI Outcomes									
	Observation Point	n	Overall	n	Men	n	Women	n	WoCBP
PASI75 response % (95% CI)	OP2	333	45.0 (39.6-50.6)	110	44.5 (35.1-54.3)	223	45.3 (38.6-52.1)	150	49.3 (41.1-57.6)
	OP4	283	77.0 (71.7-81.8)	92	76.1 (66.1-84.4)	191	77.5 (70.9-83.2)	135	77.0 (69.0-83.8)
PASI90 response % (95% CI)	OP2	333	23.4 (19.0-28.3)	110	20.9 (13.7-29.7)	223	24.7 (19.2-30.9)	150	27.3 (20.4-35.2)
	OP4	283	56.5 (50.5-62.4)	92	51.1 (40.4-61.7)	191	59.2 (51.8-66.2)	135	60.0 (51.2-68.3)
DLQI Outcomes									
	Observation Point	n	Overall	n	Men	n	Women	n	WoCBP
DLQI 0/1 response % (95% CI)	OP2	323	28.5 (23.6-33.7)	109	33.9 (25.1-43.6)	214	25.7 (20.0-32.1)	143	28.0 (20.8-36.1)
	OP4	274	59.1 (53.0-65.0)	92	68.5 (58.0-77.8)	182	54.4 (46.9-61.8)	126	55.6 (46.4-64.4)

CFB, change from baseline; CI, confidence interval; DLQI, Dermatology Life Quality Index (scores: 0–30; a DLQI score <=1 (DLQI 0/1) indicates no impact on pt's life); FAS, full analysis set; OC, observed cases; PASI, Psoriasis Area and Severity Index; pts, patients; SAS, safety analysis set;
WoCBP, women of child-bearing potential.

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Abstract N°: 5225

A Real World Analysis of Apremilast and Cardiometabolic Comorbidities in Psoriasis and Psoriatic Arthritis, Including Impact on Weight Loss and Diabetic Status

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Introduction & Objectives: Patients with psoriasis (PsO) and psoriatic arthritis (PsA) have a higher prevalence of cardiometabolic diseases including obesity, dyslipidemia and dysglycemia compared to the general population. Treatment with apremilast has been associated with weight loss in clinical trial populations, and these findings prompted further examination of weight loss by patient characteristics over a 12-month period in a real-world cohort.

Materials & Methods: Patients with a diagnosis of PsO or PsA 365 days prior to or on the apremilast initiation date (index date) in the OM1 Real-World Data Cloud between 3/2013 and 11/2021 were included. The OM1 data includes linked electronic medical records, claims, and lab measures. Included patients had a 12 month baseline period, a weight measure within 3 months prior to index and at 12 months (> 9 months to < 15 months), and were persistent on apremilast for 12 months. Patients were stratified by diabetes status (no diabetes vs pre-diabetes/type 2 diabetes mellitus [T2DM]) and obesity status (no obesity: BMI < 30, obese: 30 ≤ BMI < 34.9, severe obesity: BMI ≥ 35) during baseline. Pre-diabetes was defined by two diagnosis codes at least 30 days apart during the baseline period, HbA1c between 5.7%-6.4%, or fasting glucose between 100-125 mg/dL. T2DM was defined with two diagnosis codes at least 30 days apart or evidence of antidiabetic medication during baseline. Wilcoxon rank-sum tests and chi-squared tests were used for comparisons by comorbidity status. The percent weight change from the baseline measure to 12 months follow-up was calculated, frequencies and percentages were reported by cutoff points and cumulative proportional weight change was presented.

Results: There were 8,487 apremilast initiators included in the study. Almost a quarter of the patients (23.6%) had diabetes and 62.8% were female. Diabetes patients were older, had higher BMI and more comorbidities than patients without diabetes. Among those with diabetes, 65.0% had hypertension, 57.0% had dyslipidemia and 25.1% had cardiovascular disease. Most patients with diabetes were on antidiabetics (68.6%), anti-hypertensives (65.7%) and lipid lowering therapy (52.1%) (Table 1).

Among those with a BMI available (n=8,250), 26.9% were obese and 33.5% were severely obese. The mean age was 55.2 years and 63.1% were female. The prevalence of hypertension, dyslipidemia, and cardiovascular disease was higher among those obese or severely obese (Table 2).

Weight loss was observed consistently at 12 months. Overall, 50% of patients lost ≥ 1% of body weight, 31% gained ≥ 1% of weight, and 19% had no change. Nearly one quarter of patients lost at least 5% of their weight and 19% had no change. Among those with diabetes, 28.1% of patients lost at least 5% of weight compared to 21.6% of those without diabetes at 12 months (Figure 1). 26.7% of severely obese patients, 25.4% of obese patients and 19.0% of non-obese patients lost at least 5% of weight at 12 months. (Figure 2).

Conclusion: Half of the patients achieved weight loss at 12 months, consistent with pooled trial data showing a mean proportional weight loss of 1.3% among those treated with apremilast.1 Diabetes and obesity were associated with increased weight loss suggesting that treatment with apremilast may benefit those with the largest

burden of cardiometabolic diseases. Further research into the impact of treatment on the development of cardiometabolic conditions is needed.

1. Puig L, et al. AB151. *JAAD* 2018:79; Suppl 1.

Table 1: Baseline Characteristics of Patients Initiating Apremilast by Diabetes Status

	No Diabetes	Prediabetes/ T2DM	Total	P-Value
	6,483 (76.4%)	2,004 (23.6%)	8,487	
Age (y), Mean (SD)	54.0 (12.8)	59.0 (10.8)	55.2 (12.5)	**< 0.001**
Sex, Female (%)	4,092 (63.1%)	1,242 (62.0%)	5,334 (62.8%)	0.355
Race				**< 0.001**
Black	148 (2.3%)	83 (4.1%)	231 (2.7%)	
White	5,047 (77.8%)	1,538 (76.7%)	6,585 (77.6%)	
Other	121 (1.9%)	65 (3.2%)	186 (2.2%)	
Unknown	1,167 (18.0%)	318 (15.9%)	1,485 (17.5%)	
BMI (kg/m^2), Mean (SD)	31.8 (7.1)	35.5 (7.4)	32.7 (7.4)	**< 0.001**
Weight (lbs), Mean (SD)	199.05 (49.70)	221.02 (52.76)	204.36 (51.32)	**< 0.001**
CCI[1], Mean (SD)	0.4 (1.2)	1.2 (2.0)	0.6 (1.4)	**< 0.001**
PsO only[1]	1,950 (30.1%)	755 (37.7%)	2,705 (31.9%)	**< 0.001**
PsA only[1]	1,657 (25.6%)	394 (19.7%)	2,051 (24.2%)	**< 0.001**
Both[1]	2,876 (44.4%)	855 (42.7%)	3,731 (44.0%)	0.181
Hypertension	1,961 (30.2%)	1,302 (65.0%)	3,263 (38.4%)	**< 0.001**
Dyslipidemia	1,519 (23.4%)	1,143 (57.0%)	2,662 (31.4%)	**< 0.001**
Cardiovascular disease[2]	632 (9.7%)	503 (25.1%)	1,135 (13.4%)	**<0.001**
Antidiabetics	0 (0.0%)	1,375 (68.6%)	1,375 (16.2%)	**<0.001**
Anti-hypertensives	2,084 (32.1%)	1,316 (65.7%)	3,400 (40.1%)	**<0.001**
Lipid-lowering therapies	1,193 (18.4%)	1,044 (52.1%)	2,237 (26.4%)	**<0.001**

[1] Identified during the 12 months on or before the index date
[2] Includes coronary artery disease, peripheral vascular disease, stroke, and congestive heart failure

Table 2: Baseline Characteristics of Patients Initiating Apremilast by Obesity Status

	No Obesity	Obese	Severe Obesity	Overall	p-value
	3,263 (39.6%)	2,222 (26.9%)	2,765 (33.5%)	8,250	
Age (y), Mean (SD)	55.5 (13.4)	56.0 (12.1)	54.3 (11.7)	55.2 (12.5)	**<0.001**
Sex, Female (%)	2,033 (62.3%)	1,316 (59.2%)	1,857 (67.2%)	5,206 (63.1%)	**< 0.001**
Race					**< 0.001**
Black	67 (2.1%)	59 (2.7%)	97 (3.5%)	223 (2.7%)	
White	2,479 (76.0%)	1,772 (79.7%)	2,154 (77.9%)	6,405 (77.6%)	
Other	119 (3.6%)	31 (1.4%)	31 (1.1%)	181 (2.2%)	
Unknown	598 (18.3%)	360 (16.2%)	483 (17.5%)	1,441 (17.5%)	
BMI (kg/m^2), Mean (SD)	25.8 (2.8)	32.4 (1.4)	41.0 (5.0)	32.7 (7.4)	**< 0.001**
Weight (lb), Mean (SD)	162.4 (26.6)	203.6 (24.7)	255.4 (43.1)	204.3 (51.3)	**< 0.001**
CCI[1], Mean (SD)	0.5 (1.4)	0.6 (1.4)	0.7 (1.6)	0.6 (1.4)	**< 0.001**
PsO only[2]	1,068 (32.7%)	686 (30.9%)	849 (30.7%)	2,603 (31.6%)	0.175
PsA only[2]	856 (26.2%)	528 (23.8%)	611 (22.1%)	1,995 (24.2%)	**< 0.001**
Both	1,339 (41.0%)	1,008 (45.4%)	1,305 (47.2%)	3,652 (44.3%)	**< 0.001**
Hypertension	957 (29.3%)	903 (40.6%)	1,349 (48.8%)	3,209 (38.9%)	**< 0.001**
Dyslipidemia	921 (28.2%)	720 (32.4%)	972 (35.2%)	2,613 (31.7%)	**< 0.001**
Cardiovascular disease[3]	480 (14.7%)	534 (24.0%)	956 (34.6%)	1,970 (23.9%)	**< 0.001**
Antidiabetics	311 (9.5%)	365 (16.4%)	671 (24.3%)	1,347 (16.3%)	**< 0.001**
Anti-hypertensives	1,023 (31.4%)	926 (41.7%)	1,382 (50.0%)	3,331 (40.4%)	**< 0.001**
Lipid-lowering therapies	702 (21.5%)	646 (29.1%)	839 (30.3%)	2,187 (26.5%)	**< 0.001**

[1] Charlson comorbidity index
[2] Identified during the 12 months on or before the index date
[3] Includes coronary artery disease, peripheral vascular disease, stroke, and congestive heart failure

Figure 1: Cumulative Proportional Weight Change at 12 months by Diabetes Status

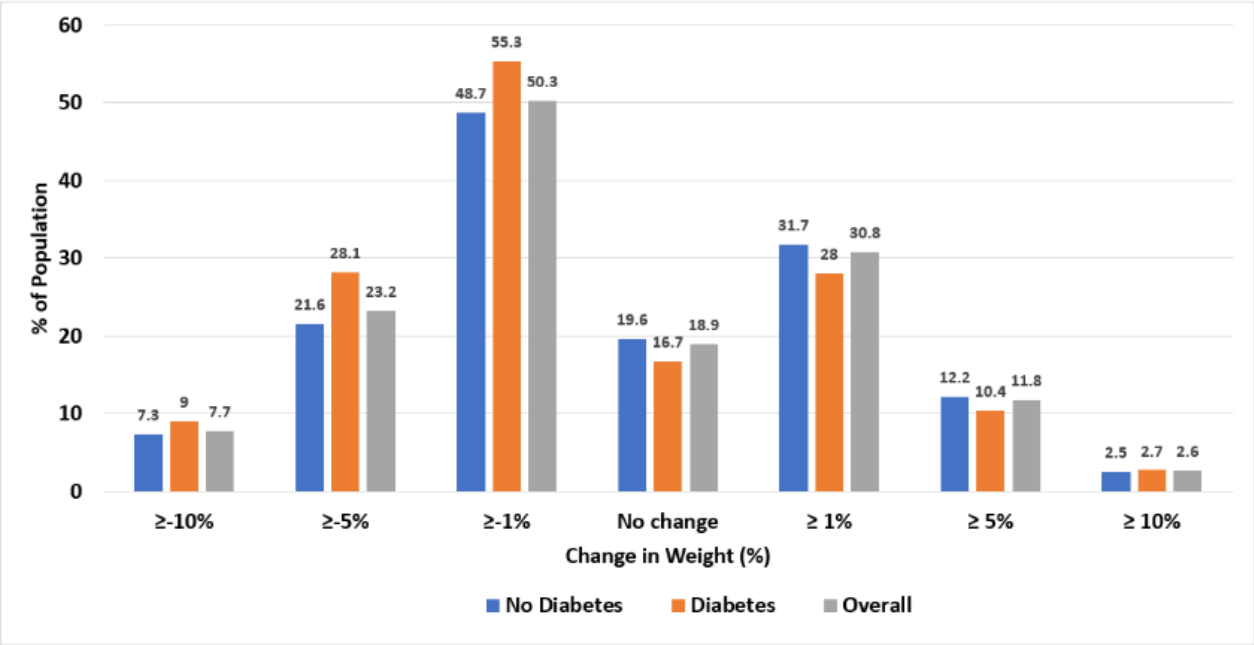
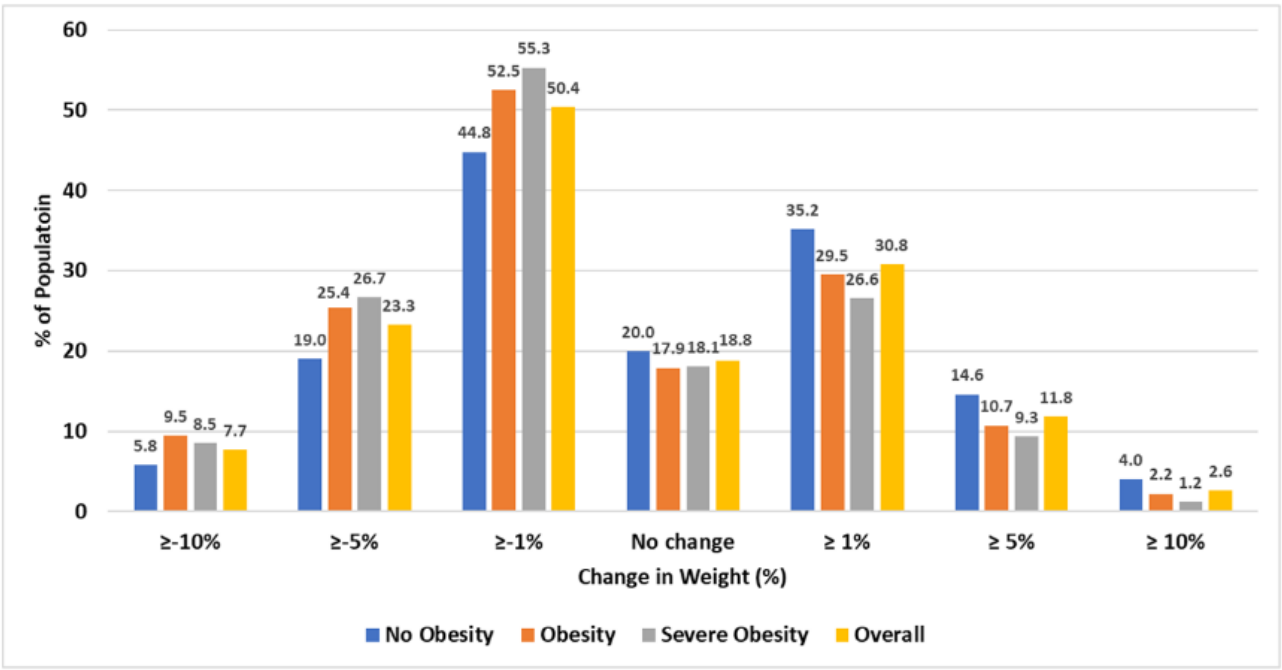


Figure 2: Cumulative Proportional Weight Change at 12 months by Obesity Status



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Abstract N°: 5241

Treatment history and symptom severity in patients with moderate to severe plaque psoriasis being initiated on bimekizumab: Use during the 1st year of routine clinical practice

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Introduction & Objectives:

Bimekizumab (BKZ), a humanized monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A1,2, is authorized for the treatment (Tx) of moderate to severe plaque psoriasis (PsO).3 ELEVATE aims to describe patient (pt)-focussed outcomes of effectiveness in adult pts with PsO in routine clinical practice, contextualized with the treatment history (TxH).

