

**Clatterbridge Cancer Centre Performance in Delivering Research Q1 2015/16**

Research Ethics Committee Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
13/LO/1020	NCRN640 Celestial Cabozantinib vs. Placebo in Subjects with HCCA Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs Placebo in Subjects with Hepatocellular Carcinoma Who have Received Prior Sorafenib	5	31/01/2017	Open	N/A	Trial still open and actively recruiting
14/NW/0020	NCRN 2630 Bayer 16507 A three arm randomized, 1 open-label Phase II study of radium-223 dichloride 50 kBq/kg versus 80 kBq/kg, and versus 50 kBq/kg in an extended dosing schedule in subjects with castration-resistant prostate cancer metastatic to the bone	6	30/09/2023	Open	N/A	Trial still open and actively recruiting
13/LO/1581	NCRN - 2643 DNIB0600A in patients with Platinum-Resistant Ovarian Cancer	4	01/01/2016	Closed - In Follow Up	N	5 patients pre-screened/approached; 3 patients consented, 2 recruited and one screen failed. Rare patient group
14/LO/0135	BAYER 15396 Radium223A phase III randomized, double-blind, placebo-controlled trial of radium-223 dichloride in combination with abiraterone acetate and prednisone/prednisolone in the treatment of asymptomatic or mildly symptomatic chemotherapy-na?ve subjects with bone predominant metastatic castration-resistant prostate cancer (CRPC)	6	30/07/2021	Open	N/A	Trial still open and actively recruiting
13/SC/0478	NCRN 567 COLUMBUS - A Phase III randomized, 3-arm, open label, multicenter study of LGX818 plus MEK162 and LGX818 monotherapy compared with vemurafenib in patients with unresectable or metastatic BRAF V600 mutant melanoma	3	21/08/2017	Open	N/A	Trial still open and actively recruiting
14/LO/0022	RAPID NCRN 2511 Renal Cell WO29074 NCRN 2511 A PHASE II, RANDOMIZED STUDY OF MPDL3280A ADMINISTERED AS MONOTHERAPY OR IN COMBINATION WITH BEVACIZUMAB VERSUS SUNITINIB IN PATIENTS WITH UNTREATED ADVANCED RENAL CELL CARCINOMA	4	07/01/2017	Closed - In Follow Up	N	Rare patient group. Competitive recruitment. 6 patients screened.
13/LO/1050	EISAI HCC - Protocol E7080-G000-304 (Unresectable Hepatocellular Carcinoma)A Multicenter, Randomized, Open-Label, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib (E7080) Versus Sorafenib in First-Line Treatment of Subjects With Unresectable Hepatocellular Carcinoma	6	01/06/2016	Open	N/A	Trial still open and actively recruiting
14/SW/0091	NCRN - 2974 VESTA: NSCLC M11089 A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	8	31/03/2016	Open	N/A	Trial still open and actively recruiting
14/SC/0199	CHECKMATE 141 - An open label, randomised phase 3 clinical trial of Nivolumab vs therapy of investigator?s choice in recurrent or metastatic platinum-refractory squamous cell carcinoma of the head and neck (SCCHN)	4	31/12/2015	Closed - In Follow Up	N	10 patients pre-screened/approached, 2 recruited. Non entry as follows: 5 were ineligible, 2 patients declined, 1 clinician decision.
14/LO/1042	NCRN 3021 GO29293 - MPDL3280A in metastatic bladder cancer	5	01/05/2018	Closed - In Follow Up	Y	
14/NW/1036	SHIONOGI BLADDER 1408P192 A multicenter, open-label, phase 2 study of S-588410 as maintenance monotherapy after first-line platinum-containing chemotherapy in patients with advanced and/or metastatic bladder cancer	4	30/09/2017	Open	N/A	Trial still open and actively recruiting

