



CARSGEN
THERAPEUTICS

CARsgen Therapeutics

September 2022

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CARsgen Background





Developing **globally revolutionary** cell therapies to **make cancer curable**



CARsgen: A Leader in CAR T-cell Therapies

- **Shanghai, China** | HQ, research, clinical development, two GMP cell therapy manufacturing facilities
- **Research Triangle Park, North Carolina** | GMP manufacturing facility
- **Houston, Texas** | Clinical development outside China
- **Publicly traded** | HKEX: 02171



Competitive CAR T-cell Product Pipeline

- Global first-in-class CLDN18.2 CAR T (CT041) targeting solid tumors
- Fully-human BCMA CAR T (zevor-cel) with competitive efficacy and favorable safety profiles
- Both CT041 and zevor-cel have been granted RMAT by US FDA and PRIME by EMA

Integrated R&D and Manufacturing Capabilities

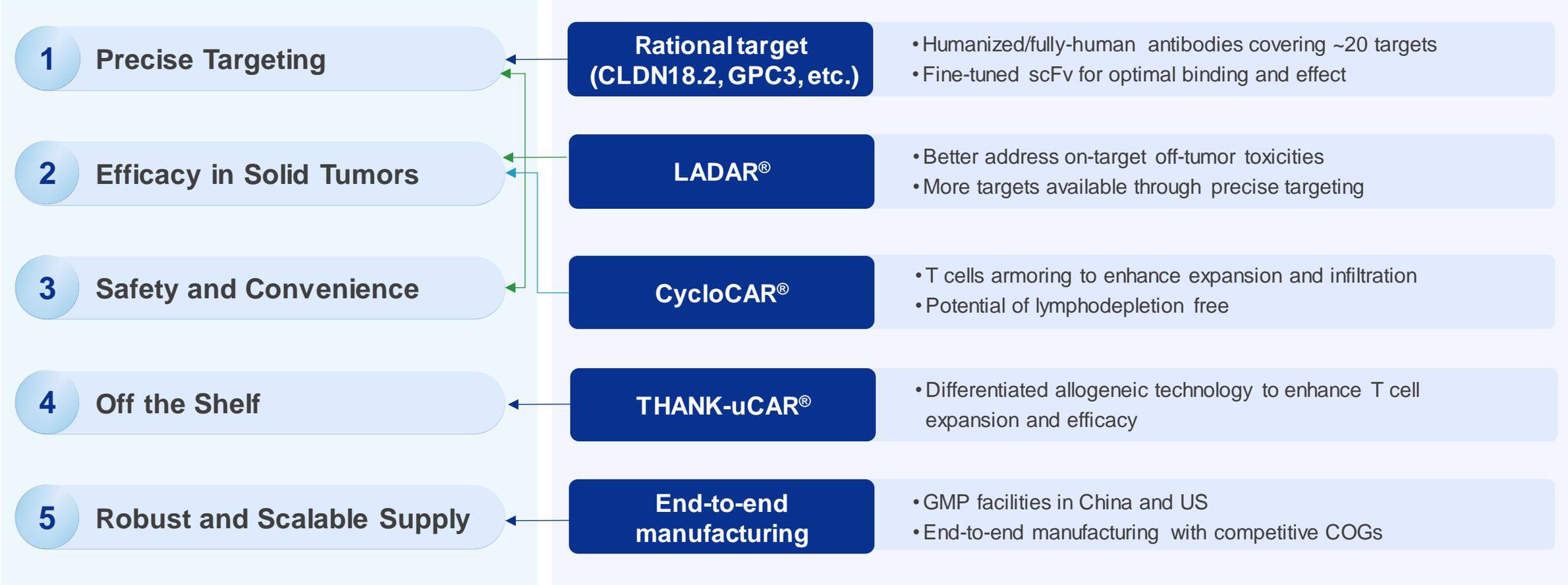
- Over 300 patents granted or under application
- Humanized / fully-human antibody platforms
- THANK-uCAR[®], a differentiated allogeneic CAR T technology
- CycloCAR[®], a next-generation CAR T technology for solid tumors
- LADAR[®], a versatile technology platform for precise targeting
- End-to-end manufacturing capabilities including production of viral vectors

CARsgen is Developing Optimal CAR T Products Now and for the Future



Key CAR T Cell Attributes

CARsgen Strategic Solutions



2

BCMA CAR T (zevor-cel)

Zevor-cel (CT053): A Fully-human BCMA CAR T for the Treatment of Relapsed/Refractory Multiple Myeloma

zevorcabtagene autoleucel (zevor-cel)

Clinical Development Status and Plan

Pivotal Phase II trial in China: **Enrollment Completed**

 China NDA submission expected in Q3 2022

Phase II trial in North America: **Ongoing**

 First patient enrolled in July 2021

Planning to initiate clinical development in 1-3 prior lines of treatment (LUMMICAR STUDY 3).

Designations

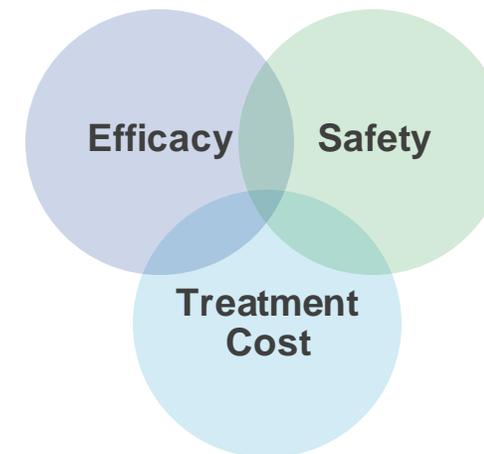
▶ **RMAT** designation from FDA

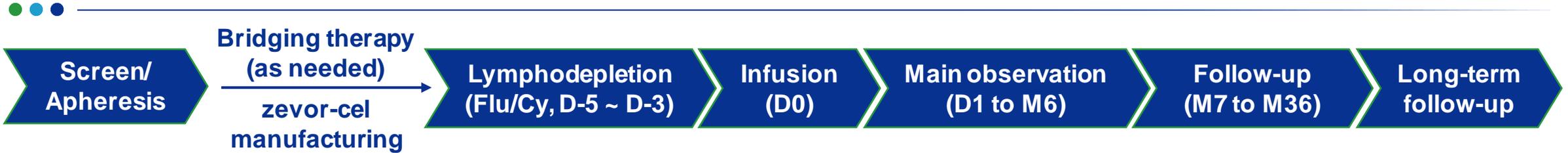
▶ **PRIME** designation from EMA

▶ **Breakthrough Therapy** designation from the NMPA

▶ **Orphan Drug** designations from EMA / FDA

Zevor-cel Competitive Advantages





Key Eligibility

Multiple Myeloma:

Phase 1b: at least 3 prior lines of therapy including anti-CD38

Phase 2: at least 4 prior lines of therapy including anti-CD38



Lymphodepletion

▶ Phase 1b

Flu: Fludarabine (25 mg/m² for 3 days)

Cy: cyclophosphamide (500 mg/m² for 2 days)

▶ Phase 2

Flu: Fludarabine (30 mg/m² for 3 days)

Cy: Cyclophosphamide (500 mg/m² for 2 days)