Materials & Methods:

ELEVATE is a multicentric, prospective observational study planned to be executed in France, Germany, Greece, Italy, and the United Kingdom. Eligible pts are adults with moderate to severe PsO who are newly initiated on BKZ as per locally approved label, and previously naïve for BKZ Tx. Pts are followed up for approximately 12 months. Pt-reported data (Dermatology Life Quality Index [DLQI], Psoriasis Symptoms and Impacts Measure [P-SIM], and treatment satisfaction [TSQM-9]) are surveyed using an app on a handheld study device at 8 observation points (OPs); weeks (wks) 0, 2, 4, 8, 12, 26, 39, and 52. Clinical assessments (Psoriasis Area and Severity Index [PASI], physician's global assessment [PGA]) occur at 5 OPs; around wks 0, 12, 26, 39, and 52. The co-primary outcomes are to characterise the TxH of pts initiating BKZ, and to describe the proportion of pts reporting that their PsO has no effect on their life (DLQI 0/1) after 26 wks of Tx (OP3) with BKZ, stratified by the TxH. Here we present a first interim analysis (data lock [DL]: October 25, 2022) on TxH and disease severity in the pts enrolled in Germany during the first year of BKZ use in routine practice. Demographics and baseline (BL) characteristics are summarised for pts in the safety set.

Results:

At DL, 196 pts from 41 German centers consented to participate. Most pts (126; 64.3%) had a TxH of any systemic Tx, of which 54 (42.9%) had received a biologic. TxH was unavailable at DL for 21 pts (11.2%). Among pts with a TxH of systemic therapy, 104 switched from a recent therapy (≤12 months before BKZ 1st dose) of which 43 had a recent biologic Tx, 22 pts had a past (≥13 months before BKZ first dose) but no recent systemic TxH, 49 (25.0%) were naïve for any systemic therapy, and overall BKZ was the 1st line biologic for 121 (61.7%) pts (**Table 1**). In pts with prior biologic use, adalimumab, secukinumab and ixekizumab were most commonly reported. **Table 2** summarises demographics and BL disease severity for pts with known TxH. At BL, 64.6% of pts had a PASI ≥10, 86.9% had ≥10% body surface area (BSA) and 57.2% pts reported a DLQI >10. For 14.3% of pts DLQI was missing at DL. The P-SIM mean score at BL was >5 for all 14 items and ≥7 for skin redness, scaling, dryness and irritation. Most pts (91.4%) were mild to severely impacted for ≥1 of the assessed high impact area (nail, scalp, palms) as per PGA. Pts with a past systemic TxH tended to be ≥5 years older, ≥7 years longer disease duration and more

likely male versus those with only a recent TxH.

Conclusion:

In ELEVATE, baseline DLQI and PASI scores confirm a profile of PsO pts suffering from moderate to severe PsO. Pts with known TxH, newly initiating BKZ in the 1st year of use in German routine practice, mostly had a history of systemic Tx, and for ~62% of the pts BKZ was their first biologic for PsO.

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Funding statement: This study was funded by UCB Pharma. Medical writing support was provided by Enago Life Sciences.

Table 1: TxH of patients screened from Germany

Variable, n (%)	Total N=196
Any prior systemic therapy	126 (64.3)
Any prior biologic Tx	54 (42.9)*
No prior biologic Tx	72 (57.1)*
No prior systemic therapy	49 (25.0)
Missing**	21 (10.7)
Recent (≤12 months) /past (≥13 months) systemic Tx	
Recent & past systemic Tx	83 (42.3)
Recent & no past systemic Tx	21 (10.7)
No recent & past systemic Tx	22 (11.2)
No recent & no past systemic Tx	49 (25.0)

Recent systemic/biologic Tx is defined as previous systemic/biologic Tx in the 12 months before the first BKZ dose.
Past systemic/biologic Tx is defined as previous systemic/biologic Tx in the 13+ months prior to the first BKZ dose.

*percentages are computed based on patients with confirmed systemic TxH.

** missing or unavailable at DL

BKZ, bimekizumab; Tx, treatment; TxH, treatment history.

Table 2: Demographics and Baseline characteristics, for patients with known TxH – safety set

Variable	Recent & past systemic Tx N=83	Recent & no past systemic Tx N=21	No recent & past systemic Tx N=22	No recent & no past systemic Tx N=49	Total N=175*
Male, n (%)	55 (66.3)	12 (57.1)	14 (63.6)	28 (57.1)	109 (62.3)
Age, mean (SD)	49.9 (13.8)	44.6 (12.7)	49.1 (14.8)	42.0 (15.6)	47.0 (14.6)
BMI (kg/m^2), mean (SD)	30.5 (5.8)	28.9 (4.9)	29.2 (5.1)	27.0 (5.6)	29.2 (5.7)
Disease duration (years), mean (SD)	20.7 (15.7)	13.7 (15.4)	22.2 (11.5)	10.4 (10.3)	17.2 (14.5)
PASI baseline, mean (SD)	11.8 (7.4)	14.8 (9.4)	16.9 (11.2)	14.8 (7.5)	13.6 (8.4)
DLQI baseline (Tx start), mean (SD)	13.4 (7.6)	19.4 (5.9)	19.8 (6.8)	15.1 (8.8)	15.3 (8.1)
P-SIM score					
Skin itching, mean (SD)	6.5 (2.5)	7.5 (2.9)	8.1 (2.2)	6.3 (3.0)	6.8 (2.7)
Skin redness, mean (SD)	6.8 (2.5)	8.4 (2.1)	8.7 (1.8)	7.3 (2.4)	7.4 (2.4)
Skin pain, mean (SD)	5.1 (3.0)	5.1 (3.6)	6.2 (2.7)	4.6 (3.2)	5.1 (3.1)

Recent systemic Tx is defined as previous systemic Tx in the 12 months before the first BKZ dose. Past systemic Tx is defined as previous systemic Tx in the 13+ months prior to the first BKZ dose.

*Patient enrolled as of Oct 25th.

BMI, body mass index; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; P-SIM, Psoriasis Symptoms and Impacts Measure; SD, standard deviation; Tx, treatment.

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Abstract N°: 5266

Exclusive Low-Salt Diet Improves Clinical Outcome of Mild to Moderate Psoriasis as Soon as After a Two-Week Period

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Introduction & Objectives: Increased salt intake represents an environmental risk factor for the development of autoimmune diseases through the induction of highly pathogenic Th17 cells, which play a key role in the immunopathology of psoriasis. Maifeld and his colleagues recently found increased sodium content in lesional and non lesional skin in psoriasis patients with PASI > 5, additionally pointing out the link between psoriasis and salt. Since psoriasis represents a prototype of Th17-mediated inflammation, we aimed to investigate if dietary reduction in salt intake could affect the disease course in psoriasis patients.

Materials & Methods: This is a prospective cohort study of patients with psoriasis, who had PASI ≥ 5 at baseline. All participants abstained from local steroids ≥ 2 weeks, as well as from systemic and biologic therapy ≥ 3 months before and during the study protocol. All participants underwent the same study protocol and were educated to follow a 2-week low-salt dietary regimen (LS diet) with a sodium intake of 1500 mg daily (3.75 g of salt) (DASH diet, U.S. Department of Health and Human Services, 2006). Psoriasis severity was determined using the Psoriasis Area and Severity Index (PASI) and Dermatological Quality of Life Index (DLQI) at baseline and after a 2-week LS diet. At the same times, venous blood samples and 24-h urine samples were taken for analysis.

Results: Twenty participants were included in the study (11 [55%] female, 9 [45%] male). 24-hour natriuresis validated that participants maintained the LS diet protocol. Mean age of the subjects was 47.7 ± 15.44 years. Average reduction in sodium intake calculated from 24-h sodium excretion was 51% ± 30. Characteristics of the study population, anthropometric measures, blood pressure, blood and urine analysis are presented in Table 1. PASI values decreased significantly after 2-week LS diet (PASI: baseline 9.5 ± 5.4 vs. LS diet 7.9 ± 5; $p < 0.001$). No statistically significant changes were observed in DLQI or hsCRP values. Furthermore, SBP and DBP decreased significantly after LS diet, compared with baseline measurements.

Conclusion: A 2-week LS diet led to clinical improvement in subjects with psoriasis, as seen in the decrease of PASI values after a short-term LS diet compared with baseline measurements. Thus, reduction in dietary salt intake could benefit psoriasis patients.

Table 1.

	Baseline	After 2-week LS diet	*p* value
N (W/M)	20 (11/9)		
age (years)	47.7 ± 15.4		
BMI (kg/m^2)	28.2 ± 3.4	26.2 ± 7.2	0.165
WHR	0.926 ± 0.094	0.917 ± 0.090	0.197
SBP (mmhg)	128.4 ±1 0,7	120 ± 12.4	0.021*
DBP (mmhg)	82.6 ± 7	79.1 ± 7.8	0.044*
MAP (mmhg)	97.7 ± 6.8	88.1 ± 22.1	0.06
PASI	9.5 ± 5.4	7.9 ± 5	<0.001*
DLQI	9.9 ± 6.9	8.4 ± 7	0.085
erythrocytes (× 10^{12}/L)	4.9 ± 0.4	4.9 ± 0.4	0.383
leukocytes (× 10^9/L)	7 ± 1.8	6.5 ± 1.5	0.082
thrombocytes (× 10^9/L)	262.6 ± 84.5	258.8 ± 76.7	0.538
urea (mmol/L)	5.3 ± 1.2	5.4 ± 1.7	0.659
creatinine (µmol/L)	71.4 ± 8	79 ± 12.8	0.003*
sodium (mmol/L)	139.4 ± 1.7	139 ± 2.3	0.330
potassium (mmol/L)	4.3 ± 0.4	4,2 ± 0.6	0.542
calcium (mmol/L)	2.3 ± 0.3	2.3 ± 0.3	0.763
hsCRP (mg/L)	3.1 ± 4.32	2,8 ± 2.9	0.539
fibrinogen activity (g/L)	3.5 ± 0.7	3.6 ± 0.8	0.566
24-h creatinine coefficient (µmol/24/kg)	149.3 ± 26	147.1 ± 27.9	0.693
24-h urine albumin (mg/dU)	10.5 ± 16.9	23.1 ± 56.3	0.333
24-h urine urea (mmol/dU)	325.3 ± 81.7	292.2 ± 92	0.201
24-h urine sodium (mmol/dU)	182.1 ± 57.3	86.1 ± 55.4	<0.001*
24-h urine potassium	60.9 ± 17.1	60.6 ± 20.8	
calculated sodium intake (mg/day)	4190.5 ± 1318.6	1982.1 ± 1275.1	<0.001*

Data are presented as average ± standard deviation (SD) and *p* value. N—number of participants; W—women; M—men; BMI—body mass index; WHR—waist-to-hip ratio; SBP—systolic blood pressure; DBP—diastolic blood pressure; MAP—mean arterial pressure; PASI—psoriasis area and severity index; DLQI — dermatological quality of life index; hsCRP —high sensitivity C-reactive protein.

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Abstract N°: 5269

Association of EQ-VAS with treatment benefits and patient-reported benefits in patients with moderate to severe psoriasis – data from the German national psoriasis registry PsoBest

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Introduction & Objectives:

Plaque psoriasis (PsO) can substantially impact patients' health-related quality of life (HRQoL).1 The EuroQol Visual Analogue Scale (EQ-VAS) is one of the most used generic measures of HRQoL in psoriasis patients.2 The patient benefit index (PBI) measures patient-reported treatment benefits in psoriasis by goal attainment scaling. As new effective therapies become available, understanding how different skin clearance levels or patient-reported benefits are integrated to capture treatment effects on HRQoL in routine clinical practice is important. We aim to explore the relationships between different levels of skin clearance and patient-reported outcomes (PROs; EQ-VAS and PBI) in the first 12 months of systemic treatment. We also report the 12-month drug survivals in relation to PROs and HRQoL.

Materials & Methods:

This observational, retrospective cohort study used data from the German psoriasis registry PsoBest and included all adult patients with moderate to severe PsO who initiated systemic treatment (index date) between January 1, 2008 and December 31, 2018, and attended a routine visit after ~12 months. The primary analysis variables were generic HRQoL measured by EQ-VAS (0 to 100, higher scores indicating better HRQoL), patient-reported benefits by PBI (0 to 4, with 0 being no benefit and 4 the highest possible benefit) and skin outcomes by the Psoriasis Area and Severity Index (PASI, 0 to 72, higher scores indicating severer PsO). A 12-month drug survival analysis from baseline was performed in relation to PBI and HRQoL items, including Dermatology Life Quality Index (DLQI, 0-30, higher scores indicating worse HRQoL).

Results:

A total of 3824 patients met the study inclusion criteria. Mean patient age was 48.6 years, 40.3% were female. Table 1 presents the results of EQ-VAS improvements from baseline to 12 months in the total sample and in relation to PASI and PBI responses; overall, a positive mean (SD) EQ-VAS improvement of 18.2 (29.1) was observed. There was a greater improvement in EQ-VAS with higher PASI and PBI scores. In total, 57.7% of patients improved by ≥10 units on EQ-VAS. Increased drug survival at 12 months was related to higher PBI, lower DLQI and higher EQ-VAS (all $p<0.001$, Table 2).

Conclusion:

Twelve months after initiating a new systemic treatment, the majority of PsO patients showed meaningful improvement in EQ-VAS; responsiveness of EQ-VAS was highest with complete skin clearance (PASI 100) and highest PBI levels (PBI 3.5 to 4), suggesting an association of treatment outcomes with EQ-VAS. Further, increased drug survival in relation to higher PBI scores and HRQoL underpins the intrinsic relevance to patients.

References:

1. Obradors M et al. Qual Life Res 2016;25(11):2739-2754.

2. Poor AK et al. Qual Life Res 2017;26(12), 3409-3419.

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Table 1: EQ-VAS improvements from baseline in relation to PASI and PBI at ~12 months routine visit

	EQ-VAS score at 12 months	Cfb in EQ-VAS	Substantial CfB in EQ-VAS score of ≥10		
Relative PASI intervals	mean (SD)	mean (SD)	Improved by ≥+10 (or remain in highest decile >90-100) n/N (%)	Worsening by ≤-10 (or remain in lowest decile <10-0) n/N (%)	Neither improved or worsened
PASI 100; N=572	86.1 (17.5)	29.7 (29.4)	404/572 (70.6)	22/572 (3.8)	58/572 (10.1)
PASI 90; N=674	83.2 (18.2)	27.0 (27.0)	488/674 (72.4)	36/674 (5.3)	78/674 (11.6)
PASI 75; N=832	76.5 (19.5)	21.7 (26.8)	537/832 (64.5)	83/832 (10.0)	127/832 (15.3)
PASI <75; N=1584	63.2 (22.8)	7.7 (27.2)	693/1584 (43.8)	347/1584 (21.9)	359/1584 (22.7)
Missing; N=162	76.6 (21.8)	14.3 (27.7)	84/162 (51.9)	32/162 (19.8)	21/162 (13.0)
Absolute PBI intervals					
PBI 4; N=29	87.7 (18.0)	15.0 (22.9)	22/29 (75.9)	2/29 (6.9)	4/29 (13.8)
PBI <4-3.5; N=896	86.8 (16.1)	33.2 (28.6)	748/896 (83.5)	43/896 (4.8)	65/896 (7.3)
PBI <3.5-3; N=762	80.1 (17.7)	23.5 (26.1)	549/762 (72.0)	55/762 (7.2)	25/762 (16.4)
PBI <3-2; N=934	69.9 (19.5)	14.3 (25.2)	525/934 (56.2)	146/934 (15.6)	216/934 (23.1)
PBI <2-1; N=525	58.1 (19.9)	3.07 (23.8)	201/525 (38.3)	154/525 (29.3)	146/525 (27.8)
PBI <1-0; N=206	45.5 (26.8)	-7.3 (28.1)	51/206 (24.8)	93/206 (45.1)	4/206 (27.2)
Missing; N=472	72.5 (23.7)	16.1 (32.1)	110/472 (23.3)	27/472 (5.7)	31/472 (6.6)
Total sample					
N=3824	73.4 (22.5)	18.2 (29.1)	2206/3824 (57.7)	520/3824 (13.6)	643/3824 (16.8)

Cfb, Change from baseline; EQ-VAS, EuroQol-visual analogue scales; PBI, Patient Benefit Index; PASI, Physician-reported Psoriasis Area and Severity Index; SD, Standard deviation.