13/EM/0230	NCRN636 - VS-6063 in mesothelioma - A phase II randomised, double blind, placebo-controlled, multicentre study of VS-6063 in subjects with malignant pleural mesothelioma	8	31/12/2016	Open	N/A	Trial still open and actively recruiting
14/LO/1052	A Phase 2, Randomized, Open-Label, Parallel Group Study Evaluating the Safety and Efficacy of TAK-385, an Oral GnRH Antagonist, for Patients With Localized Prostate Cancer Requiring Neoadjuvant and Adjuvant Androgen Deprivation Therapy With External Beam Radiation Therapy (EBRT)	10	14/09/2015	Closed - In Follow Up	N	1 patient recruited. 5 patients pre-screened/approached, non entry as follows: 3 patients declined, 1 non entry due to study closing to recruitment prior to consent.
14/NW/0350	A Randomized Phase IIB Open Label Study of Nivolumab or Nivolumab in Combination with Ipilimumab versus Bevacizumab in Adult Subjects with Recurrent Glioblastoma (GBM) (CheckMate 143: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 143)	3	31/01/2018	Closed - In Follow Up	N	1 patient recruited. Rare patient group. 5 patients pre-screened/approached, non entry as follows: 2 patients declined, 2 ineligible.
14/NE/1079	RELIEVE 1 A randomized, double-blind, placebo-controlled study to evaluate the Efficacy of two different dose levels of orvepitant (10 and 30mg) compared with placebo on EGFRi- induced intense pruritus in oncology subjects	5	24/02/2015	Closed - In Follow Up	N	1 patient recruited. Study closed to recruitment nationally earlier than planned.
14/LO/1151	A Phase Ib/II, Multicentre, Open Label, Randomised Study of BI 836845 in Combination with Enzalutamide, versus Enzalutamide alone, in Metastatic Castration-Resistant Prostate Cancer (CRPC) Following Disease Progression on Docetaxel-Based Chemotherapy and Abiraterone	15	30/08/2015	Open	N/A	Trial still open and actively recruiting
14/SC/1167	PHASE 3, RANDOMIZED, PLACEBO CONTROLLED, DOUBLE BLIND, MULTI-CENTER, TWO-PART STUDY OF PATRITUMAB (U3-1287) IN COMBINATION WITH ERLOTINIB IN EGFR WILD-TYPE SUBJECTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON AT LEAST ONE PRIOR SYSTEMIC THERAPY U31287-A-U301	6	03/08/2015	Open	N/A	Trial still open and actively recruiting
14/LO/1672	Polo Pancreatic 217674	2	22/11/2017	Open	N/A	Trial still open and actively recruiting
14/NW/1258	NCRN - 3041:ODM-201 IN MEN WITH HIGH-RISK NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER	6	30/06/2020	Open	N/A	Trial still open and actively recruiting
14/WM/1055	NCRN - 3246: Masitinib/Placebo + FOLFIRI in Metastatic Colorectal Cancer	6	01/09/2015	In set up	N/A	Study not yet activated to recruit.
14/EM/0089	A phase III, randomized, open label, multicenter, controlled trial of niraparib versus physician's choice in previously-treated, HER2 negative, germline BRCA mutation-positive breast cancer patients.	2	31/10/2015	Open	N/A	Trial still open and actively recruiting
14/LO/1385	REASURE (Radium-223: Evaluation of Activity and SURrogate REsponse)	6	04/05/2017	Open	N/A	Trial still open and actively recruiting
14/LO/1490	A Single-Arm, Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) for Subjects with Histologically Confirmed Stage III (unresectable) or Stage IV Melanoma Progressing Post Prior Treatment Containing an Anti-CTLA-4 Monoclonal Antibody	6	30/04/2019	Open	N/A	Trial still open and actively recruiting
14/LO/1739	NCRN - 3036 PRESIDE Continuing enzalutamide in chemo-naive CRPC	10	01/01/2018	Open	N/A	Trial still open and actively recruiting
14/LO/1798	A Phase III open-label multicenter randomised study to investigate the efficacy and safety of MPDL3280A (Anti-PD-L1 antibody) compared to chemotherapy in patients with locally advanced or metastatic bladder cancer after the failure with platinum-containing chemotherapy	6	18/12/2017	Open	N/A	Trial still open and actively recruiting
14/SC/1014	A Randomized, Double-Blind, Phase 3 Study of the JAK1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or Are Intolerant to First-Line Chemotherapy (The JANUS 1 Study)	5	26/01/2016	Open	N/A	Trial still open and actively recruiting
15/EE/0013	CA209040 Phase 1 of Nivolumab in Advanced HCC- A Phase I Dose Escalation Study to Investigate the Safety, Immunoregulatory Activity, Pharmacokinetics, and Preliminary Antitumor Activity of Anti-Programmed-Death-1 (PD-1) Antibody (BMS-936558) in Advanced Hepatocellular Carcinoma in Subjects with or without Chronic Viral Hepatitis	4	27/05/2016	Open	N/A	Trial still open and actively recruiting

15/LO/0016	MONARCH-3 - A randomized, double-blind, placebo-controlled, phase 3 study of nonsteroidal aromatase inhibitors (anastrozole or letrozole) plus LY2835219, a CDK4/6 inhibitor, or placebo in postmenopausal women with hormone receptor-positive, HER2-negative locoregionally recurrent or metastatic breast cancer with no prior systemic therapy in this disease setting	6	30/11/2015	Open	N/A	Trial still open and actively recruiting
14/SW/1164	D4193C00001 (HAWK)	3	01/02/2017	Open	N/A	Trial still open and actively recruiting