Study Objectives



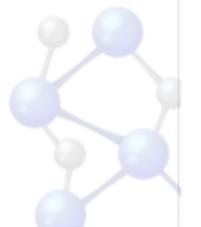
Phase 1b

- ▶ Evaluate the safety of zevor-cel and determine the recommended Phase 2 dose



Phase 2

- ▶ Determine the efficacy of zevor-cel
- ▶ Evaluate the safety of zevor-cel



Clinicaltrials.gov [NCT03915184](https://clinicaltrials.gov/ct2/show/study/NCT03915184)

LUMMICAR STUDY 2 Phase 2: Demographic and Disease Characteristics



Baseline characteristics	N=17
Median age (range), years	59 (45-74)
Female, (%)	5 (29.4%)
Extramedullary disease \geq 1 plasmacytoma, (%)	5 (29.4%)
Bone marrow plasma cells, median (range %)	27.5 (0-95%)
BCMA expression in plasma cells, median (range %)	64.3 (6.0- 96.5)
Median years since diagnosis (range)	7 (4 – 17)
High-risk cytogenetics, ¹ %	9 (52.9%)
R-ISS staging at baseline, %	
I	2 (11.7%)
II	12 (70.6%)
III	3 (17.6%)

1. Presence of t(4;14), t(14;16), del17p

2. Triple-drug exposed: PIs, IMiD, anti-CD38 agent; triple refractory: refractory to these three categories.

Prior treatment history	N= 17
Prior lines of therapy, median (range)	6 (4-17)
Triple-drug exposed, ² n (%)	17 (100%)
Treatment	N=17
Bridging therapies Response to Bridging	8/17 MR 1 SD 2 PD 1 Not available 4
Leukapheresis to LD, median (range, days)	38 (29-100)
Outpatient infusion Days of hospitalization (range)	3 (17.6%) 0-2
Zevor-cel dose	A single infusion of 1.8×10^8 cells
Median Follow-up Days (range)	113 (9,373)

Data cutoff date: August 31, 2022

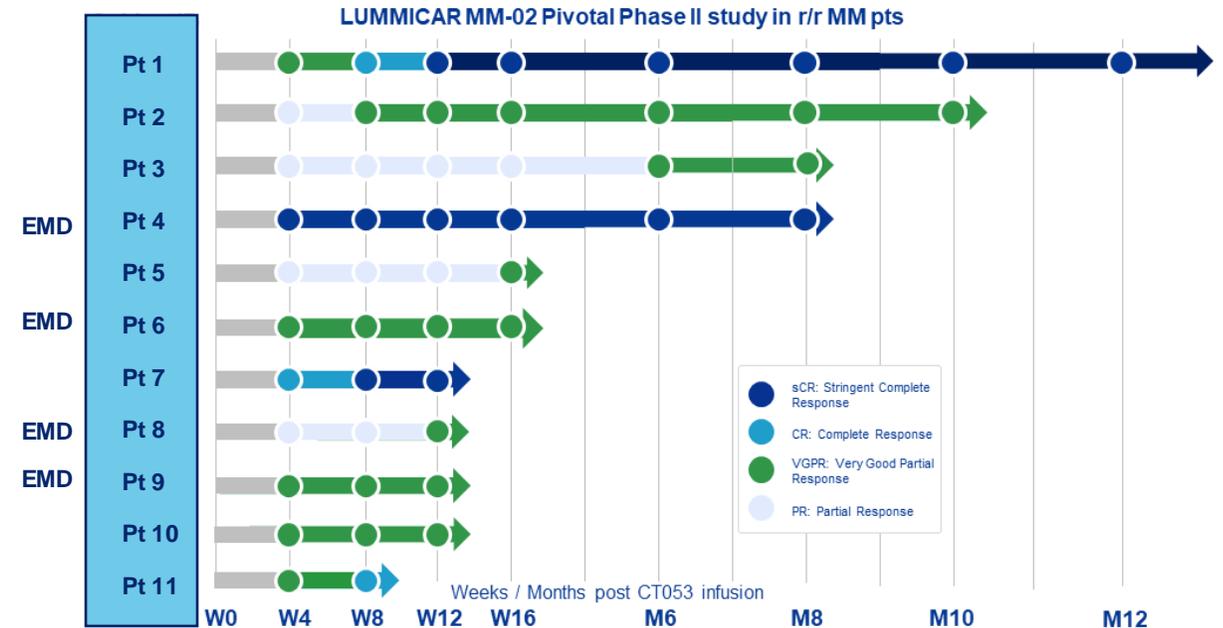
LUMMICAR STUDY 2 Phase 2: Preliminary Data Suggest a Best-in-class Profile in the US with Competitive Efficacy

Competitive efficacy

- **100%** responses at Week 4 (VGPR, CR or sCR) and ongoing
- **100%** leukapheresis patients were treated
- Responses deepened with longer follow-up
- **100%** MRD negative in all patients with available results at Week 4 by next-generation sequencing

	LUMMICAR-2 Phase 2
Region	North America
Sample size	17 treated 11 evaluated for efficacy
Patient population	5/17 (29.4%) EMD 9/17 (52.9%) high risk
No. of prior therapies, median (range)	6 (4-17)
ORR	11/11 (100%)
CR/sCR rate	Not mature
mPFS	Not mature

LUMMICAR STUDY 2 Phase 2 trial in North America



Data cutoff date: August 31, 2022

LUMMICAR STUDY 2 Phase 2: Preliminary Data Suggest a Best-in-class Safety Profile in the US

Best-in-class safety profile

	LUMMICAR STUDY 2 Phase 2
Region	North America
Sample size	17 treated, 11 evaluated
Patient population	5/17 (29.4%) EMD 9/17 (52.9%) high risk
No. of prior therapies, median (range)	6 (4-17)
CRS	10/17 (59%)
Grade 1 CRS	6/17 (35%)
Grade 2 CRS	4/17 (24%)
≥Grade 3 CRS	0
ICANS	3/17 (17.6%)
Grade 1 ICANS	2/17 (11.8%)
Grade 2 ICANS	0
Grade 3 ICANS	1/17 (5.9%)
Toxicity Mgmt: tocilizumab	5/17 (29%)
Toxicity Mgmt: corticosteroid	1/17 (5.9%)
Treatment related death	0

Safety profile highlights

- **No treatment related death** and no patient was admitted to ICU for CRS/ICANS
- **Neurotoxicity**
 - 1/17 (5.9%) Grade 3 ICANS and fully resolved
 - No long-term neurotoxicity
 - No parkinsonism
- **CRS**
 - 41% without any grade of CRS
 - No Grade 3 or higher CRS
- **Toxicity management**
 - Tocilizumab: 5 (29%)
 - Corticosteroid: 1 (5.9%)
 - No IL-1 inhibitor usage
- **Outpatient treatment**
 - 3 patients have received outpatient treatment and 2 were admitted into the hospital for symptom management for 1 and 2 days.

Study Population Summary

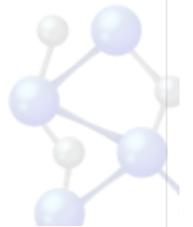
- Heavily pretreated patients with at least 4 prior lines of therapy were enrolled
- 29.4% patients with EMD (≥ 1 plasmacytoma) and 52.9% with high-risk cytogenetic features
- All patients were refractory to the last line of therapy

Safety Summary

- No treatment-related death was reported.
- Grade 1 or Grade 2 CRS occurred in 59% subjects, no \geq Grade 3 CRS reported;
- 1 Grade 3 ICANS was reported; no parkinsonism type long-term neurotoxicity was observed.
- 29.4% treated with tocilizumab and 5.9% treated with corticosteroid for toxicity management
- Outpatient infusion seems feasible and safe.