Table 2: 12-month drug survival estimates in relation to PBI, HRQoL and EQ-VAS measured across routine visits following index date

PBI	n (%)	p-values
0-<1; N=206	64.6	<0.001
1-<2; N=525	75.5	
2-<3; N=934	83.8	
3-<3.5; N=762	85.4	
3.5-<4; N=896	90.9	
4; N=29	82.8	
DLQI		
>1; N=1896	79.2	<0.001
0/1; N=1805	88.0	
EQ-VAS		
≤70; N=1412	78.7	<0.001
>70; N=2235	86.4	

DLQI, Dermatology Life Quality Index; EQ-VAS, EuroQol-visual analogue scales; PBI, Patient Benefit Index

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Abstract N°: 5291

Temporal impact of infection-related treatment emergent adverse events on patient-reported outcomes in patients with moderate to severe psoriasis – analysis of the German national registry PsoBest

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Introduction & Objectives:

Plaque psoriasis (PsO) can substantially impact patients' health-related quality of life (HRQoL).1 As new effective therapies become available, it is important to understand how skin clearance relates to patient-relevant benefits, but also how adverse events of special interest (AESI) impact HRQoL in routine practice. This analysis aims to describe the effects of system organ class (SOC) "infections and infestations" under systemic treatments on HRQoL and patient benefit.

Materials & Methods:

This observational, retrospective cohort study used data from the German psoriasis registry PsoBest and included all adult patients with moderate to severe PsO who began systemic treatment (index date) between January 1, 2008 and December 31, 2018, and attended the ~12 month routine visit (RV). We evaluated HRQoL (Dermatology Life Quality Index [DLQI, score range 0-30]) and patient benefit (Patient Benefit Index [PBI, 0-4]) at the 12 months RV after baseline in the total sample with regard to an AESI of SOC "infections and infestations", occurring under the treatment started at index date. The temporal effect was described through two periods; i) if the AESI onset occurred **within the 30 days window** before the PsOBest 12 months RV; ii) if the AESI onset occurred **more than 30 days before** the PsOBest 12 months RV.

Results:

A total of 3824 patients with PsO met the inclusion criteria and attended the 12 months RV. Mean age was 48.6 years, 40.3% were female, 394 (10.4%) reported an adverse event (AE) and 60 (1.6%) a serious AE (SAE) related to the SOC Infections and infestations over the first 12 months. Of these, 361 AEs and 46 SAEs occurred under initial treatment started at index date. Mean DLQI was 6.6 at the 12 months RV in patients reporting within 30 days of AESI onset (n=32) and 3.9 if reported >30 days after AESI onset (n=350), while 3.7 in the total sample population (n=3701). Fewer patients (22.2%) reported a DLQI of 0/1 with an AESI ≤30 days before the 12 months RV compared to patients with an AESI >30 days before RV (46.4%) and the total sample (47.2%). Mean PBI was 2.4 in patients with an AESI onset ≤30 days (n=27) while 2.8 with an AESI onset >30 days before (n=308), and 2.8 in the total sample population (n=3352). Fewer patients (22.2%) reported a PBI of ≥3.0 with an AESI ≤30 days before compared to patients with an AESI >30 days prior (44.7%) and the total sample (44.1%).

Conclusion:

In general, over the 12 month's treatment period the impact of an AESI of the SOC Infections and infestations was minimal on HRQoL and patient benefit. Patients were observed to endure only a temporal impairment within the first 30 days following such AESI. Limitation is the small number and wide variety of AESI's reported within the SOC Infections and infestations, as well as unknown influence of concurrent medical conditions.

References:

1. Obradors M et al. Qual Life Res 2016;25(11):2739-2754.
2. Augustin M et al., Arch Dermatol Res. 2009;301(8):561-571.

Funding: This study was funded by UCB Pharma. Medical writing support was provided by Enago Life Sciences.

Table 1: DLQI and PBI in relation to AESI of the SOC Infections and infestations up to ~12 months RV

Reported DLQI / PBI values at 12 months RV	Total sample up to 12 months RV		AESI during Inclusion therapy up to 12 months RV		AESI during Inclusion therapy ≤30 days prior to 12 months RV		AESI during Inclusion therapy >30 days prior to 12 months RV	
	N/n		N/n		N/n		N/n	N/n
DLQI	3824		394		36		358	
Mean (SD)	3701	3.7 (5.0)	382	4.1 (5.4)	32	6.6 (6.9)	350	3.9 (5.2)
% by category								
0-1	1805	47.2	174	44.2	8	22.2	166	46.4
2-5	1004	26.3	105	26.6	9	25.0	96	26.8
6-10	512	13.4	53	13.5	8	22.2	45	12.6
>10	380	9.9	50	12.7	7	19.4	43	12.0
missing	123	3.2	12	3.0	4	11.1	8	2.2
PBI	8824		394		36		358	
Mean (SD)	3352	2.8 (1.0)	335	2.7 (0.9)	27	2.4 (1.0)	308	2.8 (0.9)
% by category								
3.5-4	925	24.2	76	19.3	3	8.3	73	20.4
3-<3.5	762	19.9	92	23.4	5	13.9	87	24.3
≥3	1687	44.1	168	42.7	8	22.2	160	44.7
2-<3	934	24.4	97	24.6	11	30.6	86	24.0
1-<2	525	13.7	47	11.9	5	13.9	42	11.7
0-<1	206	5.4	23	5.8	3	8.3	20	5.6
missing	472	12.3	59	15.0	9	25.0	50	14.0

Inclusion therapy refers to the systemic therapy started at the index date.
AESI, Adverse event of special interest (refers to the date of onset); DLQI, Dermatology Life Quality Index (scores: 0–30, higher score indicates greater impact of PsO on patient's life); RV, routine visit observational point; PBI, Patient Benefit Index (0 to 4, higher scores indicating higher benefit); SD, standard deviation; SOC, system organ class.

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Abstract N°: 5344

Tildrakizumab experience in real clinical practice

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Introduction & Objectives:

Tildrakizumab is a high-affinity, humanized IgG1κ monoclonal antibody targeting the p19 subunit of IL-23, which is a key regulatory cytokine in psoriasis. Based on evidence from clinical trials, tildrakizumab is approved for the treatment of moderate-to-severe plaque psoriasis in patients eligible for systemic therapy.

Materials & Methods:

We report our clinical experience with 51 patients followed up to 12 weeks in the Hospital Universitari Son Espases, Mallorca (Balearic Islands).

Patients received 100 mg tildrakizumab at weeks 0 and 4 and then every 12 weeks by subcutaneous injection. This treatment was performed as recommended according to current clinical practice.

Patients were assessed at baseline and at week 12 by a clinical visit and recordings of PASI score.

Results:

No adverse event were observed. A total of 51 patients with moderate-to-severe plaque psoriasis were included, 17 women (33.33%) and 34 men (66.66%), with a mean age of 50.76 years. Among comorbidities, the presence of psoriatic arthropathy was(7.84%), although others such as dyslipidemia (47.05%), diabetes (15.68%), arterial hypertension (29.41%) were also found. Nine cases of latent tuberculosis were detected which had received prophylaxis according to the current protocols.

All patients had received previous systemic therapy and 19/51 (37.25%) had never been treated with biologic drugs. Fourteen patients had received previous anti-TNFα biologic therapy, 16 patients had received anti-IL17 biological therapy, 13 patients received anti-IL12/IL23 biological therapy, and one patient had received previous treatment with guselkumab.

Regarding PASI values, our patients presented at baseline, mean values of 20.01 which progressed to 3.49a t week 12, with a 82.565% of PASI score mean reduction.

Conclusion:

Tildrakizumab 100 mg was well tolerated and no adverse event was reported by our patients during the whole 12-week follow-up period. The therapy was as effective as expected based on data from clinical trials suggesting that the time to response may be shorter than demonstrated by clinical trials. The improvement of plaque psoriasis was already seen at 12 weeks of therapy with an 82.565% of mean PASI score reduction.

In conclusion, our experience confirms the efficacy and safety of tildrakizumab when used in real-life practice. It remains to be checked whether these efficacy and safety results in real clinical practice are maintained in the medium and long term.

Tildrakizumab represents an efficient strategy for subjects with moderate-to-severe disease, who need long-term

persistent efficacy and safety of treatment.

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Abstract N°: 5395

Secukinumab in the treatmen of psoriasis - a single centre experience

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Introduction & Objectives: Psoriasis is a chronic, multi-systemic immune-mediated inflammatory skin disease. Secukinumab is a recombinant, fully human, monoclonal anti-IL-17 antibody approved for the treatment of moderate to severe psoriasis.

We retrospectively evaluated data in order to assess the overall outcomes with the use of secukinumab in psoriasis patients treated in the period from November 2016 to February 2023.

Materials & Methods: In the examined period, a total of 44 patients were prescribed with secukinumab, 27 (61%) men and 17 (39%) women. The median age of patients was 53.5 years (range 29-71). Concomitant psoriatic arthritis (PsA) was present in 72% of patients. Other comorbidities included arterial hypertension (18%), diabetes mellitus II (6.8%), and cardiovascular disease (25%).

Of all treated patients, 27 (61%) were biologically naive. Secukinumab was a second line of treatment for 15 (34%) patients, and third line of treatment for 2 (5%) patients. Secukinumab response was evaluated every 6 months since beginning of treatment and annually during the 5-year period. The average duration of therapy was 2.9 years. Disease severity was assessed by the Psoriasis Area and Severity Index (PASI) and the Dermatology Life Quality Index (DLQI).

Results: At baseline, mean PASI was 18.5 (range 1.5-42) and mean DLQI was 18 (range 0-30). During the first 6 months of therapy 36 patients reached PASI 100 response. Additional 2 patients reached PASI 100 response within the first year of therapy. DLQI also showed excellent improvement in the first 6 months of therapy with 43 patients reaching DLQI 0.

During the observed period, 6 patients (14%) discontinued secukinumab for treatment-related adverse reactions or due to loss of clinical response, 3 of them were non-naive to biologics. Additionally, 3 of them experienced a drug failure, in 2 patients we observed development of IBD and 1 patient developed sarcoidosis during treatment.

Conclusion: In conclusion, secukinumab has an excellent efficiency both in bionaive patients and as a second line treatment with a good safety profile without serious adverse events. It improved the complete spectrum of psoriasis manifestations, with fast clinical response and sustained therapeutic effect even after 5 years of treatment.

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Abstract N°: 5406

Treatment reality for women with psoriasis in childbearing age – data from the PsoFem study

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Introduction & Objectives: For patients with moderate to severe psoriasis and current childbearing or pregnancy, the choice of therapy is limited. The aim of the present study was to conduct a comparative survey of disease burden and systemic therapies in women of childbearing age with and without current wish for pregnancy in routine care at a university hospital centre.

Materials & Methods: Female patients aged 18 to 45 years with moderate to severe psoriasis vulgaris were consecutively assessed for disease characteristics, current therapies, psychosocial variables and specific family planning issues in routine care at our university clinics. Psoriasis severity was assessed using the Psoriasis Area and Severity Index (PASI) and quality of life impairments was assessed using the Dermatology Life Quality Index (DLQI).

Results: 152 female patients of childbearing age were included in the survey: 72 (47.4%) reported a desire to conceive (Group CI+), either in the next 12 months (n = 18) or in the future (n = 51); 77 (50.7%) reported no wish to have (more) children (Group CI-); and 3 patients (2.0%) were excluded because of current pregnancy (n = 1) or missing data in the family planning variables (n = 2). Comparative analyses between the two groups (CI- vs. CI+) showed that patients with childbearing wishes were, in average, slightly younger and had the psoriasis diagnosis for a shorter time; no significant differences in clinical features or DLQI impairments between the groups were found (Table 1). A significantly higher proportion of the CI+ group used TNFα blockers, particularly certolizumab pegol (Table 2). No significant differences were found between the groups regarding the frequency of other prescriptions for systemic treatment. The one patient that was pregnant was being treated with tildrakizumab. According to medical documentation, individual treatment goals were discussed with all patients; contradictorily, patients' childbearing preferences were discussed in only 66 cases (44.3%; 23 (29.9%) in the group CI- and 43 (59.7%) in the group CI+, p <0.001) and those were considered in the choice of treatment in 69 cases (46.3%; 31 (40.3%) in the group CI- and 38 (52.8%) in the group CI+; Table 2).

Conclusion: For women of childbearing age, a systemic treatment of psoriasis includes several options in the choice of medication prescribed in a university focus centre. Following current guidelines and recommendations, for women with an active desire to conceive, TNFα blockers among other biologics are frequently prescribed. Considerations for changes in therapy during pregnancy have to regard specifics of medication and the vulnerable stages in pregnancy as well as the limited volume of recommended systemic therapeutics for psoriasis in pregnancy.

Table 1. Clinical characteristics of patients with and without childbearing wishes.

		No childbearing wish (CI-) n = 77	Childbearing wish (CI+) n = 72	t/ χ^2	p
Age (years), M ± SD		36.78 ± 6.72	30.04 ± 5.89	6.49	<0.001
Type of psoriasis, n (%)	Plaque-type	73 (94.8%)	67 (93.1%)	1.59	0.451
	Guttate	3 (3.9%)	9 (12.5%)	4.57	0.102
	Intertriginous	8 (10.4%)	10 (13.9%)	1.33	0.514
	Pustular	3 (3.9%)	1 (1.4%)	1.86	0.394
	Psoriatic Arthritis	15 (19.5%)	8 (11.1%)	2.00	0.179
Disease duration (years), M ± SD		16.77 ± 10.34	13.61 ± 8.20	2.03	0.044
%BSA, M ± SD		3.26 ± 7.59	2.29 ± 6.75	0.82	0.412
PASI, M ± SD		1.90 ± 3.20	1.48 ± 3.33	0.80	0.427
DLQI, M ± SD		4.81 ± 6.32	3.57 ± 4.81	1.34	0.184
Comorbidities, n (%)		37 (48.1%)	31 (43.1%)	0.37	0.622

BSA – Body Surface Area; PASI – Psoriasis Area and Severity Index; DLQI – Dermatology Life Quality Index; M – mean; SD – standard-deviation; n – number of patients; t – independent samples t-test for continuous variables; χ^2 – chi-squared test for categorical variables; p – level of significance, two-tailed.

Table 2. Current systemic treatment of patients with and without childbearing wishes

	No childbearing wish (CI-) n = 77	Childbearing wish (CI+) n = 72	χ^2	p
TNF alpha blockers	**12 (15.6%)**	**23 (31.9%)**	**5.54**	**0.021**
Adalimumab	6 (7.8%)	7 (9.7%)	0.17	0.775
Certolizumab pegol	5 (6.5%)	16 (22.2%)	7.60	0.009
Infliximab	1 (1.3%)	0 (0.0%)	0.94	1.000
Januskinase (JAK) inhibitors				
Upadacitinib	0 (0.0%)	1 (1.4%)	1.08	0.483
Other biologics (anti-IL-17; anti-IL-12/23; anti-IL-23)	52 (67.5%)	39 (54.2%)	2.80	0.130
Bimekizumab	1 (1.3%)	0 (0.0%)	0.94	1.000
Brodalumab	1 (1.3%)	1 (1.4%)	0.002	1.000
Guselkumab	10 (13.0%)	10 (13.9%)	0.03	1.000
Ixekizumab	9 (11.7%)	4 (5.6%)	1.76	0.249
Risankizumab	4 (5.2%)	5 (6.9%)	0.20	0.739
Secukinumab	10 (13.0%)	8 (11.1%)	0.12	0.804
Tildrakizumab	5 (6.5%)	1 (1.4%)	2.51	0.211
Ustekinumab	12 (15.6%)	10 (13.9%)	0.09	0.820
Other non-biologic systemic treatment	8 (10.4%)	3 (4.2%)	2.11	0.212
Apremilast	1 (1.3%)	1 (1.4%)	0.002	1.000
Dimethylfumarat	1 (1.3%)	0 (0.0%)	0.94	1.000
Fumaric acid	6 (7.8%)	2 (2.8%)	1.84	0.278
Antimetabolites				
Methotrexate	6 (7.8%)	2 (2.8%)	1.84	0.278
No systemic treatment	3 (3.9%)	5 (6.9%)	0.68	0.483
Shared therapy goals [a]	72 (93.5%)[‡]	69 (95.8%)[‡]	-	-
Communication about childbearing preferences [b]	**23 (29.9%)**	**43 (59.7%)**	**13.44**	**<0.001**
Childbearing preferences taken into account in clinical decision [c]	31 (40.3%)	38 (52.8%)	2.35	0.141

n – number of patients; χ^2 – chi-squared test for categorical variables; p – level of significance, two-tailed.
[a] Did you set therapy goals together with the patient?; [b] Has the patient ever commented on her wish to have (or not to have) children?; [c] Were the patient's birth wishes taken into account in the current (or last to date) treatment choice?
[‡] Corresponding to a valid percentage = 100%; remaining cases were missing values.

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Abstract N°: 5437

From clinical trials to real-life practice life in practice: experience with brodalumab

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Introduction & Objectives:

Brodalumab is a monoclonal antibody that binds to subunit A of the IL-17 receptor, blocking several cytokines of that family. It has shown great efficacy in their clinical trials but there is limited real-life evidence. Our objectives were to characterize a series of patients in real clinical practice undergoing treatment with brodalumab, to assess the clinical outcomes obtained as well as the causes of treatment withdrawal and to report any adverse events.

Materials & Methods:

This is a longitudinal and prospective study, during a 2 year period in the area of Aragón (Spain), in which demographic variables (age, sex), disease characteristics (duration, joint involvement and activity measured on scales), as well as comorbidities were collected.

At baseline and follow-up at 12, 24, 36, 52 and 104 weeks, PASI (Psoriasis Area and Severity Index), BSA (Body Surface Area), PGA (Physician Global Area and Severity Index (PASI), Body Surface Area (BSA), Physician Global Assessment (PGA), Dermatology Life Quality Index (DLQI), and VAS (Visual Analog Scale) and adverse effects or changes in dosage were collected.

Results:

Our series provide 15 patients (median age = 60, 60% male). They were refractory to other systemic treatments, except one. Brodalumab was initiated on monotherapy according to the usual dosage.

Significant differences were observed in the reduction of the absolute PASI at week 12 (PASI 0.51; 0-1.2, $p<0.001$; $n=15$), week 24 (PASI 0.23; 0-0.6, $p<0.001$; $n=13$), week 36 (PASI 0.09; 0-0.13, $p<0.001$; $n=11$), week 52 (PASI 0.13; 0-0.26, $p<0.001$; $n=9$) and week 104 (PASI 0.4; 0-1.17, $p<0.001$; $n=5$). Significant improvements were also observed in BSA, PGA, DLQI and VAS pruritus scale values (Figure 2).

Efficacy data (PASI response) of the patients were analysed according to weight (BMI) and to the number of treatments prior brodalumab not finding statistically significant differences

Brodalumab was discontinued in two patients. The first one due to clinical worsening of a previously diagnosed depression, despite skin clearance was achieved. The second one, experienced secondary failure after two year of treatment.

Conclusion:

In this series we observed a rapid and sustained improvement in both the extent and severity of psoriasis and in the impact on patients' quality of life. These good results are consistent with those obtained in the AMAGINE-1, AMAGINE-2 and AMAGINE-3 clinical trials, achieving better rates of PASI 75 and 90 at week 12 in real clinical practice (PASI 75: 100% and PASI 90: 93%) compared to the trials (PASI 75: 83-86% and PASI 90:70-79%).

Authors conclude that brodalumab in clinical practice has demonstrated an excellent efficacy and safety profile for the treatment of moderate-severe psoriasis.

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Abstract N°: 5455

Apremilast therapy in patients with nail psoriasis

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Introduction & Objectives:

The prevalence of nail changes in patients with psoriasis is about 80%. Nail psoriasis is difficult to treat and respond slowly to therapy. The efficacy of the first line in the management of skin psoriasis such as phototherapy and systemic therapy (methotrexate) is limited for nail psoriasis. Apremilast is the first oral phosphodiesterase-4 inhibitor approved by the Ministry of Health of Russian Federation for the treatment of moderate to severe psoriasis in the Russian Federation. In clinical trials apremilast has been shown to be highly effective against nail psoriasis. The aim of the study is to evaluate the efficacy of apremilast therapy in patients with nail psoriasis and cutaneous involvement.

Materials & Methods:

26 patients with nail psoriasis (19 men, 7 women; mean ± SD age 40.4±12.6 years, range 21-65) were enrolled in the study. Mean duration of psoriasis was 20.8±11.3 years (range 4 – 44). Mean PASI was 20.8±11.3 (range 10 – 47). Moderate psoriasis was registered in 11 (42%) patients, severe psoriasis - in 15 (58%) patients. All patients had a history of methotrexate therapy failure. All patients were prescribed apremilast 30 mg PO BID. The efficacy of therapy was evaluated by the Nail Psoriasis Severity Index (NAPSI) at week 26.

Results:

At baseline the values of the NAPSI index ranged from 0 to 160 points (50.5±46.5); for hand nail plates NAPSI varied from 0 to 80 (17.3±22.3); for foot nail plates - from 0 to 80 (33.5±27.6). The characteristics of psoriatic nails were recorded: subungual hyperkeratosis (35.9%), discoloration (29.7%), onycholysis (23.5%), pitting (10.9%). By the 14th week of therapy, the NAPSI index decreased to 40.1±36.1 ($p<0.0004$), and by the 26th week to 36.5±35.2 ($p<0.0002$). Only hand nail plates NAPSI decreased by week 14 of therapy to 13.2±17.2 ($p<0.005$), by week 26 to 11.5±14.7 ($p<0.007$); only foot nail plates NAPSI up to 26.9±24.2 ($p<0.0003$) by week 14 and up to 23.1±24.2 ($p<0.0003$) by week 26, respectively.

By the 26th week of therapy, the achievement of NAPSI50 and higher was recorded in 7 (27%) patients, NAPSI30 and higher - in 11 (42%) patients.

Conclusion:

The phosphodiesterase-4 inhibitor (apremilast) has shown high efficacy in the treatment of nail psoriasis in patients with moderate to severe psoriasis with a history of methotrexate therapy failure.

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Abstract N°: 5599

Generalized pustular psoriasis - a new IL36RN mutation

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Introduction:

Generalized pustular psoriasis is a rare form of psoriasis. Subpopulations of patients with mutations in a specific gene, IL36RN, which encodes for the IL-36 receptor antagonist, have been described in the literature.

Case report:

We describe the case of a 26-year-old woman with no significant medical history, who was regularly taking oral contraceptives. She was referred to our service due to episodic pustular lesions, occasionally pruritic, with a 10-year history. On physical examination, she presented with erythematous and scaly patches with pustules predominantly distributed at the periphery of the lesions. These lesions were grossly symmetrical and were located in the axillary region, inner aspects of the arms, abdomen, thighs, and inguinal region. Complementary studies revealed elevated inflammatory markers, while microbiological examination of the pustules and a basic immunological study were negative. A skin biopsy was performed, which showed findings consistent with a diagnosis of psoriasis. Direct immunofluorescence testing was negative. The patient initiated treatment with cyclosporine and later with methotrexate, but was refractory to both treatments. A genetic study targeting the IL36RN gene was conducted, identifying a heterozygous mutation (c.333C>T). Subsequently, the patient was proposed for treatment with adalimumab, which has shown a good response thus far.

Discussion:

Deficiency of the IL-36 receptor antagonist (DITRA) should be considered when generalized pustular psoriasis occurs in pediatric patients, along with evidence of systemic inflammation, as described in this case. The mutation found in this case has a very low frequency in the population and, to our knowledge, has not been reported in the literature in patients with pustular psoriasis. Therefore, we emphasize the need for a high degree of clinical suspicion in such cases, as well as, as advised by some authors, the performance of targeted genetic studies in cases of early onset pustular psoriasis.

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Abstract N°: 5610

Deucravacitinib, an allosteric, selective tyrosine kinase 2 inhibitor, in plaque psoriasis: long-term safety results of patients from Asia in the phase 3 POETYK PSO-1 and PSO-3 trials

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious and well tolerated in the global, 52-week, phase 3 POETYK PSO-1 trial (NCT03624127; N=666), as well as in the subgroup of patients from Asia (n=106). Deucravacitinib was also efficacious and well tolerated in the 52-week, phase 3 POETYK PSO-3 trial (NCT04167462) in a larger population of patients from Asia (mainland China, Taiwan, and South Korea; N=220). Upon completion, patients could enter the ongoing POETYK long-term extension (LTE) trial (NCT04036435). Here, we report the pooled safety analysis of deucravacitinib through 3 years (148 weeks) of treatment in patients from Asia with moderate to severe plaque psoriasis from PSO-1 and PSO-3.

Materials & Methods: In PSO-1, patients were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily. In PSO-3, patients were randomized 1:2 to oral placebo or deucravacitinib. At Week 16, patients randomized to placebo crossed over to deucravacitinib. At Week 52, patients could enter the LTE trial and receive open-label deucravacitinib. Patients in PSO-1 from Asia (mainland China, Taiwan, South Korea, and Japan) and all patients from PSO-3 who received ≥1 dose of deucravacitinib through the cutoff date (June 15, 2022) were included in this pooled safety analysis. Adverse events (AEs) were expressed as exposure-adjusted incident rates (EAIRs) per 100 person-years (PY) to adjust for differences in deucravacitinib exposure. EAIR is calculated as 100*(# of patients with AE)/(total exposure time for all patients at risk [time to initial AE occurrence for patients with AE + total exposure time for patients without AE]).

Results: A total of 312 patients from Asia received ≥1 dose of deucravacitinib in PSO-1/PSO-3/LTE. At data cutoff, 240 (76.9%) patients were receiving ongoing deucravacitinib treatment, 19 (6.1%) had completed treatment in the parent trial and did not enter the LTE, and 53 (17.0%) had discontinued treatment (patient withdrawal, 19 [6.1%]; AEs, 13 [4.2%]; lack of efficacy, 5 [1.6%]; noncompliance, 3 [1.0%]; lost to follow-up, 2 [0.6%]; pregnancy, 1 [0.3%]; other, 10 [3.2%]). Median (range) duration of exposure was 755.5 (1, 1303) days. Cumulative exposure from randomization was 626.3 PY for these EAIR analyses. Overall, EAIRs with deucravacitinib treatment were 256.2/100 PY for AEs, 7.5/100 PY for serious AEs, and 2.5/100 PY for AEs leading to discontinuation. No deaths were reported. The most common AEs (EAIR ≥5/100 PY) were upper respiratory tract infection (14.4/100 PY) and nasopharyngitis (12.3/100 PY). Rates for other AEs were as follows: serious infections, 1.7/100 PY; influenza, 0.7/100 PY; COVID-19, 2.2/100 PY; herpes zoster, 2.0/100 PY; tuberculosis, 0.2/100 PY; malignancies, 0.3/100 PY;

MACE, 0.3/100 PY; and extended MACE, 0.5/100 PY. No thromboembolic events were reported.

Conclusion: Deucravacitinib was generally safe and well tolerated in patients from Asia through 3 years of treatment. The safety profile of deucravacitinib at 3 years was consistent with that shown in the global POETYK trials. These findings further support the long-term use of deucravacitinib, a once-daily oral treatment, in Asian patients with plaque psoriasis.

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Abstract N°: 5766

Association of monocyte-to-high density-lipoprotein-cholesterol index with coronary subclinical atherosclerosis in patients with psoriasis: results from an observational cohort

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Introduction & Objectives: Cardiovascular risk prediction systems fail in patients with psoriasis. They do not consider key elements in the development of atherosclerosis in this population, such as systemic inflammation or insulin resistance. Our aim was to evaluate the association of the monocyte to HDL index (MHR), an index accessible in a basic blood test and which includes inflammatory and metabolic information, with the presence of coronary subclinical atherosclerosis.

Materials & Methods: The patients belonged to the Early Detection of Sublinical Atherosclerosis in Psoriasis (EDSAP) cohort, a cohort that includes patients with psoriasis without prior cardiovascular disease who are candidates for biologic therapy. A cross-sectional study was designed using data from the baseline visit, which included anamnesis and physical examination, laboratory tests and coronary CT angiography with contrast. A significant coronary lesion was defined as a lesion with > 50% of the lumen of the anterior descending/right coronary artery/circumflex/coronary artery. MHR was obtained from a fasting blood sample according to previously published calculations.

Results: Baseline characteristics are described in table 1. Significantly higher MHR levels were observed in the 37 patients (33.9%) with significant lesions (mean -IQR-; 13.6 -10.2 to 17.2- vs. 9.9 -7.7 to 14.0; p<0.001). Figure 2 shows MHR levels in patients with and without atheroma plaques. These differences were maintained in logistic regression models adjusted for age, sex, BMI, blood pressure, total cholesterol, smoking and statin use (LogMHR OR 4.9, 95% CI 1.07-22.6, p=0.041). In this multivariate logistic regression, MHR had a stronger association with coronary lesions than age, sex, total cholesterol and smoking.

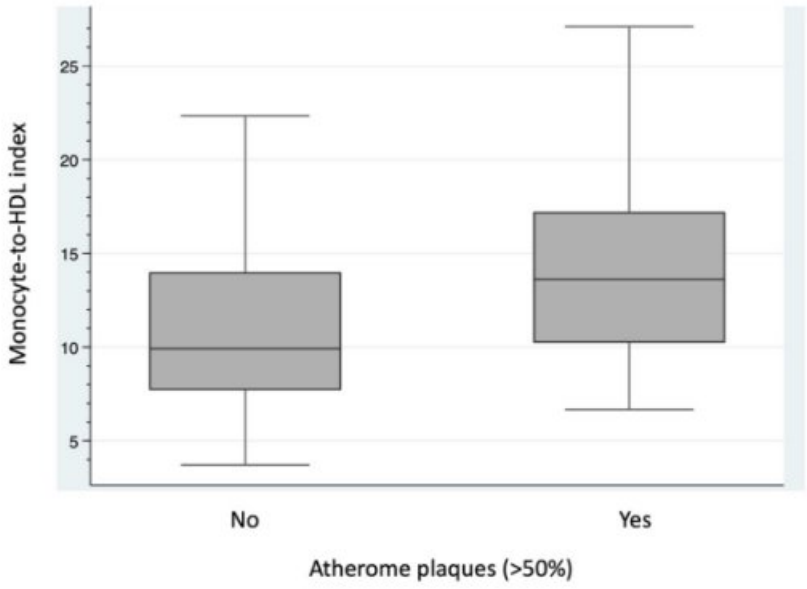
Conclusion: MHR, a biomarker easily calculated and accessible in a basic blood panel, was associated with the presence of coronary atherosclerosis in patients with psoriasis independently of other classical cardiovascular risk factors, suggesting that it may help to improve the characterization of cardiovascular risk in a high-risk population. Further studies with larger sample sizes and involving different populations will be needed to confirm these findings.

Table 1: Baseline characteristics of the participants.

	Atheroma Plaques	
	No (n=74)	**Yes (n=37)**
Age	46.4 (40.3-51.0)	53.1 (48.2-57.2)
Male, n(%)	47 (64%)	32 (86%)
BMI	27.0 (24.7-31.8)	30.3 (27.3-32.2)
Hypertension, n (%)	19 (26%)	23 (62%)
Current smoker, n(%)	31 (42%)	13 (35%)
Hyperlipidemia, n(%)	28 (38%)	25 (68%)
Diabetes, n(%)	1 (1%)	5 (14%)
Statins, n (%)	10 (14%)	15 (41%)
hsCRP, mg/l	2 (1-5)	2.5 (1.4-4.6)
PASI	9 (5-13)	8 (5.6-13)
MHR	9.9 (7.7-14.0)	13.6 (10.2-17.2)

BMI: Body Mass Index; hsCRP: high-sensitivity C-reactive protein; PASI: Psoriasis Area and Severity Index; MHR: Monocyte-to-HDL index.

Figure 2. Box and whisker chart to characterize MHR levels in patient with and without atheroma plaques.



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Abstract N°: 5785

Comparative Analysis of Cardiovascular Risk in Psoriasis: Assessing Disparities between Black/African American and White Non-Hispanic Patients

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Introduction & Objectives:

Increased risk of cardiovascular disease (CVD) has been recently associated with psoriasis, a systemic, immune-mediated inflammatory skin disorder. However, there is currently limited information available elucidating potential differences in CVD outcomes between racial and ethnic groups affected by psoriasis. Our study aimed to assess differences in cardiovascular outcomes between Black/African American and White Non-Hispanic patients, at 1 year, 5 years, and 10 years following the onset of psoriasis.

Materials & Methods:

A federated health research network database, TriNetX, was used to query patient outcomes from the subset named US Collaborative Network, including 56 Health Collaborative Organizations. A retrospective cohort analysis was performed to compare cardiovascular clinical outcomes between Black/African American and White Non-Hispanic patients following the onset of psoriasis. Stratification was based on validated ICD-10 codes. A 1:1 matched propensity score analysis (PSM) was conducted adjusting for age at index and potential confounders such as essential hypertension, overweight/obesity, diabetes mellitus, nicotine dependence, alcohol-related disorders, and family history of ischemic heart disease and other circulatory system diseases. Values tabulated by the TriNetX analytic feature were presented as adjusted Risk Ratios (aRR) with 95% CI at 1-year, 5-year, and 10-year clinical outcomes.