Efficacy Summary

- The preliminary ORR was 100% (VGPR and higher). The mPFS, mOS and mDOR have not been reached.
- All patients with available MRD results at week 4 were MRD negative by next-generation of sequencing



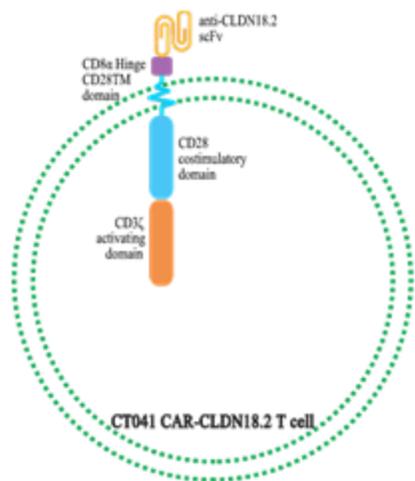
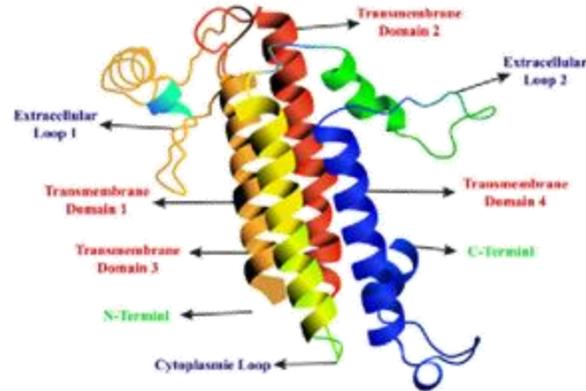
Zevor-cel at 1.8×10^8 CAR T cells was well tolerated in patients with R/R MM with promising efficacy and MRD negativity. Additional data will be presented in future major medical conferences.

3

Claudin18.2 CAR T (CT041)

CT041: Humanized Claudin18.2-directed CAR T cells

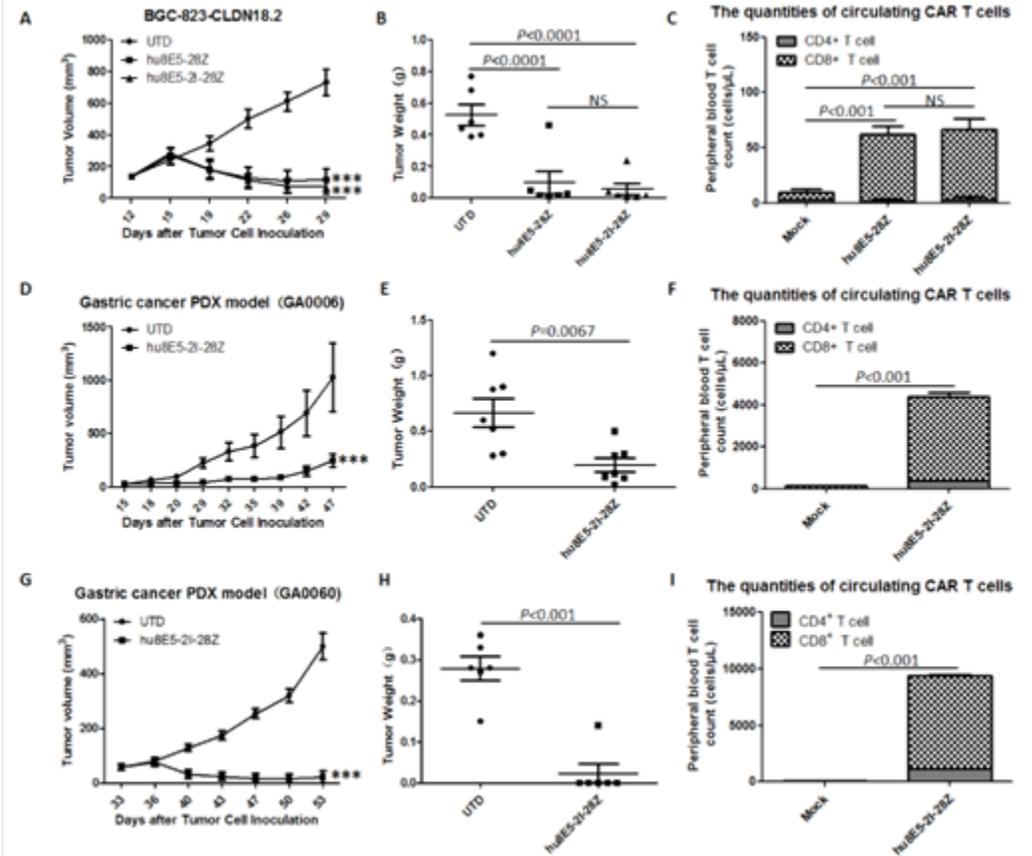
- Claudin18.2 (CLDN18.2) is a pan-cancer target
- Expressed in a diverse variety of epithelial tumor types¹
- Medium to high expression in ~60% GC/GEJ patients²



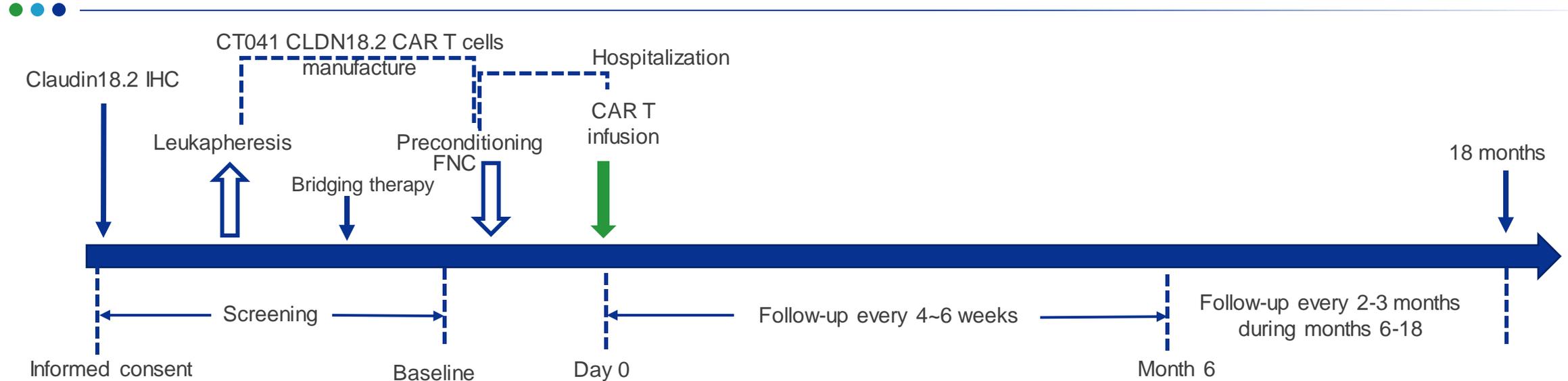
- Patient-derived (autologous) CAR T cell product
- Chimeric antigen receptor design⁴:
 - Humanized CLDN18.2 scFv
 - CD8α hinge region, CD28 transmembrane region
 - CD28 intracellular signal domain
 - CD3ζ intracellular signal region
- IND clearance by China NMPA, US FDA and Health Canada
- Received orphan drug designation from FDA, EMA
- Received RMAT from FDA and PRIME from EMA
- Pivotal Phase II trial in China: Ongoing
- Phase 1b/2 trial in US/Canada: Ongoing