Results:

Following propensity score matching, 30,057 well-matched patients per cohort were identified. African Black/African American with psoriasis demonstrated increased risk for heart failure ((aRR [95% CI]) = 1.36[1.18, 1.57] at 1 year, 1.29[1.19, 1.40] at 5 years, and 1.24[1.15, 1.33] at 10 years), acute myocardial infarction (aRR = 1.31[1.06, 1.61] at 1 year, 1.22[1.08, 1.38] at 5 years, and 1.17[1.06, 1.30] at 10 years), cardiac arrest (aRR = 1.97(1.28, 3.03) at 1 year, 1.49(1.18, 1.88) at 5 years, and 1.42[1.16, 1.73] at 10 years), cerebral infarction (aRR = 1.54[1.25, 1.90] at 1 year, 1.39[1.23, 1.57] at 5 years, and 1.41[1.27, 1.57] at 10 years), and other venous embolism and thrombosis (aRR = 1.22[1.08, 1.38] at 5 years, and 1.24[1.12, 1.38] at 10 years) compared to White Non-Hispanic patients.

Discussion & Conclusion:

Findings presented in this study reveal significant disparities in CVD outcomes between Black/African American and White Non-Hispanic patients affected with psoriasis. Black/African American demonstrated a higher risk of all assessed cardiovascular events across all time points despite controlling for potential confounders. This study highlights the need for targeted interventions to mitigate the elevated risk of cardiovascular events among Black/African American patients with psoriasis. Additional research is warranted to elucidate the underlying mechanisms leading to these disparities and initiate the development of strategies for prevention, management, and risk stratification in this population group. Addressing healthcare disparities among Black/African American

patients can potentially result in more positive clinical outcomes.

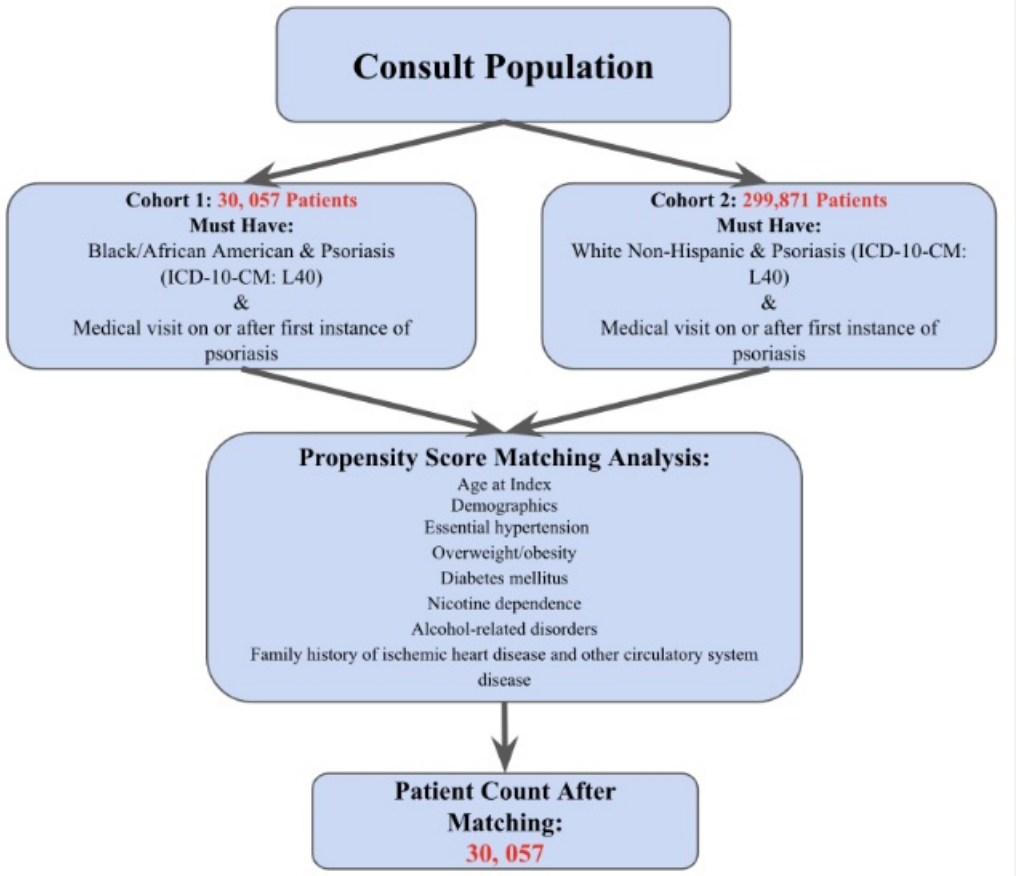

Figure 1 - Flow Diagram for Consult Population

Supplementary Table: Baseline demographic characteristics of Black/African American and White Non-Hispanic Patients with Psoriasis following propensity score analysis			
	No. (%)		
Characteristic	**Black/ African American (n = 30.057)**	**White Non-Hispanic (n=30,057)**	***P* value**
Demographics			
Age at Index	46.257942 (19.94)	46.27 (19.90)	0.94
Male	11598 (38.59%)	11616 (38.65%)	0.88
Female	18456 (61.40%)	18441 (61.35%)	0.90
Comorbidities			
Essential (primary) hypertension	12218 (40.65%)	12248 (40.75%)	0.80
Overweight & Obesity	6605 (21.98%)	6607 (21.98%)	0.98
Diabetes Mellitus	6103 (20.31%)	6101 (20.30%)	0.98
Nicotine Dependence	4433 (14.75%)	4418 (14.70%)	0.86
Alcohol related disorders	1347 (4.48%)	1305 (4.34%)	0.40
Family history of ischemic heart disease & circulatory system disease	1074 (3.57%)	1038 (3.45%)	0.43

Cardiovascular Outcome	1-Year Risk Ratio	5-Year Risk Ratio	10-Year Risk Ratio
Heart Failure	**1.36**	**1.29**	**1.24**
Acute Myocardial Infarction	**1.31**	**1.22**	**1.17**
Cardiac Arrest	**1.97**	**1.49**	**1.42**
Cerebral Infarction	**1.54**	**1.39**	**1.41**
Other Venous Embolism and Thrombosis	1.15	**1.22**	**1.24**

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EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 5826

Real-world Efficacy of Bimekizumab Treatment in Psoriasis: A Case Series of 25 Patients

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Introduction & Objectives: Psoriasis, a chronic inflammatory skin disease, affects a significant number of individuals worldwide. Bimekizumab, a monoclonal antibody targeting interleukin (IL)-17A and IL-17F, has demonstrated promising outcomes in clinical trials for psoriasis. However, there is a need for real-world evidence to validate its effectiveness.

Materials & Methods: We conducted a retrospective case series involving 25 adult patients with moderate to severe psoriasis who initiated bimekizumab treatment at our hospital. Patients received subcutaneous injections of bimekizumab 320 mg at weeks 0, 4, and every 8 weeks thereafter. Effectiveness was assessed using the Psoriasis Area and Severity Index (PASI) scores and the Dermatology Life Quality Index (DLQI) at baseline, week 4, and will be performed at week 12.

Results: The average age of the participants was 54 years, with a predominance of females (54%). Of the patients, 11 (46%) were bionaive, 13 (54%) switched from other biologic agents, and 12 (48%) had previously used IL-17 inhibitors. Additionally, 7 patients (29%) had psoriatic arthritis, 9 (36%) had palmoplantar psoriasis, 3 (12%) had nail psoriasis, 3 (12%) had scalp psoriasis, and 1 (4%) had genital involvement. At week 4, the mean PASI score improved from 12.7 at baseline to 4.2, and the mean DLQI improved from 10.9 at baseline to 2.5. Furthermore, 13 patients (56%) achieved PASI 90, and 4 (16%) achieved PASI 100 at week 4. No adverse events were reported.

Conclusion: Our case series of 25 patients provides evidence supporting the effectiveness of bimekizumab in improving psoriasis, even in patients who have previously received multiple biological agents. Moreover, no serious adverse events were observed. These promising results support the use of bimekizumab in real-world clinical practice. Nevertheless, further studies with larger sample sizes and longer follow-up periods are necessary to confirm and consolidate these findings.

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Predicting Psoriasis Incidence based on Environmental Factors using Machine Learning

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease affecting 2-4% of the world population. It has a significant negative effect on patient's quality of life as well as a high economic burden on both patients and the health care systems. As family history is positive in only ~30% of patients, external exposures/modifiable factors play an important role. The objective of this study was to determine the incidence of psoriasis over time in using a populational database and to build a prediction model to identify the predictors of high incidence of psoriasis from the built environment (e.g social/material deprivation and neighborhood characteristics, using machine learning techniques.

Materials & Methods:

Quebec provincial health administrative database (1997-2015) in Canada was used to select adult psoriasis patients (≥20-years-old) based on ICD-9/10 codes, per Forward Sortation Area (FSA; geographical unit). The patient was required to have ≥2 billing codes for psoriasis in outpatient setting or ≥1 during a hospitalization. The population of adult patients covered by provincial drug plan for each FSA was used as the denominator to calculate the incidence rate. Linear regression analysis was performed to determine trend in incidence over time. Geographic distribution of incidence rates per FSA was mapped using ArcGIS 10.8. Data on environmental exposures was obtained from Canadian Urban Environmental Health Research Consortium (CANUE) per year and per FSA. The machine learning algorithm used environmental data in the year prior to predict next year's high incidence of psoriasis (i.e whether an FSA had the highest 10% vs 90% incidence rates). Gradient boosting model provided ranking of the most important features contributing to high incidence of psoriasis.

Results:

Decreasing trends in incidence over time were observed from 135.55/100,000 individuals in 1999 to 90.93/100,000 in 2014. Uneven geographic distribution of the incidence rate was also found. The top-ranking features identified by gradient boosting model included domains of weather, socioeconomic status (SES), and neighborhood characteristics. The top two predictors were Vitamin D level at sea level during summer months and daily maximum temperature. Descriptive characteristics for these variables suggested that higher Vitamin D levels, higher temperatures, and extremely lower and higher SES may predict low incidence of psoriasis, whereas middle SES and high nighttime brightness predict high incidence of

psoriasis.

Conclusion:

We used a machine learning model to systematically and comprehensively evaluate all environmental data obtained from CANUE over an 18-year period to predict high incidence of psoriasis in the following year. Top factors identified were climate factors, SES, and neighbourhood characteristics. Identifying which neighbourhood characteristics predict high incidence of psoriasis can help better identify triggers and implement changes to

reduce incidence of this common disease associated with multiple comorbidities and reduced quality of life.

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Abstract N°: 5853

nevi, biologics for psoriasis and the risk of skin cancer - a real concern?

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Introduction & Objectives:

Psoriasis is a systemic inflammatory cutaneous disease that affects approximately 2% of the world's population. Systemic treatments and biologic treatment therapies are a powerful option for patients with moderate to severe psoriasis. Some studies from the literature indicate an overall small, but increased, risk of neoplasia in patients with psoriasis treated with phototherapy or systemic medication. The relationship between psoriasis and malignancy is not very well established; there are few studies with conflicting results.

Materials & Methods:

We present the case of a 31-year old male patient, non-smoker, non-alcoholic, who was referred to the Dermatology Department of 'St. Parascheva' Clinical Infectious Diseases Hospital of Galati in due to the presence of widespread, sharply demarcated erythemato-squamous, irregularly shaped lesions, ranging from 2 to 4 cm, located on the trunk and lower extremities. The patient reported the onset of cutaneous lesions as early as childhood. He underwent various topical treatments, ointments and calcipotriol without significant changes.

Results:

In summary, the risk of new or recurrent systemic malignancies is similar between patients with biologic and non-biologic treatments. The risk of additional non-melanoma skin cancer occurrences in patients with a history may be increased, and data concerning additional primary melanomas and melanoma recurrence are inconclusive in melanoma survivors. Despite evidence suggesting the short-term efficacy and safety of biologic therapy as compared to classic conventional systemic therapies, there are concerns regarding the long-term risk of developing cancer in patients treated with biologic therapy as compared to those treated by conventional systemic therapies . Based on high-level evidence, therapies for psoriasis appear to be safe. Additional long-term data are warranted for newer treatments and for their use in cancer survivors .

Conclusion:

The newer biologic and non-biologic agents appear to be promising and effective, but additional studies are needed to evaluate the malignancy risk in these agents. We should also remind patients of the importance of prophylaxis and the use of sunscreen products among patients of this group.

To conclude, the risk of new or recurrent systemic malignancies is similar between patients on biologic and non-biologic treatments. Recent research concerning the development of new melanocytic lesions in patients under immunosuppressive therapy showed that the treatment with biologic agents was associated with increased nevi count and the appearance of dermoscopic changes in existing nevi, but none of the changes, or any of the subsequently excised nevi, were malignant. Based on high-level evidence, psoriasis therapies appear to be safe. Any clinical or dermoscopic changes in existing melanocytic nevi in patients undergoing biological treatment or other immunosuppressive therapies should be carefully

monitored as alternative to excision. As in other dermatological conditions, temporization and follow-up with both clinical and dermoscopic monitoring of pigmented lesions are an alternative to surgical excision. Additionally, reflectance confocal microscopy or optical coherence tomography could be used. Further long-term data are warranted for novel treatments and for their use in patients with malignancies.

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Abstract N°: 5863

Real-World Achievement of Absolute Psoriasis Area and Severity Index Thresholds With Persistent 18-Month Risankizumab Use in Patients With Moderate to Severe Psoriasis From the CorEvitas Psoriasis Registry

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Introduction & Objectives: Risankizumab, an interleukin-23 inhibitor, was efficacious in the treatment of moderate to severe plaque psoriasis in phase 3 trials as absolute Psoriasis Area Severity Index (PASI) thresholds of 0, ≤1, and ≤3 were achieved by 58%, 70%, and 87% of patients at 52 weeks, respectively. To assess outcomes in a real-world setting, skin clearance at 18 months after risankizumab initiation was assessed among patients from a North American psoriasis registry.

Materials & Methods: This analysis used data from the independent, observational, prospective CorEvitas Psoriasis Registry that includes patients ≥18 years of age treated for psoriasis by a dermatologist who were recruited from practices in the United States and Canada. Patients with moderate to severe plaque psoriasis (Investigator's Global Assessment [IGA] ≥3) who initiated risankizumab at a registry visit (eg, baseline) between April 2019 and December 2021 with persistent use at 18 (±3) months follow-up were included in this analysis. The percentage of patients with PASI >3 at baseline who achieved absolute PASI thresholds of 0, ≤1, or ≤3 at 18 months after initiation of risankizumab was assessed. Stratification by prior biologic use (bio-naive and bio-experienced) was also conducted.

Results: A total of 257 patients with baseline IGA ≥3 and persistent risankizumab use at 18 months were included in this analysis. The mean (SD) age was 49.0 (15.1) years and 57.6% were male. Mean (SD) psoriasis duration was 17.4 (14.1) years and 53.7% (n=138) had prior biologic use at baseline. Baseline mean (SD) PASI was 10.5 (7.8). In patients with baseline PASI >3 (n=229), 58.5% (95% CI, 51.8%–65.0%; n=134) of patients achieved PASI=0, 70.3% (63.9%–76.1%; n=161) achieved PASI ≤1, and 88.2% (83.3%–92.1%; n=202) achieved PASI ≤3 after 18 months of risankizumab use (**Figure**). Among biologic-naive patients (n=111), 70.3% (60.9%–78.6%; n=78), 82.0% (73.6%–88.6%; n=91), and 96.4% (91.0%–99.0%; n=107) achieved PASI=0, ≤1, and ≤3, respectively; among biologic-experienced patients (n=118), 47.5% (38.2%–56.9%, n=56), 59.3% (49.9%–68.3%; n=70), and 80.5% (72.2%–87.2%; n=95) achieved PASI=0, ≤1, and ≤3 at 18 months, respectively (**Figure**).

Conclusion: Persistent 18-month risankizumab use was highly effective in achieving skin clearance, as measured by absolute PASI thresholds, among patients with moderate to severe plaque psoriasis in a real-world setting.

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BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 5870

Differentially expressed proteins in skin and blood in patients with psoriasis: a systematic review of proteomic studies

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Introduction & Objectives:

Proteins play a central role in the inflammation and structural changes in psoriasis. The objective of this systematic review is to identify the differentially expressed proteins (DEPs) that have been reported in at least two proteomic studies in psoriasis with consistency regarding direction of change.

Materials & Methods:

We searched PubMed, EMBASE and Web of Science using the following search string: “psoria* AND proteom*”. We included proteomic studies of skin and blood in patients with psoriasis that identified and compared expression levels of at least 10 proteins in at least one of four comparisons (lesional versus non-lesional skin; lesional versus healthy skin; non-lesional versus healthy skin; blood-derived samples from patients with psoriasis compared with healthy individuals). We performed a network analysis of the DEPs reported in more than one study. The protocol for this review was registered in the PROSPERO database (ref: CRD42022363226).