1. Singh et al. *JHO*, 2017; 10:105
 2. Sahin U, et al. *CCR*, 2008;14:7624-34
 3. Jiang H, et al. *JNCI*, 2019;111(4):DJY134
 4. Qi, C. et al. *Nat Med*, 2022;28:1189–1198

Potent antitumor activities of CT041 in NOD/SCID mouse models bearing gastric cancer xenografts³



CT041 — CLDN18.2 CAR T Study Design



	CG4006 (NCT03874897)	CT041-ST-01 (NCT04581473)	CT041-ST-02 (NCT04404595)
Study population	CLDN18.2+ solid tumors ≥ 1 prior line of therapy	Phase 1: Subjects with GC/GEJ ≥ 2 prior lines of therapy or PC ≥ 1 prior line of therapy Phase 2: Subjects with GC/GEJ ≥ 2 prior lines of therapy	Subjects with GC/GEJ ≥ 2 prior lines of therapy or PC ≥ 1 prior line of therapy
Preconditioning regimen	flu 25 mg/m ² Day-5 and Day-4, cy 250 mg/m ² Day-5, -4 and -3, nab-paclitaxel 100 mg/m ² or 100 mg Day-4 (gemcitabine rather than nab-paclitaxel can be used for subjects with PC.)	flu 25 mg/m ² Day-5 and Day-4, cy 250 mg/m ² Day-5, -4 and -3, nab-paclitaxel 100 mg Day-4	flu 25 mg/m ² Day-5 and Day-4, cy 250 mg/m ² Day-5, -4 and -3, nab-paclitaxel 100 mg/m ² or 100 mg Day-4
CT041 dose levels	2.5 × 10 ⁸ 3.75 × 10 ⁸ 5.0 × 10 ⁸	2.5 × 10 ⁸ 3.75 × 10 ⁸	2.5-3.0 × 10 ⁸ 3.75-4.0 × 10 ⁸ 6.0-8.0 × 10 ⁸

Additional Nab-paclitaxel for Conditioning May Provide Favorable Tumor Immune Microenvironment to Maximize Efficacy of CT041 CAR T-cell Therapy in Solid Tumors

- CAR T cells together with the fludarabine and cyclophosphamide (FC)-based preconditioning regimen have not seen much success against solid tumors.
- Nab-paclitaxel is a novel albumin-stabilized and water-soluble nanoparticle formulation of paclitaxel.
- Relevant to its application for CT041, preclinical and clinical studies have showed that nab-paclitaxel can be transported across the endothelial cells, accumulate in the tumor stroma, and disrupt the cancer-stromal interactions (Neuzillet, 2013; Feng, 2018; Chen, 2015; Narayanan 2015*)
- Neoadjuvant therapy with gemcitabine plus nab-paclitaxel reduced the number of cancer-associated fibroblasts via depletion of pancreatic stroma, which improved the intratumoral concentration of gemcitabine and led to a significant improvement in survival (Miyashita, 2018; Von Hoff, 2011; Frese, 2012; Von Hoff, 2013*).
- Administration of low-dose paclitaxel significantly decreased the accumulation and immunosuppressive activities of tumor-associated myeloid-derived suppressor cells without altering bone marrow hematopoiesis (Sevko, 2013*)
- Therefore, a low dose of nab-paclitaxel can decrease the production of inflammatory mediators and fine-tune the tumor microenvironment for enhancing the efficacy of concomitant anticancer therapies.



CT041: Efficacy Breakthrough for CAR T-Cell Therapy in Solid Tumors

CT041 CG4006 Clinical Trial

13:30 - 14:50 Proffered Paper session - Gastrointestinal tumours, non-colorectal

2021 ESMO congress

CLDN 18.2-targeted CAR-T cell therapy (CT041) in patients with cancers of the digestive system

Changsong Qi¹, Yanru Qin², Dan Liu¹, Jifang Gong¹, Sai Ge¹, Miao Zhang¹, Zhi Peng¹, Jun Zhou¹, Xiaotian Zhang¹, Xiaohui Peng³, Huamao Wang³, Daijing Yuan³, Jun Xiao³, Zonghai Li³, Lin Shen^{1*}

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³CARsgen Therapeutics Ltd., Co., Shanghai, China
*Corresponding author



Changsong Qi

CLDN 18.2-targeted CAR-T cell therapy in patients with cancers of the digestive system

Changsong Qi et al. 2021 ESMO, 13720

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ARTICLES

<https://doi.org/10.1038/s41591-022-01800-8>

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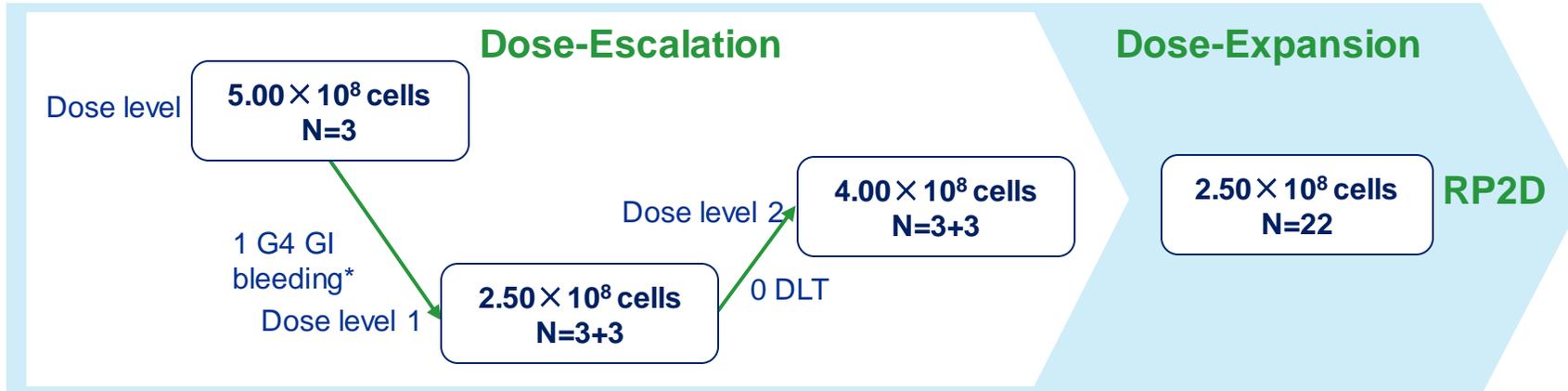
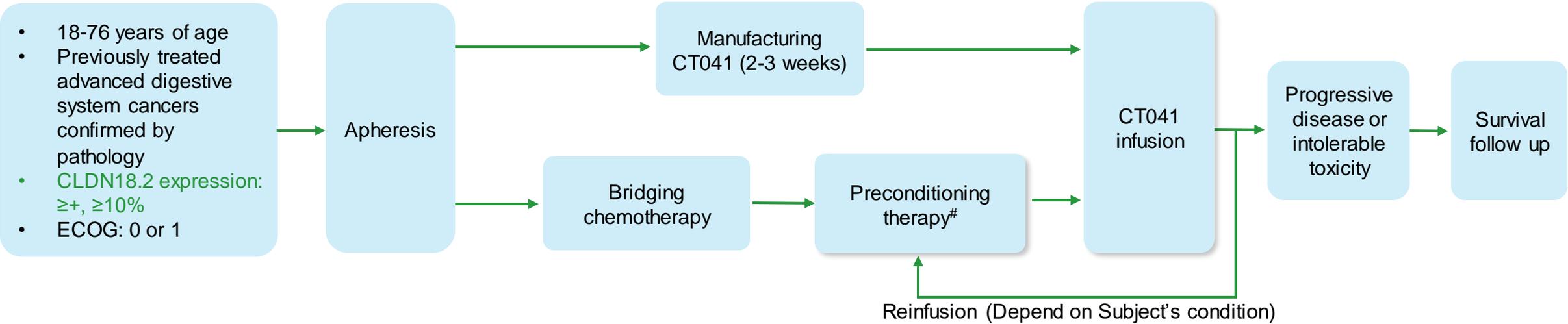
Claudin18.2-specific CAR T cells in gastrointestinal cancers: phase 1 trial interim results

Changsong Qi^{1,5}, Jifang Gong^{1,5}, Jian Li^{1,5}, Dan Liu², Yanru Qin³, Sai Ge¹, Miao Zhang², Zhi Peng¹, Jun Zhou¹, Yanshuo Cao¹, Xiaotian Zhang¹, Zhihao Lu¹, Ming Lu¹, Jiajia Yuan¹, Zhenghang Wang¹, Yakun Wang², Xiaohui Peng⁴, Huiping Gao⁴, Zhen Liu⁴, Huamao Wang⁴, Daijing Yuan⁴, Jun Xiao⁴, Hong Ma⁴, Wei Wang⁴, Zonghai Li⁴ and Lin Shen¹✉

Qi, C., Gong, J., Li, J. et al. Nat Med (2022)

CT041: Study Design

A multicenter, open-label, phase I ongoing study



Primary Objectives: Safety and tolerability
Secondary Objectives: Efficacy, Pharmacokinetics
Exploratory Objectives: Covariate analysis for efficacy, biodistribution of CT041

#Fludarabine 25 mg/m²/day(D-4~D-3) + Cyclophosphamide 250 mg/m²/day (D-4~D-2) + Nab-paclitaxel 100 mg or gemcitabine 1000 mg (D-3)

*One patient suffered gastrointestinal hemorrhage on D51 after reinfusion, which was considered to be caused by obvious tumor regression. After discussion among the investigators, DMC and partners, it was decided to lower the dose to 2.5 × 10⁸ cells.

CT041: Patient Demographics and Baseline Characteristics

Characteristics of all patients	Total (N = 37)
Median age (range), year	53.0 (25–74)
Disease Type, n(%)	
GC/GEJ	28 (75.7)
PC	5 (13.5)
Other	4 (10.8)
ECOG, n (%)	
0	2 (5.4)
1	35 (94.6)
Bridging therapy, n (%)	28(75.7)
Expression intensity and rate of CLDN 18.2 in tumor tissue, n (%)	
Low expression	5 (13.5)
Medium expression	13 (35.1)
High expression	19 (51.4)
Numbers of metastatic organs	
Median	3.0
Min, Max	1.0, 7.0
Median no. of previous lines, n (%)	
1	6 (16.2)
2	19 (51.4)
≥ 3	12 (32.4)

Characteristics of patients with GC	Total (N = 28)
Histological classification(WHO classification), n (%)	
Mucinous adenocarcinoma	1 (3.6)
Signet ring cell carcinoma	12 (42.9)
Other	14 (50.0)
Expression intensity and rate of CLDN 18.2 in tumor tissue, n (%)	
Low expression	2 (7.1)
Medium expression	7 (25.0)
High expression	19 (67.9)
Numbers of metastatic organs	
Median	2.5
Min, Max	1.0, 7.0
Peritoneal metastases, n (%)	19 (67.9)
Liver metastases, n (%)	10 (35.7)
Lauren classification, n (%)	
Intestinal type	10 (35.7)
Diffuse type	9 (32.1)
Mixed type	7 (25.0)
Previous systemic therapies, n (%)	
Fluorouracil	28 (100)
Platinum	27 (96.4)
Taxanes	21 (75.0)
Paclitaxel	18 (64.3)
Albumin paclitaxel	7 (25.0)
Anti-PD-(L)1 antibody	12 (42.9)
Polykinase inhibitor	10 (35.7)

GC/GEJ: gastric carcinoma / gastroesophageal junction
 PC: pancreatic adenocarcinoma