Results:

We identified and assessed 772 studies of which 30 studies met the inclusion- and data availability criteria for analysis. The included studies reported a total of more than 5000 DEPs. Most of the consistently and non-divergently reported DEPs were identified in lesional versus non-lesional skin (n=313), followed by lesional versus healthy skin (n=185), blood from diseased versus healthy individuals (n=140), and non-lesional versus healthy skin (n=1). Fourteen DEPs were mutually upregulated in both lesional skin and blood from patients with psoriasis while none were downregulated in both tissues. Network analysis revealed different functional clusters of DEPs with IL-6, CXCL-8, IL-17A, STAT3 and IFN-γ playing central roles. The proteomic dysregulation also included antimicrobial peptides, angiogenic factors and proteins involved in transcription and translation processes. Additionally, some of the reported changes were associated with anti-inflammatory effects.

Conclusion:

The results from this systematic review underline the central role of known inflammatory mediators in psoriasis pathogenesis and support the notion of psoriasis as a systemic inflammatory disease. Some of the dysregulated proteins in the included studies have not been extensively discussed in the context of psoriasis previously and could represent relevant topics for future research. Our study shows that summarizing proteome-wide research can reveal central and novel aspects of disease pathology, thus providing a potential framework for future reviews of proteomic studies in other diseases.

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Abstract N°: 5896

Drug survival and effectiveness of secukinumab through five years in French patients with moderate to severe plaque psoriasis in real-life setting: long-term results from the LOGIC study.

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Introduction & Objectives:

Psoriasis (PsO) is a chronic systemic disease that requires long-term therapeutic outcomes. Secukinumab (SEC) is an approved biological therapy for moderate-to-severe plaque PsO and PsA. It showed safety and efficacy in numerous real-world experiences. However, long-term real-world data of SEC in French PsO patients remains limited. We analysed 5-year follow-up data of SEC from the LOGIC study, a non-interventional, retrospective, French, multicentre study, conducted using historical data.

Materials & Methods:

The aim of the LOGIC study was to describe a cohort of patients with PsO who initiated SEC treatment, and to assess the long-term drug survival, effectiveness and safety of SEC, during a follow-up period up to 5 years under real-world conditions in French patients with moderate to severe PsO. The study enrolled 422 patients in 3 centers in France (from May 2022 to October 2022). The efficacy was measured by improvement in IGA score through the follow-up period and the drug survival rate was assessed with Kaplan-Meier analysis.

Results:

Among the 422 patients enrolled, 63.0% were male and 57.6% had a BMI ≥25. At SEC initiation, mean (SD) age and disease duration were 53.4 (15.4) and 17.1 (13.2) years, respectively. Almost all patients received the on-label dosing of SEC (99.8%). 23.0% of patients experienced at least one prior biological treatment (only one line mainly (15.6%)): anti-TNF-alpha (14.9%), anti-IL-12/IL-23 (10.4%). Only few patients used anti-IL-17 or anti-IL-23. The mean follow-up period after SEC initiation was of 2.9 years (8.0 months – 7.0 years). The baseline IGA score was mostly 3 (63.7%) and 4 (31.0%). At month 6, 93.5% and 86.9% of patients achieved IGA 0/1 and IGA 0, respectively (data available on 214 patients).

Out of 422 patients, 14.5% permanently discontinued the treatment, two-third of them for inefficacy. The persistence rates (temporary or permanently discontinuation) of SEC by Kaplan-Meier method were 98.1%, 88.7%, 80.9%, 74.8% and 63.6% at 1, 2, 3, 4, 5 years for bio-naïve patients respectively (n=325).

For the bio-experienced population, the persistent rates of SEC were 96.9%, 84.2%, 72.8%, 64.9% and 61.6% at 1, 2, 3, 4, 5 years respectively (n=97).

A multivariate Cox model was developed, age <35 years (HR 2.07 [1.18 ; 3.65] (p=0.01)), obesity (HR 1.80 [1.05 ; 3.06] (p=0.03)) and disease duration <25 years (HR 2.31 [1.16 ; 4.60] (p=0.02)) seem to be negative predictors of drug survival.

The safety profile was in line with data from clinical trials. No new or unexpected safety signals were reported.

Conclusion:

The LOGIC study presents a cohort of patients with a high rate of persistence over 5 years for SEC despite a late initation of the treatment during the course of the disease. In this experience, drug survival of SEC is higher than some recent real-life studies. These findings are likely affected by the high rate of patients naive to biologic therapy (77.0%). Drug survival rates were numerically lower for biologic-experienced than biologic-naïve patients. The age, the disease duration and the obesity were found to modify the drug survival. These findings remind on the possibility of on-label dosing optimization for patients >90 kgs and the need of educational tool to increase treatment adherence. The study presents the first long-term data of a Frencch cohort of patients initiating SEC as first-line biologics, as recently recommended by the 2022 French Expert Consensus.

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Abstract N°: 5934

Generalized pustular psoriasis - a new IL36RN mutation

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Introduction & Objectives:

Generalized pustular psoriasis is a rare form of psoriasis. Subpopulations of patients with mutations in a specific gene, IL36RN, which encodes for the IL-36 receptor antagonist, have been described in the literature. We describe a case in which a new mutation was identified.

Materials & Methods:

Retrospective review of medical records from a patient diagnosed with pustular psoriasis.

Results:

We describe the case of a 26-year-old woman with no significant medical history, who was regularly taking oral contraceptives. She was referred to our service due to episodic pustular lesions, occasionally pruritic, with a 10-year history. On physical examination, she presented with erythematous and scaly patches with pustules predominantly distributed at the periphery of the lesions. These lesions were grossly symmetrical and were located in the axillary region, inner aspects of the arms, abdomen, thighs, and inguinal region. Complementary studies revealed elevated inflammatory markers, while microbiological examination of the pustules and a basic immunological study were negative. A skin biopsy was performed, which showed findings consistent with a diagnosis of psoriasis. Direct immunofluorescence testing was negative. The patient initiated treatment with cyclosporine and later with methotrexate, but was refractory to both treatments. A genetic study targeting the IL36RN gene was conducted, identifying a heterozygous mutation (c.333C>T). Subsequently, the patient was proposed for treatment with adalimumab, which has shown a good response thus far.

Conclusion:

Deficiency of the IL-36 receptor antagonist (DITRA) should be considered when generalized pustular psoriasis occurs in pediatric patients, along with evidence of systemic inflammation, as described in this case. The mutation found in this case has a very low frequency in the population and, to our knowledge, has not been reported in the literature in patients with pustular psoriasis. Therefore, we emphasize the need for a high degree of clinical suspicion in such cases, as well as, as advised by some authors, the performance of targeted genetic studies in cases of early onset pustular psoriasis.

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Abstract N°: 5937

Successful treatment of some characteristic on psoriatic mouse model with adipose-derived stem cells transplantation

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Introduction & Objectives:

Adipose tissue is an important source of MSCs due to their abundance, availability and accessibility, when compared to other sources of MSCs. Adipose-derived stem cell (ADSCs) have been applied in treating some immune diseases because of its immunomodulatory properties. Therefore, we conducted the study to evaluate the effectiveness of treatment for psoriatic mouse model by allogeneic adipose-derived mesenchymal stem cells transplantation

Materials & Methods:

Experimental study on three groups of BALC/b mice. Each group had 5 mice. IMQ cream (5%) was used to induce psoriasis-like skin inflammation in mice. From 1st day, mice received a consecutive daily topical dose of 62.5 mg IMQ cream 5% (3.125 mg of the active compound) on the shaved back skin for 6 days. Mouse ADSCs (mADSCs) with a dose of 2.5x106 cells/mouse or PBS as a vehicle control were injected subcutaneously on 3rd day. On the 6th day, clinical symtoms and modified Psoriasis severity and activity index (PASI) for mouse were assessed, tissue samples were collected, and H&E staining and real-time PCR were performed.

Results:

On 6th day, psoriatic lesions of control group were diagnosed by an erythematous papulosquamous lesions with silver scales on the surface and the score of severity of 10.2±0.84. In histological section, they also showed the characteristic changes associated with psoriasis skin lesions, such as inflammatory infiltration, parakeratosis, hyperkeratosis with elongation of the rete ridges and dilated blood vessels compared with the normal group . However, the ADSC-treated group exhibited a milder form of the disease in comparison to the control group, with decreased scale, redness, and skin thickness. The severity score of the ADSC-treated group significant lower than the control group (5 vs 10.2±0.84, p <0.001). In histological analysis, the IMQ-induced epidermal thickness was significantly decreased by mADSC treatment. Additionally, the ADSC-treated group showed less infiltration of inflammatory cells in the dermis and less sign of epidermal hyperkeratosis with elongation of the rete ridge. The expression of proinflammatory cytokines such as IL-17A, and IL-23 in the skin was also inhibited by ADSC injection**.**

Conclusion:

Transplantation of mADSCs have therapeutic potential for the treatment of psoriasis-like skin inflammation on mouse model.

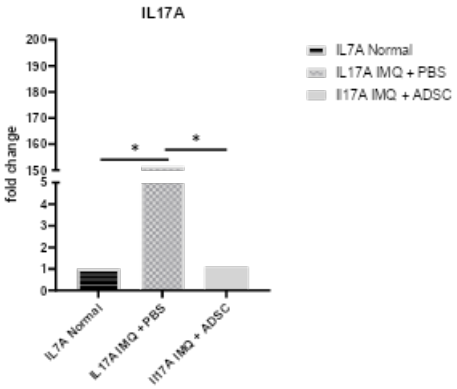
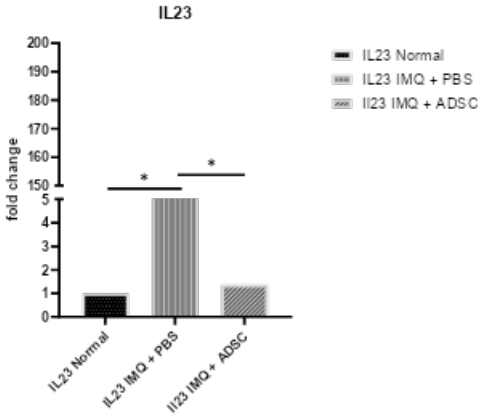


Figure: Effect of mADSCs on the skin cytokine IL17A and Il23



Total RNA was isolated from mouse back skin in each group and quantitive real-time PCR was performed. Statistical significance is displayed for all the sample. *p<0.05

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Abstract N°: 5940

Incidence of PsA among patients receiving secukinumab treatment for psoriasis: real-world progression of psoriatic disease, the LOGIC study

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Introduction & Objectives:

Psoriasis (PsO) is a chronic systemic disease closely related to Psoriatic arthritis (PsA): about 30% of patients with PsO will eventually develop a PsA. On average, 10 years separate the onset of the two diseases.** Secukinumab (SEC) is an approved biological therapy for moderate-to-severe plaque PsO and PsA. There is increasing evidence on the protective effects of biologics on PsA incidence in retrospective cohort of PsO patients but specific data on SEC effect are missing. In this study, we analysed the progression of psoriatic disease in patients initiating SEC in real-life setting.

Materials & Methods:

The LOGIC study is a non-interventional, retrospective, French, multicentre study, conducted using historical data. The aim of the study is to describe a cohort of patients with PsO who initiated SEC treatment, and to assess the incidence of new PsA cases, during a follow-up period that could exceed 5 years. The study enrolled 422 moderate-to-severe plaque PsO patients in 3 centers in France (from May 2022 to October 2022). Incidence rates were calculated as number of onset events (PsA) per 100 patient-years with associated 95% CIs. A survival analysis for PsA onset was evaluated using Kaplan–Meier methodology.

Results:

The included patients presented a long disease duration (17.1 years), with 62.7% of patients with a disease history >10 years at SEC initiation. Baseline characteristics of patients found known risk factors for the development of PsA: 18.8% of patients had a BMI ≥30 and 16.4% had a family history of PsO or PsA. The disease was moderate to severe at baseline with IGA score of 3 (63.7%) and 4 (31.0%). The proportion of scalp or nail involvement, and inverse PSO were 34.1%, 13.6% and 14.6% respectively. 23.0% of the patients were bio-experienced. The mean follow-up period was of 2.9 years (8.0 months – 7.0 years).

In total, 11 cases of PsA were reported (2.6%) with symptoms of joint swelling and pain (81.8%) reported. Total incidence rates (per 100 patient-years) of new PsA onset over 5 years are 0.72 [0.64 ; 0.80], 0.96 [0.90 ; 1.04], 0.88 [0.82 ; 0.94], 0.88 [0.82 ; 0.94] and 1.01 [0.95 ; 1.07]. Kaplan-Meier analysis showed that PsA apparition rate at 3 years was 2.5% [1.2 ; 5.2]. Secukinumab treatment was maintained after PsA onset for 7 patients and mainly with an adequate control of the symptoms without treatment combination.

Baseline characteristics of the 11 patients who develop PsA were similar to the entire cohort, with more patients obese (nearly half of the patients with BMI ≥30), with inverse psoriasis (27.3%) and with a family history of PSO or PsA (27.3%).

Conclusion :

The LOGIC study presents a multicenter cohort of patients with a long history of PsO (17.1 years) at time of SEC initiation, with a follow-up period up of 5 years.

Despite the presence of risk factors among the cohort (severity and topography of psoriasis), the incidence rate of PsA among PsO patients with newly initiated SEC in a real-world setting seems to be low (1.01 per 100 patient-year after 5 years of follow-up). There is a trend towards obesity and family history of PsO and PsA in patients who developed PsA.

SEC patients seem to take longer to develop PsA according to the low rates of reported new onset PsA.

The study provides insights into the interception of the natural course of the psoriatic disease and suggests that targeting IL17 pathway may be protective against the development of PsA. Nevertheless, more studies are needed ideally to conclude on this topic.

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Abstract N°: 5990

Long-Term Safety of Risankizumab in Patients With Psoriatic Disease: Integrated Analysis of Psoriasis and Psoriatic Arthritis Clinical Trial Data

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Introduction & Objectives: Risankizumab, an interleukin-23 inhibitor, was efficacious and well tolerated in plaque psoriasis (PsO) and psoriatic arthritis (PsA) clinical trials. The objective of this integrated data analysis of multiple PsO and PsA clinical trials was to report long-term safety of risankizumab in patients with psoriatic disease.

Materials & Methods: Integrated risankizumab safety data sets (data cutoff March 25, 2023) were compiled from 20 phase 1–4 clinical trials in PsO and 4 phase 2–3 trials in PsA. Treatment-emergent adverse events (AEs) and AEs of safety interest were reported for patients receiving ≥1 dose of risankizumab. Exposure adjusted event rates are presented as events per 100 patient years (E/100 PY).

Results: Among 3658 patients with PsO (13, 329.3 PY exposure), median (range) of treatment duration was 4.1 years (81 days–8.8 years); among 1542 patients with PsA (3803.0 PY exposure), median (range) treatment duration was 2.8 years (84 days–4.0 years).*** Rates of treatment-emergent AEs (145.5 events [E]/100PY), serious AEs (7.4 E/100PY), and AEs leading to discontinuation (1.9 E/100PY) in patients with PsO were similar to those in patients with PsA (142.6 E/100PY, 8.6 E/100PY, and 1.8 E/100PY, respectively; **Table**). Similar rates of infections (46.2 and 41.3 E/100 PY) and serious infections (1.2 and 2.0 E/100PY) were reported among PsO and PsA groups, respectively. Nasopharyngitis (12.1 E/100PY), upper respiratory infection (6.4 E/100PY) and COVID-19 (3.2 E/100PY) were the most common infections in PsO and COVID-19 (8.0 E/100PY), nasopharyngitis (5.7 E/100PY) and upper respiratory infection (4.1 E/100PY) were the most common infections in PsA. The most common serious infections were sepsis, COVID-19, and pneumonia in PsO (0.1, <0.1, and <0.1 E/100PY, respectively) and COVID-19 pneumonia, COVID-19, and pneumonia in PsA (0.3, 0.2, and 0.2 E/100PY, respectively). Rates of opportunistic infections excluding tuberculosis and herpes zoster (both <0.1 E/100PY) and herpes zoster (0.5 and 0.3 E/100 PY, respectively) were comparable in PsO and PsA. Rates of non-melanoma skin cancer (NMSC) were 0.6 and 0.5 E/100PY and malignant tumors excluding NMSC were 0.6 and 0.5 E/100PY in PsO and PsA, respectively.

Conclusion: Rates of AEs, AEs of safety interest, and AEs leading to discontinuation remained low in this largest and longest safety reporting for risankizumab in patients with psoriatic disease to date. Rates of AEs of safety interest were within reported benchmarks for both PsO and PsA. Rates of COVID-19 infection were as expected. Overall, these results support the safety profile of risankizumab for the long-term treatment of patients with psoriatic disease.