CT041: Adverse Event Summary

Overall well tolerated

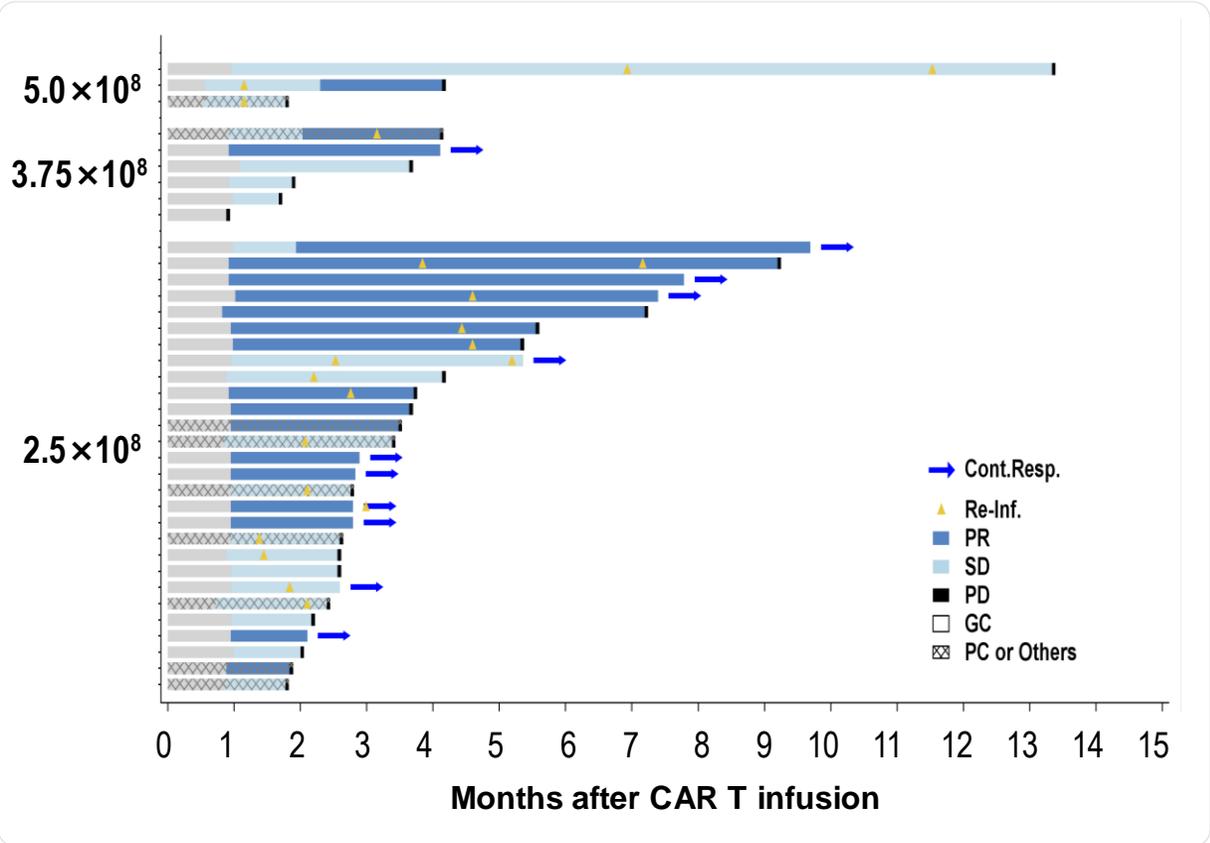
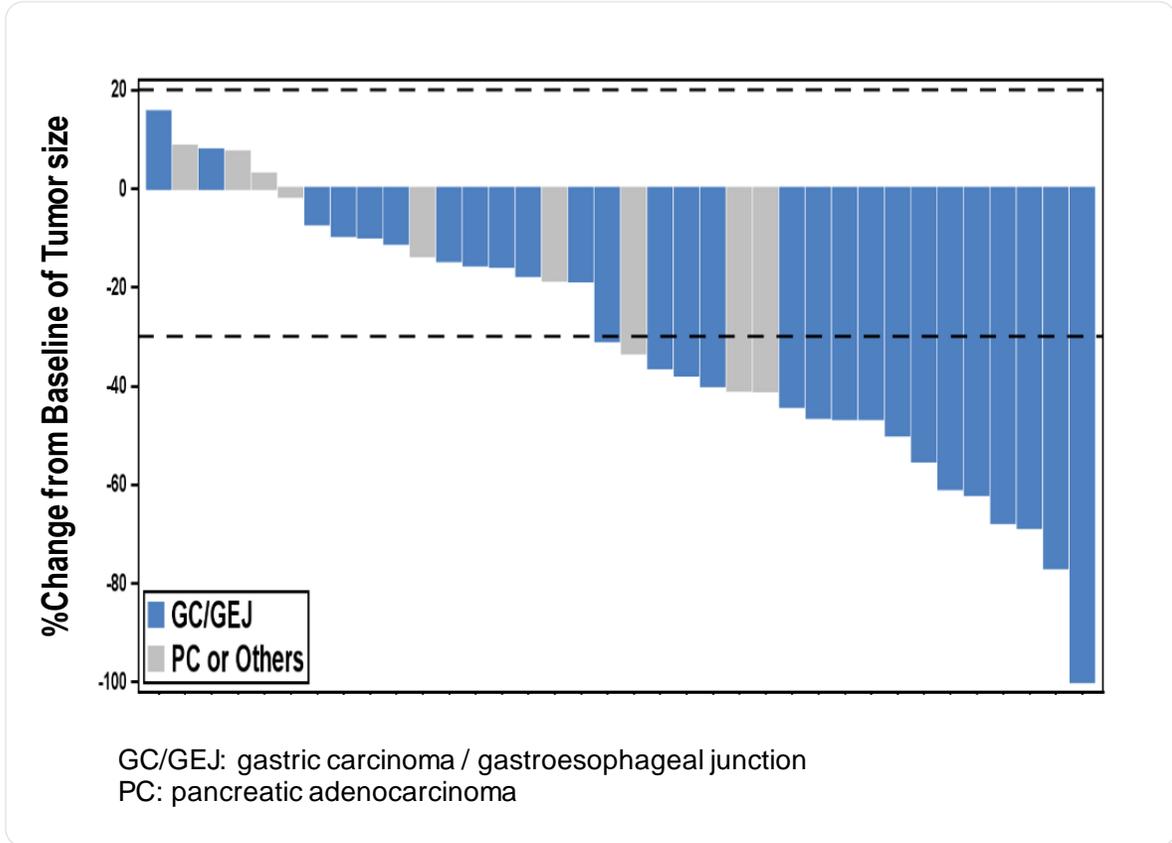
- Most common AEs \geq Grade 3 were hematologic toxicities and recovered within 2 weeks.
- 35 patients (94.5%) experienced Grade 1/2 CRS, no \geq Grade 3 CRS occurred.
- No CRES.
- 1 DLT of gastrointestinal hemorrhage post 2nd infusion on D51, resulted in dose reduction for further enrollment.
- No obvious difference in safety profile among 3 dose levels.
- No treatment-related death.

	Dose Escalation			Dose Expansion	Total (N=37)
	2.5 \times 10 ⁸ (N=6)	3.75 \times 10 ⁸ (N=6)	5 \times 10 ⁸ (N=3)	2.5 \times 10 ⁸ (N=22)	
All AEs, n (%)	6 (100)	6 (100)	3 (100)	22 (100)	37 (100)
DLT, n (%)	0	0	1 (33.3)	0	1 (2.7)
AE leading to study withdrawal, n (%)	0	0	0	0	0
AE leading to drug withdrawal, n (%)	0	0	1 (33.3)	0	1 (2.7)
AE leading to death, n (%)	0	0	0	0	0
Treatment-related SAEs, n (%)	0	0	1 (33.3)	2 (9.1)	3 (8.1)
Treatment-related AEs, n (%)	6 (100)	6 (100)	3 (100)	22 (100)	37 (100)
\geqGrade 3 fever, n (%)	1 (16.7)	0	1 (33.3)	1 (4.5)	3 (8.1)
Grade 3	1 (16.7)	0	1 (33.3)	1 (4.5)	3 (8.1)
Grade 4	0	0	0	0	0
\geqGrade 3 hematological toxicity, n (%)	6 (100)	6 (100)	3 (100)	22 (100)	37 (100)
Grade 3	6 (100)	6 (100)	3 (100)	22 (100)	37 (100)
Grade 4	5 (83.3)	6 (100)	3 (100)	21 (95.5)	35 (94.6)
CRS, n (%)	5 (83.3)	6 (100)	3 (100)	21 (95.5)	35 (94.6)
Grade 1	2 (33.3)	4 (66.7)	0	11 (50.0)	17 (45.9)
Grade 2	3 (50.0)	2 (33.3)	3 (100)	10 (45.5)	18 (48.6)
\geqGrade 3 neurotoxicity, n (%)	0	0	0	0	0
\geqGrade 3 infections, n (%)	0	0	0	0	0
Gastric mucosal injury, n (%)	0	0	0	6 (27.3)	6 (16.2)
\geq Grade 3	0	0	0	1 (4.5)	1 (2.7)

CT041 Efficacy: All Patients



- ▶ Thirty-six of the 37 subjects had target lesions, and 31 subjects had varying degrees of shrinkage of target lesions.
- ▶ According to RECIST 1.1, ORR and DCR reached **48.6%** (18/37) and **73.0%** (27/37) respectively.



CT041 Efficacy: GC/GEJ Patients with ≥ 2 Prior Lines

GC/GEJ patients who failed at least 2 prior lines of therapy (especially above 40% patients ever exposed to anti-PD-(L)1 antibody) at a dose of 2.5×10^8 CAR T cells achieved:

- ORR of **61.1%**
- DCR of **83.3%**

- mPFS* of **5.6 m**
- mDOR of **6.4 m**
- mOS* of **9.5 m** with a median follow up duration* of 7.6 m (95%CI 5.6, 8.6)

GC patients with ≥ 2 lines at 2.5×10^8 cells (N=18)

Best Overall Response

CR	0
PR	11 (61.1%)
SD	4 (22.2%)
PD	3 (16.7%)

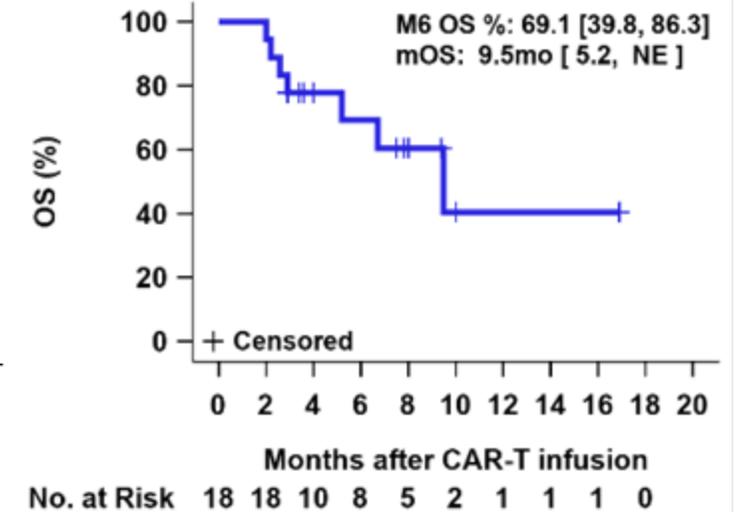
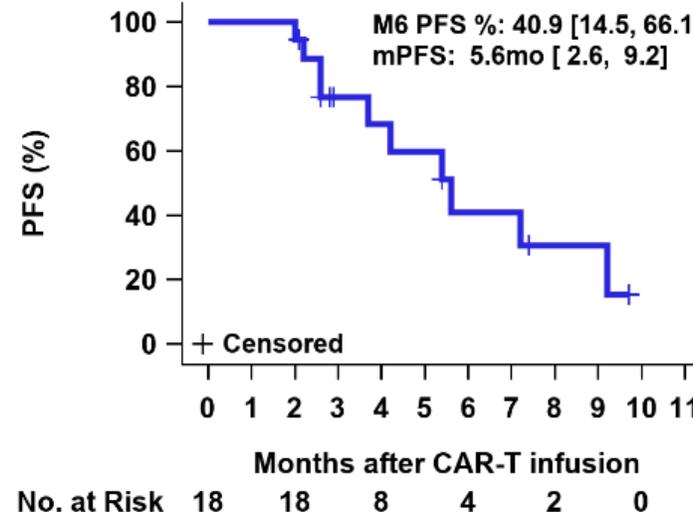
ORR [95% CI] **11 (61.1%) [35.75, 82.70]**

DCR [95% CI] **15 (83.3%) [58.58, 96.42]**

mPFS* **5.6 m [2.6, 9.2]**

mOS* **9.5 m [5.2, NE]**

mDOR **6.4 m [2.7, NE]**



*PFS, OS and follow-up duration were calculated from CT041 infusion date.

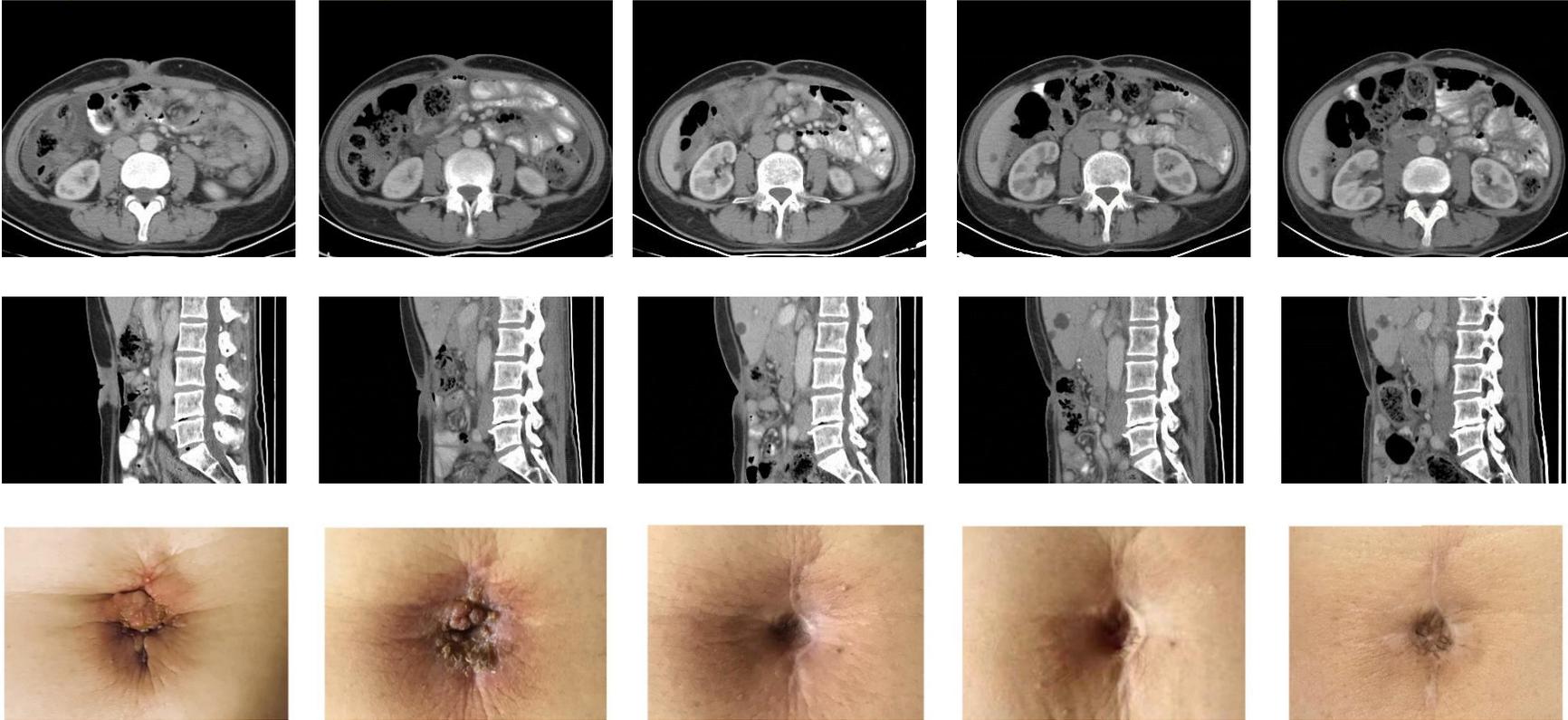
CT041: Subgroup Analysis of ORR in GC/GEJ Patients

	Number of subjects	ORR
CLDN18.2 expression		
High expression ($\geq 2+$, $\geq 70\%$)	19	57% (37.2, 75.5)
Medium expression ($\geq 2+$, $\geq 40\%$ and $< 70\%$)	7	58% (33.5, 79.7)
Low expression (+ or $< 40\%$)	2	50% (1.3, 98.7)
Anti-PD-(L)1 Antibody		
Not used	16	63% (35.4, 84.8)
Used	12	50% (21.1, 78.9)
Peritoneal Metastasis		
Yes	19	58% (33.5, 79.7)
No	9	56% (21.2, 86.3)
WHO Classification		
Signet ring cell carcinoma	12	58% (27.7, 84.8)
Others	15	60% (32.3, 83.7)
Lauren Classification		
Intestinal	10	70% (34.8, 93.3)
Diffused / Mixed	16	50% (24.7, 75.3)

CT041: Case Sharing: Long-term Tumor Response



Pt08, 57/F, GC with peritoneal metastasis and Sister Mary Joseph nodule, achieved PR and ongoing response more than 56 weeks, had received 3 prior lines of therapy including PD-1 antibody, CLDN18.2 2+ 80%.