Table. Treatment-Emergent AEs in Patients with Psoriasis and Psoriatic Arthritis

	PsO (n=3658, 13,329.3 PY) E (E/100PY) [95% CI]	PsA (n=1542, 3803.0 PY) E (E/100PY) [95% CI]
AEs	19,390 (145.5) [143.4–147.5]	5423 (142.6) [138.8–146.4]
Serious AEs	986 (7.4) [6.9–7.9]	327 (8.6) [7.7–9.6]
AEs leading to discontinuation	250 (1.9) [1.7–2.1]	68 (1.8) [1.4–2.3]
Infections	6157 (46.2)	1570 (41.3)
Nasopharyngitis	1619 (12.1)	217 (5.7)
URTI	853 (6.4)	156 (4.1)
COVID-19	426 (3.2)	306 (8.0)
Herpes zoster	70 (0.5) [0.4–0.7]	12 (0.3) [0.2–0.6]
Serious infections	165 (1.2) [1.1–1.4]	75 (2.0) [1.6–2.5]
Sepsis	15 (0.1)	3 (<0.1)
COVID-19[a]	13 (<0.1)	8 (0.2)
Pneumonia	13 (<0.1)	7 (0.2)
COVID-19 pneumonia	7 (<0.1)	12 (0.3)
Opportunistic infection[b]	11 (<0.1) [0.0–0.2]	3 (<0.1) [0.0–0.2]
Active tuberculosis	1 (<0.1) [0.0–0.04]	0
Fungal infections	319 (2.4) [2.1–2.7]	61 (1.6) [1.2–2.1]
Tinea infections	186 (1.4)	11 (0.3)
Candida	69 (0.5) [0.4–0.7]	17 (0.4) [0.3–0.7]
Malignant tumors	161 (1.2) [1.0–1.4]	39 (1.0) [0.7–1.4]
NMSC	76 (0.6) [0.5–0.7]	19 (0.5) [0.3–0.8]
Malignant tumors excluding NMSC	85 (0.6) [0.5–0.8]	20 (0.5) [0.3–0.8]
Gastrointestinal cancers[c]	23 (0.2) [0.1–0.3]	2 (<0.1) [0.0–0.2]
Breast cancer	13 (<0.1) [0.1–0.2]	3 (<0.1) [0.0–0.2]
Prostate cancer	12 (<0.1) [0.1–0.2]	5 (0.1) [0.0–0.3]
Melanoma	8 (<0.1) [0.0–0.1]	2 (<0.1) [0.0–0.2]
Serious hypersensitivity[d]	10 (<0.1) [0.0–0.1]	3 (<0.1) [0.0–0.2]
Injection site reaction	373 (2.8) [2.5–3.1]	35 (0.9) [0.6–1.3]

AE, adverse event; E, event; NMSC, non-melanoma skin cancer; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient-years; URTI, upper respiratory tract infection.

[a]Clinical trial data for patients with psoriasis mostly pre-dated the onset of the COVID-19 pandemic.

[b]Excluding tuberculosis and herpes zoster.

[c]Events for PsO: pancreatic carcinoma (n=5), adenocarcinoma of colon (n=3), colorectal adenocarcinoma (n=2), colorectal cancer (n=2), gastric cancer (n=2), rectal cancer (n=2), anal cancer (n=1), colon cancer metastatic (n=1), colon cancer stage 0 (n=1), intestinal adenocarcinoma (n=1), esophageal carcinoma (n=1), pancreatic carcinoma stage IV (n=1), and rectal adenocarcinoma (n=1); events for PsA: adenocarcinoma of colon (n=1) and colorectal cancer (n=1).

[d]Events for PsO: eczema (n=2), Steven-Johnson syndrome (n=2), urticaria (n=2), angioedema (n=1), drug hypersensitivity (n=1), erythema multiforme (n=1), and hypersensitivity (n=1); events for PsA: anaphylactic reaction (n=1), hypersensitivity (n=1), and immune thrombocytopenia (n=1).

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Abstract N°: 5996

Bridging the gap in psoriasis care: the development and implementation of a nurse-led intervention through Experience-based Co-design to improve shared-decision making

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Introduction & Objectives:

Psoriasis can have a profound impact on a person's life, resulting in physical discomfort, psychological distress, and social stigma that significantly restrict daily activities and diminish quality of life. Therefore, it is essential to prioritize comprehensive management and ensure access to a wide range of treatment options. The availability of information about and access to all treatment options is of utmost importance.

Experience-Based Co-Design (EBCD) emerges as a highly encouraging approach to bridge the gap between the necessary and current care. This collaborative approach involves conducting interviews and observations to gather insights into the needs and perspectives of patients and healthcare professionals (HCP). Subsequently, these valuable insights guide the design process, enabling patients and HCP to collaborate on developing improvements and solutions that ultimately lead to enhanced outcomes. Given the limitations in healthcare resources, nurse specialists can play a vital role in facilitating these improvements. The aim of this study is to investigate the impact of an intervention in psoriasis care designed with the EBCD approach.

Materials & Methods:

In two EBCD sessions 5 patients and 4 HCP watched a 30-minute montage of 18 in-depth interviews, had a brainstorm session and discussed the properties of the intervention needed to support the unmet needs in current care. From the interviews, 'shared decision-making' (SDM) was identified as one of the most significant themes related to unmet needs in current care. A nurse-led SDM intervention was incorporated into the existing specialized consultation program named PsoPlus for first time patient visits. Intervention patients received a comprehensive appraisal of all treatment options, including an exploration of their preferences utilizing the decision aid proposed by van der Kraaij et al. Control patients received a regular PsoPlus consultation, approaching the patient in an integrated and holistic matter by a specialized nurse without extra attention for SDM.

Results:

76 patients were enrolled in the study to investigate the impact of the treatment decision tool. There is no significant difference between the intervention group and the control group. However, there is a significant increase in the degree of shared decision-making after the patients' consultation with PsoPlus, compared to the consultation they received elsewhere before PsoPlus. At the follow-up visit after three months the satisfaction with the treatment in the intervention group was significantly higher compared to before the first consultation, while there is no significant increase in the control group.

Conclusion:

This study presents the first example of EBCD in dermatology. The impact of the decision instrument, applied by a nurse specialist, on the degree of shared decision-making does not differ significantly from that of a standard PsoPlus consultation. It was the PsoPlus approach itself that increased the degree of SDM.

Further research is needed to identify the elements that influence the degree of SDM. The involvement of specialized nurses could enhance SDM, while alleviating the burden on dermatologists.

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Abstract N°: 6082

Short-term Effectiveness and Safety of Bimekizumab in Psoriatic Disease: a Real World Retrospective Single-Centered Study

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Introduction & Objectives:

Psoriasis and psoriatic arthritis (PsA) are chronic immune-mediated disorders with the involvement of interleukin (IL)-17 cytokines in their pathogenesis. IL-17A has been the most biologically active, but IL-17F is also over-expressed in the skin and synovial tissues of patients with these diseases. Bimekizumab, a dual inhibitor and humanized bispecific immunoglobulin G1 (IgG1) monoclonal antibody (mAb) simultaneously targeting IL-17A and IL-17F, could provide better disease control. Phase I/II/III clinical trials of Bimekizumab have demonstrated its efficacy and safety in psoriasis and PsA but real-world data are still lacking. Bimekizumab has been available for use in Greece since the 13th of February 2023.

Materials & Methods:

A single-center retrospective study was performed to analyze the short-term effectiveness and safety of IL-17A/F inhibitor bimekizumab, in 15 patients with psoriasis and/or active PsA.

Primary endpoints were, firstly, to evaluate the mean absolute Psoriasis Area and Severity Index (PASI) and Disease Activity Index for PsA (DAPSA) at baseline and up to 8 weeks of treatment.

Secondary endpoints were the assessment of the Dermatology Life Quality Index (DLQI) as well as the proportion of patients achieving absolute PASI ≤ 1 and PASI 75/90/100 at weeks 4 and 8. Short-term safety data of bimekizumab for up to 10 weeks were also recorded.

Other objectives were to describe patient profiles managed with bimekizumab in the real-world setting concerning demographics, disease subtype and severity, and previous treatment regimen. All analyses were conducted using the as-observed data.

Results:

Patients' characteristics were recorded. A statistically significant reduction of absolute mean PASI (7,92 [n=15] and 8,06 [n=6]), DAPSA (16,31 [n=8] and 21,65 [n=2]), and DLQI (9,5 [n=15] and 8 [n=6]) as soon as week 4 and 8 of treatment with bimekizumab, accordingly. PASI ≤ 1 and PASI 75/90/100 at weeks 4 and 8 were achieved by 13/7/11/15 out of 15 patients and 6/5/6/6 out of 6 patients at weeks 4 and 8, accordingly. Previous exposure to biological treatment, gender, obesity, or comorbidities did not affect treatment outcome. No major safety signals were documented during the study.

Conclusion:

The present study from real-world conditions confirms the short-term clinical efficacy and safety of bimekizumab in psoriasis (including hard-to-treat skin regions) and PsA reported from large-scale clinical trials. Moreover, the rapid improvements in signs and symptoms of both psoriasis and PsA were observed as early as Week 4. However, larger, and longer prospective, population-based, and retrospective studies need to be conducted to determine the safety profiles and clinical characteristics affecting treatment response in the real world.

Bimekizumab was well tolerated; the safety profile was consistent with prior studies with no unexpected safety findings.

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Abstract N°: 6085

Correlations between oxidative stress and inflammation in an Eastern European population of patients with psoriasis

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Introduction & Objectives:

Oxidative stress occurs as a result of the imbalance between free radicals and the body's antioxidant systems. This balance is the basis of the initiation and perpetuation of numerous chronic diseases, including psoriasis, an erythemato-squamous dermatosis frequently encountered in countries with an increased socio-economic level.

Materials & Methods:

The present study aims to evaluate the level of oxidative stress, the total antioxidant capacity and the chronic inflammatory status in patients with psoriasis admitted to the dermatology clinic of a tertiary centre in Romania. The study is carried out in accordance with the ethical standards of the Declaration of Helsinki from 1975. All patients signed consent forms expressing their agreement to participate in the study, provided confidentiality is respected. The inclusion criteria were represented by: age over 18 years old, newly diagnosed psoriasis or which has not undergone topical or systemic treatment in the last 3 months. The exclusion criteria are represented by: patients under 18 years old and the presence of chronic conditions that significantly increase oxidative stress. The evaluation of the parameters is carried out at the first presentation through spectrophotometric determinations from capillary blood for FORT (Free radical oxygen test) and FORD (Free oxygen radical defence) using the Callegari CR3000 spectrophotometer, respectively from venous blood for the other parameters (complete blood count, ESR (erythrocytes sedimentation rate), C reactive protein, fibrinogen etc).

Results:

The results of the first stage of the study include 27 patients with psoriasis (mean age = 45.74±15.82, 41% men. The average duration of the disease is 9.89±10.27 years with a mean PASI of 13,96±12,32. After evaluating the level of FORD and FORT, the following values were found: FORT=342.59±133.72 (normal value<310 units), FORD=0.44±0.25 (normal value>1.25 units). Moreover, the presence of statistically significant correlations between white blood cells-FORT ($r=-0.673$, $p<0.001$), systemic inflammatory index-FORT ($r=-0.68$, $p<0.001$), ESR-FORT ($r=-0.889$, $p<0.001$), fibrinogen-FORT ($r=-0.881$, $p<0.001$) and PASI-FORT ($r=-0.43$, $p=0.00087$) were found.

Conclusion:

Psoriasis is a disease in which oxidative stress remains an important factor in its pathogenesis, being characterized by an increased level of free radicals and a low antioxidant capacity in the stages prior to treatment. Moreover, oxidative stress correlates not only with the clinical extension of the disease (PASI), but also with subclinical inflammation, potentially representing an important marker for assessing the risk of developing other chronic diseases associated with psoriasis (metabolic syndrome, hypertension, atherosclerosis, ischemic heart disease, etc.). The present study wants to follow not only the presence of these correlations, but also the changes associated with the presence of a systemic treatment.

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Abstract N°: 6120

Rapid response to initial doses of ustekinumab in severe psoriasis: Case report

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Rapid response to initial doses of ustekinumab in severe psoriasis: Case report

Introduction & Objectives:

Psoriasis is a common inflammatory chronic condition that affects 2-3% of the world population, affecting all age ranges, specifically between 20 to 30 years and 50 to 60 years. The most common presentation is psoriasis vulgaris in 90% of affected patients, characterized by multiple large scaling plaques with a predilection for elbows, knees, sacral gluteal region, scalp, palms and soles. The immunopathological origin of psoriasis brought new treatments and targets directed to abnormal immunologic responses, including interleukin 12 and 23 as important desenvolving factors in the physiopathology of this disease. Ustekinumab is an Ig monoclonal antibody that targets the p40 protein subunit of interleukin 12 and 23, indicated in adult and adolescent patients with moderate to severe psoriasis. In published clinical trials the maximum efficacy of the biologic was evaluated between the twentieth and twenty-fourth week of use. We present a severe psoriasis vulgaris case being treated with ustekinumab.

Our objective is to report a severe case of psoriasis vulgaris refractory to classical treatment, with and effective response and rapid improvement of clinical manifestations after initial doses of ustekinumab.

Materials & Methods:

A comprehensive review of the literature was carried out for this case.

Results:

34-year-old male patient presenting a history of psoriasis vulgaris for over 8 years, refractory to topical treatment with corticosteroids and systemic treatment with methotrexate and acitretin, with impaired liver function and worsening of lesions. Dermatological exam showed well-defined scaly erythematous plaques on the trunk, scalp and cervical regions; erythematous annular plaques, slightly scaly on the lower limbs and erythematous plaques without scaling in the armpits and groin, with PASI 11, DLQI 22 in the first evaluation. The case was characterized as severe psoriasis. Treatment with subcutaneous ustekinumab 45 mg was initiated, following the guidelines of patients weighing less than 100 kg, assessment of complementary exams was required. Following the therapeutic scheme, after 4 weeks, the second application of the immunobiological was calculated with PASI 7, DLQI 20 during the third dose in the clinical evaluation with significant improvement of the initial lesions with a 1.8 PASI score and a DLQI score of 8.

Patient showed a quick and effective response to treatment with 3 doses of ustekinumab, with clinical resolution and an improved quality of life.

Conclusion:

Treatments with biological drugs have transformed the management of moderate to severe psoriasis. Ustekinumab, a biological agent with a selective target of the inhibition of interleukins 12 and 23, is the most

indicated agent in the specific conditions of the patient. In the staging of moderate to severe psoriasis, it is necessary to achieve adequate control of the disease in the long term, aiming to improve the clinical manifestations and emotional conditions that affect patients affected by this disease, with the continuous maintenance of safe and effective treatments available to the population. Ustekinumab, showed its effectiveness by the PASI75 response and improved quality of life by the DLQI score with a follow-up of 12 to 24 weeks, according to the PHOENIX 1 and 2 pivotal studies, and other randomized and controlled studies used for its approval in moderately severe psoriasis.

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Abstract N°: 6151

Are interleukin 17 and interleukin 23 inhibitors associated with malignancies? – Insights from an international population-based study

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Introduction & Objectives:

Cancer risk after long-term exposure to interleukin (IL)-23 inhibitors (IL-23i) and IL-17 inhibitors (IL-17i) remains to be delineated. Our object is to evaluate the risk of malignancies in patients with psoriasis treated with IL-23i and IL-17i relative to those prescribed tumor necrosis factor inhibitors (TNFi) during the first 5 years following drug initiation.

Materials & Methods:

A global population-based cohort study included two distinct analyses comparing patients with psoriasis under different therapeutic modalities; (i) new users of IL-17i(n=15,331) versus TNFi(n=15,331) and (ii) new users of IL-23i(n=5,832) versus TNFi(n=5,832).

Results:

Patients prescribed IL-17i experienced a decreased risk of non-Hodgkin lymphoma (NHL; HR, 0.58; 95% CI, 0.40-0.82; P=0.002), colorectal cancer (HR, 0.68; 95% CI, 0.49-0.95; P=0.024), hepatobiliary cancer (HR, 0.68; 95% CI, 0.58-0.80; P<0.001), ovary cancer (HR, 0.48; 95% CI, 0.29-0.81; P=0.005), melanoma (HR, 0.52; 95% CI, 0.37-0.73; P<0.001), and basal cell carcinoma (BCC; HR, 0.57; 95% CI, 0.48-0.67; P<0.001). IL-23i was associated with a reduced risk of NHL (HR, 0.39; 95% CI, 0.19-0.78; P=0.006), hepatobiliary cancer (HR, 0.44; 95% CI, 0.31-0.62; P<0.001) and BCC (HR, 0.76; 95% CI, 0.57-0.99; P=0.046). In a sensitivity analysis comparing patients managed by IL-17i and IL-23i with their biologic-naïve counterparts, these classes were associated with decreased risk of several malignancies.

Conclusion:

IL-17i and IL-23i are associated with decreased risk of several malignancies. These findings should be considered prior to the prescription of biologics.

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Abstract N°: 6175

Elevated Serum Aldosterone Levels in Patients with Psoriasis and Systemic Arterial Hypertension.

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Introduction & Objectives:

Epidemiological studies suggest a higher prevalence of systemic arterial hypertension (HTN) and other cardiovascular diseases in patients with psoriasis. The mechanism of this association is not fully understood, but may involve activation of the renin-angiotensin-aldosterone system (RAAS). This study aimed** to compare plasma renin and serum aldosterone between psoriasis patients and non-psoriasis individuals.

Materials & Methods:

Prospective, cross-sectional study carried out with consecutive patients from the dermatology outpatient clinic of a university hospital. After clinical evaluation, blood samples were drawn to measure plasma renin and serum aldosterone; these levels were compared between patients with and without psoriasis. Stratified analyses were carried out in patients with and without HTN. One-way ANOVA was performed, followed by Bonferroni's post-hoc test for multiple comparisons. Finally, a multiple linear regression analysis was performed to detect independent predictors of higher renin and aldosterone levels.

Results:

We evaluated 170 patients with a mean age of 55 ± 13 years, 50.6% men, 85.9% non-white, 57.6% with psoriasis and 44.1% with HTN. Mean serum renin levels were similar in patients with and without psoriasis (26.3 ± 51.4 versus 23.9 ± 48.7 uIU/ml, respectively, p = 0.764). However, mean serum aldosterone levels were significantly higher in patients with psoriasis (25.3 ± 49.4 versus 11.7 ± 10.7 ng/dl, p = 0.009). When we stratified the patients into four subgroups: 1) psoriasis plus HTN, 2) psoriasis only, 3) HTN only and 4) neither psoriasis nor HTN, it became evident that only patients with psoriasis plus HTN had significantly higher serum aldosterone levels than the patients of the other subgroups. A linear regression analysis demonstrated a statistically significant interaction between HTN and psoriasis on aldosterone levels. In multivariate linear regression analysis including hypertensive subjects, the presence of psoriasis was independently associated with higher aldosterone levels, even after adjustment for use of RAAS blockers. In individuals without HTN, the presence of psoriasis was not associated with higher levels of aldosterone.

Conclusion:

Our findings support the association between psoriasis and serum aldosterone levels, particularly when combined with HTN. These results contribute to our understanding of the pathophysiology mechanisms underlying psoriasis and its potential implications for the RAAS. Further research is warranted to explore the clinical implications of these findings and to identify potential therapeutic targets in the management of psoriasis-related comorbidities, particularly HTN.

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Abstract N°: 6415

When dermocopy elucidates recalcitrant psoriasis

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When dermocopy elucidates recalcitrant psoriasis

Introduction & Objectives:

Psoriasis is a chronic inflammatory dermatosis affecting the skin, appendages, mucosa and joints. Diagnosis is clinical, manifested by erythematosquamous plaques. It evolves by flare-ups and remissions, and usually responds favorably to well-adapted treatment. The association of psoriasis and leishmaniasis remains rare. Leishmaniasis is an infectious disease caused by the parasitization of cells of the mononuclear phagocyte system by flagellate protozoa of the genus Leishmania. It is characterized by great clinical polymorphism and occurs in epidemic form.

Materials & Methods:

We report the case of a child with treatment-resistant psoriasis superinfected by cutaneous leishmaniasis. The patient was examined by dermoscopy. The diagnosis was confirmed by smear

Results:

This is a 9-year-old patient with no notable pathological history, treated for plaque psoriasis on dermocorticoids, who had been presenting with erythematous, scaly lesions on the lower limbs for a year, progressively increasing in size with no tendency to heal. Dermatological examination revealed a well-limited, scaly, crusty erythematous plaque with clean margins measuring 4 cm in diameter, located on the legs and forearms.

Dermoscopy revealed a tear-like, starburst pattern, with linear, hairpin and stippled vascularization. Given this dermoscopic appearance, superinfection of psoriasis plaques by leishmaniasis was suspected. A skin smear revealed leishmanial bodies. The patient was treated with meglumine antimonate (Glucantime®) for 21 days. This was followed by dermocorticoids with good improvement.

Conclusion:

When psoriasis is resistant to well-administered treatment, dermoscopic examination may reveal specific signs of superinfection of cutaneous leishmaniasis, enabling treatment to be adapted.

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Abstract N°: 6532

Drug survival of interleukin-23 p19 inhibitors compared to other biologics for psoriasis: a cohort study from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR)

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Introduction & Objectives: Risankizumab, an interleukin (IL)-23 p19 inhibitor, has high efficacy and a good safety profile for psoriasis from randomised controlled trial evidence, but little is known about its effectiveness and safety when used in routine clinical settings. Our group have previously reported on the real-world outcomes of the IL-23p19 inhibitor guselkumab. Drug survival is a proxy for treatment effectiveness and safety. Our aim was to assess the drug survival of guselkumab and risankizumab compared with other biologics for psoriasis.

Materials & Methods: We conducted a cohort study using BADBIR, a national pharmacovigilance registry of UK and Republic of Ireland psoriasis patients, with data collected between November 2007 and June 2023. We conducted survival analysis and fitted separate multivariable, flexible parametric models for drug survival measuring discontinuation due to ineffectiveness or adverse effects for the exposures of adalimumab (tumour necrosis factor inhibitor), brodalumab, ixekizumab, secukinumab (IL-17 inhibitors), guselkumab, and risankizumab compared with ustekinumab (IL12/23p40 inhibitor), accounting for missing baseline data using multiple imputation. Each treatment course was considered separately. We report the 1-year drug survival for effectiveness and safety and the hazard ratios from the model.

Results: A total of 19,034 treatment courses from 11,877 participants were included with a median follow-up of 2.3 years (interquartile range 0.9-4.4) with 6,815 adalimumab, 5,639 ustekinumab, 367 brodalumab, 1,072 ixekizumab, 3,051 secukinumab, 1,258 guselkumab, and 832 risankizumab exposures. The unadjusted survival functions at year 1 for effectiveness were adalimumab 0.80 (95% confidence interval 0.79-0.81), ustekinumab 0.88 (0.87-0.89), brodalumab 0.80 (0.75-0.84), ixekizumab 0.88 (0.86-0.90), secukinumab 0.85 (0.84-0.86), guselkumab 0.94 (0.93-0.95), and risankizumab 0.95 (0.93-0.96). Treatment with the IL-23p19 inhibitors had the highest survival (guselkumab, adjusted hazard ratio[aHR], 0.28 [0.15-0.53]; risankizumab 0.38 [0.16-0.87]) whereas adalimumab (1.98 [1.76-2.23]) had lower survival compared with ustekinumab for effectiveness. Brodalumab, ixekizumab, and secukinumab had similar drug survival earlier and lower drug survival later in follow-up compared with ustekinumab.

The unadjusted survival functions at year 1 for safety were adalimumab 0.91 (0.90-0.91), ustekinumab 0.94 (0.94-0.95), brodalumab 0.91 (0.87-0.93), ixekizumab 0.91 (0.89-0.93), secukinumab 0.93 (0.92-0.94), guselkumab 0.95 (0.94-0.97), and risankizumab 0.97 (0.96-0.98). The IL-23p19 inhibitors had higher survival due to safety than ustekinumab (guselkumab, aHR 0.66 [0.49-0.89], risankizumab 0.50 [0.27-0.91]); while secukinumab had a similar survival (1.14 [0.98-1.34]); and adalimumab (1.56 [1.39-1.75]), ixekizumab (1.44 [1.15-1.81]), and brodalumab (1.61 [1.15-2.27]) had lower survival for safety compared with ustekinumab.

Conclusion: The results of this study, which includes the largest cohort of psoriasis patients on IL-23p19 inhibitors reported thus far, showed guselkumab and risankizumab had similar drug survival and had the highest drug survival associated with both effectiveness and safety compared with other biologics in BADBIR. Our findings should be taken into consideration for people with psoriasis who value treatment effect longevity and are due to commence biologic therapy.**

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Abstract N°: 6624

Efficacy and safety of ME3183 administered orally in subjects with moderate to severe plaque psoriasis: A multicenter, randomized, double-blind, placebo-controlled, parallel group, Phase 2a study

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Introduction & Objectives:

We evaluated the efficacy and safety of ME3183, a novel oral, highly potent, selective phosphodiesterase-4 inhibitor, characterized by low blood–brain barrier transmission, in adults with moderate to severe plaque psoriasis.

Materials & Methods:

This multicenter, randomized, double-blind, placebo-controlled, parallel group study had a 4-week screening period, 16-week treatment period, and 4-week follow-up period. Patients were randomly assigned to one of four treatment groups (ME3183 5 mg twice daily [BID], 10 mg once daily [QD], 7.5 mg BID, or 15 mg QD) or placebo with stratification by previous treatment with biologics.

Results:

In total, 132 patients were randomly assigned to ME3183 (n=26, 26, 26, and 27, respectively) or placebo (n=27). Mean Psoriasis Area and Severity Index (PASI) score at baseline was 15.9–17.6 and 16.8 in the ME3183 and placebo groups, respectively. A significantly greater proportion of patients in the ME3183 5 mg BID, 7.5 mg BID, and 15 mg QD groups achieved ≥75% reduction from baseline PASI score (PASI-75) at Week 16 (primary endpoint) versus placebo (58.3%, 61.5%, and 52.0% vs 14.8%, P<0.001; 10 mg QD group: 36.0%). A greater proportion of patients in the ME3183 groups versus placebo achieved PASI-90, PASI-100, and Static Physician's Global Assessment 0/1 combined with 2-point reduction (secondary endpoints). Early PASI improvement after administration was observed in the ME3183 groups. The most frequent treatment-emergent adverse events were diarrhea, nausea, and headache. In the ME3183 5 mg BID, 10 mg QD, 7.5 mg BID, 15 mg QD and placebo groups, 2, 2, 4, 3, and 1 patients, respectively, discontinued because of adverse events. ME3183 was well tolerated. No unexpected safety signals were observed.

Conclusion:

ME3183 administered orally was effective in the treatment of plaque psoriasis and had an acceptable safety profile.

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Abstract N°: 6626

Effects of oral roflumilast therapy on body weight and cardiometabolic parameters in patients with psoriasis – findings from the PSORRO study

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Title:

Effects of oral roflumilast therapy on body weight and cardiometabolic parameters in patients with psoriasis – findings from the PSORRO study

Introduction & Objectives:

Oral roflumilast, a phosphodiesterase (PDE)-4 inhibitor approved for chronic obstructive pulmonary disease, has weight loss as a frequently reported side effect. Recently, oral roflumilast has shown efficacy in the treatment of psoriasis, a disease strongly linked to overweight/obesity. The aim was to examine the effects of oral roflumilast on body weight and cardiometabolic parameters in patients with moderate-to-severe psoriasis.

Materials & Methods:

Patients** with plaque psoriasis were randomized 1:1 to oral roflumilast 500 µg once-daily or placebo for 12 weeks, followed by active, open-label treatment through week 24 in both groups. Changes in body weight, blood pressure, gastrointestinal symptoms, and laboratory tests were registered. No lifestyle or dietary interventions were applied. Outcomes were evaluated based on intention-to-treat and tested with Fisher's exact tests (binary outcomes) and Mann-Whitney U tests (numeric variables). Missing data were handled with non-responder imputations for binary outcomes and last observation carried forward (LOCF) for numeric outcomes.

Results:

Forty-six patients were randomized. Baseline characteristics across groups were comparable. In the active treatment arm, mean body weight was 102.0 kg (BMI 33.3 kg/m2); in the placebo arm, mean body weight was 105.1 kg (BMI 32.2 kg/m2). A total of 13% and 9% of patients in the roflumilast and placebo group, respectively, had type 2 diabetes. In patients receiving roflumilast, median weight change was -2.6% and

-4% at week 12 and 24, respectively. Corresponding numbers were 0.0% and -1.3% in patients initially allocated to placebo. During the 24-week study, a total of 57%, 30%, 17%, and 13% of patients treated with roflumilast since randomization lost ≥3%, ≥5%, ≥10%, and ≥15%, respectively, of their baseline body weight. Reduced appetite was more frequent with active therapy. No changes in blood pressure or laboratory tests were observed. No patients received bariatric surgery or body weight-lowering medications before or during the trial.

Conclusion:

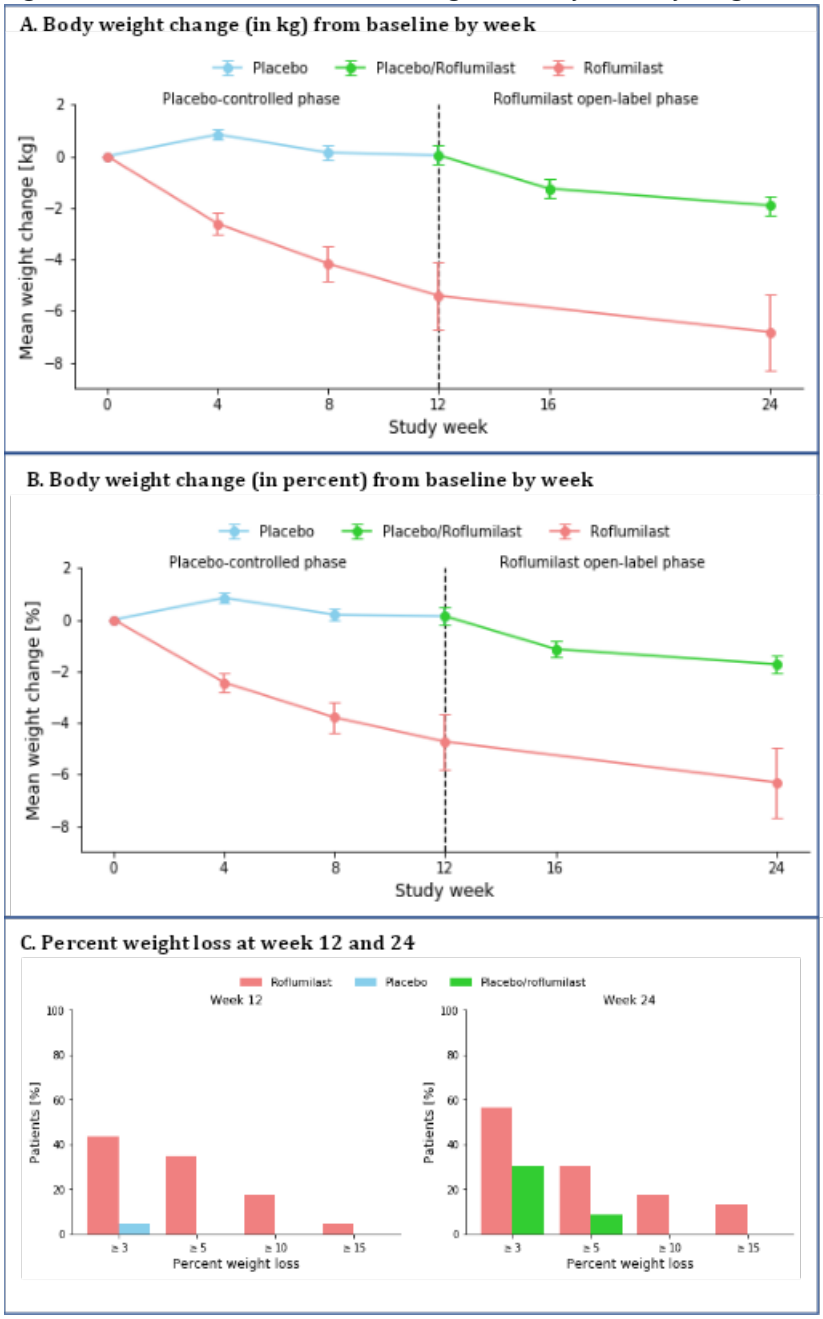
Weight loss and reduced appetite was observed after 24 weeks of oral roflumilast therapy in patients with psoriasis. With psoriasis being a chronic disease, strongly linked to overweight and obesity, the current findings support the growing evidence of roflumilast as an attractive, oral treatment alternative in, especially, overweight patients with moderate-to-severe plaque psoriasis.

B. Body weight change (in percent) from baseline by week

A. Body weight change (in kg) from baseline by week

C. Percent weight loss at week 12 and 24

Figure 1. Effect of oral roflumilast 500 µg once daily on body weight, as compared



with placebo