Pre-infusion

Post-infusion W4

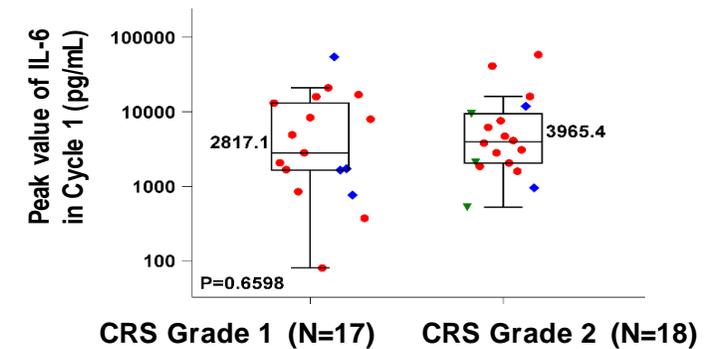
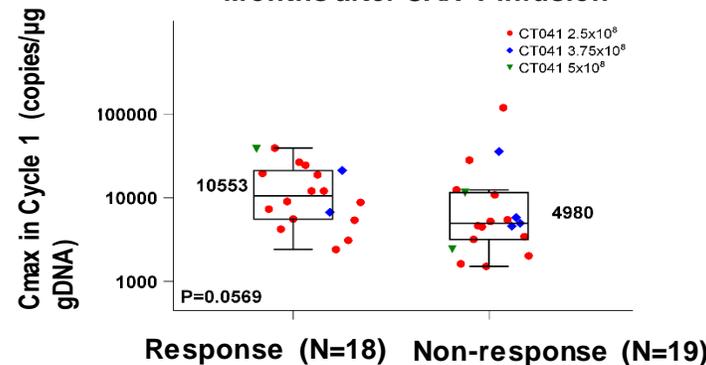
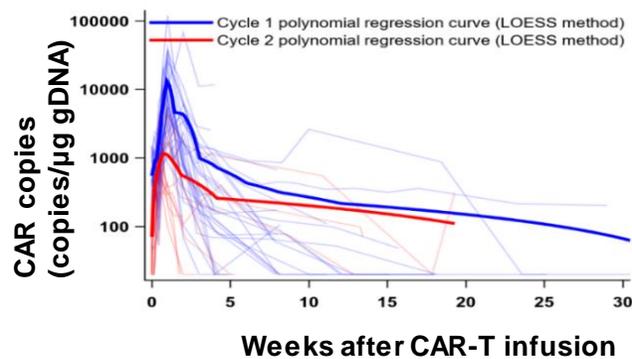
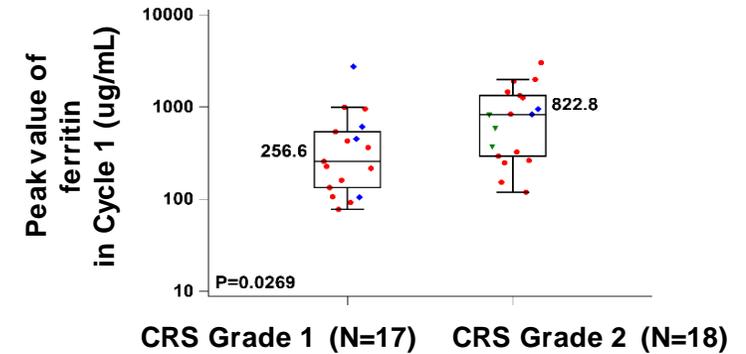
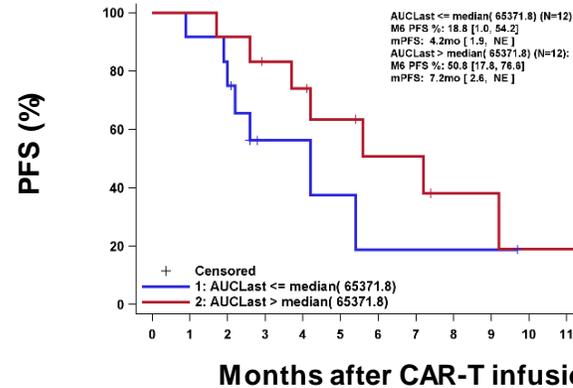
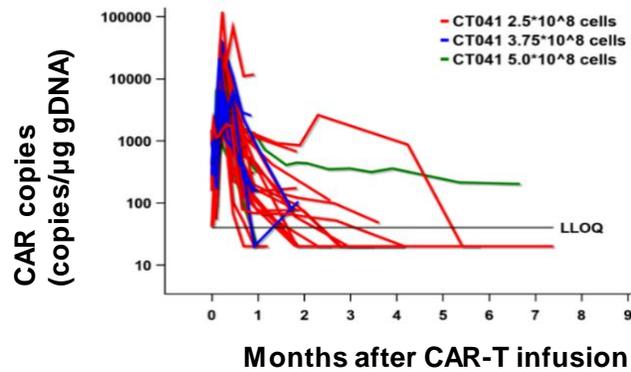
W12

W24

W40

CT041: CAR T-cell Expansion and Serum Biomarkers

- The CAR copies peaked around 7 days, persisted was about one month, CAR copies peak decreased post 2nd - 3rd dose.
- Responders had relative higher CAR expansions.
- The prolonged PFS positively correlated with increased AUC_{last}.
- Patients with Grade 2 CRS had higher IL-6 and ferritin peak value than those with Grade 1.



Safety Summary

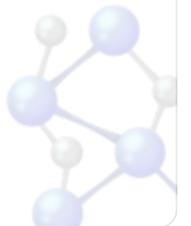
- No treatment-related death, DLT, and immune effector cell-associated neurotoxicity syndrome (ICANS) were reported.
- Grade 1 or Grade 2 CRS occurred in 94.6% subjects, no \geq Grade 3 CRS reported.

Efficacy Summary

- The ORR for all patients was 48.6%, and DCR reached 73%. The mOS and mDOR have not reached.
- GC/GEJ patients who failed at least 2 prior lines of therapy (especially more than 40% patients ever exposed to anti-PD-(L)1 antibody) at a dose of 2.5×10^8 CAR T cells achieved ORR of **61.1%**, DCR of **83.3%**, PFS of **5.6 months** (95%CI, 2.6, 9.2), OS of **9.5 months** (95%CI, 5.2, NE).

Pharmacokinetics Characteristics

- The CAR copies peaked around 7 days with median persistent duration of 1 month
- The CAR copies peak was significantly higher in the responders than in the non-responders. The prolonged PFS positively correlated with increased AUC_{last} .



CT041 at dose levels of $2.5-5.0 \times 10^8$ CAR T cells was well tolerated in patients with CLDN18.2-positive digestive system cancers and delivers a high response rate and sustained remission in previously treated GC/GEJ patients.

4 Strategic Pillars

to address major challenges of CAR T-cell therapies



Efficacy against Solid Tumors

CycloCAR[®]
co-expression of
IL-7 + CCL21



Safety Profile

Technologies to **minimize safety concerns** including CRS, neurotoxicity, on-target off-tumor toxicities



Patient Accessibility

Allogeneic
THANK-uCAR[®]
technology



Target Availability

LADAR[®] technology for precise targeting new targets (e.g., GPRC5D, B7-H3)



 CARSGEN
THERAPEUTICS

 CARSGEN
THERAPEUTICS

Making Cancer Curable