

**Clatterbridge Cancer Centre Performance in Initiating Research Q2 2015/16**

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited	Date of First Patient Recruited	Benchmark Met	Comments
13/EE/0397	NIMRAD: A randomised placebo-controlled trial of synchronous NIMorazole versus RADiotherapy alone in patients with locally advanced head and neck squamous cell carcinoma not suitable for synchronous chemotherapy or cetuximab	09/12/2014	18/12/2014	Yes	20/03/2015	No	Issues with completion of Radiotherapy QA - complex QA completion
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	20/10/2014	06/11/2014	Yes	23/12/2014	Yes	Target achieved
14/SC/1167	NCRN - 2957 Patritumab + Erlotinib in NSCLC: 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	10/11/2014	13/11/2014	Yes	31/12/2014	Yes	Target achieved
14/SS/0095	EORTC-1202-STBSG: Randomised phase II trial of cabazitaxel or prolonged infusional ifosfamide in metastatic or inoperable locally advanced dedifferentiated liposarcoma	27/10/2014	11/12/2014	No		No	Rare Disease Group. 2 patients have been pre-screened, 1 consented and failed on screening tests. 1 patient ineligible on pre-screening.
14/NE/1079	CANC - 3546 RELIEVE1: 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	20/10/2014	23/10/2014	Yes	17/11/2014	Yes	Target achieved
14/LO/1672	Polo Pancreatic 217674	20/11/2014	27/11/2014	No		No	3 patients pre-screened, 2 consented and failed on screening tests. 1 ineligible on pre-screening. Rare cancer group. Also delayed as study was temporarily in suspend. Northwest Coast CRN informed that we were unable to grant NHS permission until the lead site had completed the relevant checks in CSP.
13/LO/0822	VINCAP: A Phase II Trial of Vinflunine chemotherapy in locally advanced and metastatic carcinoma of the penis	10/10/2014	13/10/2014	Yes	28/01/2015	No	Rare Disease Group

13/EM/0266	METRO-BIBF: Phase II, randomised, placebo controlled, multicentre, feasibility study of low dose (metronomic) cyclophosphamide with or without nintedanib (BIBF 1120) in advanced ovarian cancer (METRO-BIBF)	18/09/2014	09/10/2014	Yes	11/12/2014	No	Rare Disease Group
14/NW/1258	NCRN - 3041:ODM-201 IN MEN WITH HIGH-RISK NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER	08/01/2015	13/01/2015	Yes	17/03/2015	Yes	Target achieved
14/LO/1739	NCRN - 3036 PRESIDE Continuing enzalutamide in chemo-naive CRPC	08/01/2015	13/01/2015	Yes	16/02/2015	Yes	Target achieved
14/SC/1014	JANUS 1: 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.	14/01/2015	20/01/2015	No		No	3 patients screened, 1 consented on screening tests, 1 ineligible on pre-screen and 1 declined. Rare disease group. Also delay incurred due to issue with sub-contract with partner Trust.
14NW1027	SORAMIC Evaluation of Sorafenib in combination with local micro-therapy guided by Gd-EOB-DTPA enhanced MRI in patients with inoperable hepatocellular carcinoma	22/12/2014	27/01/2015	Yes	28/05/2015	No	A partner Trust is also opening as a full site in order to deliver the study. The partner Trust had not given NHS permission therefore as both Trusts had to open at the same time, the Sponsor would not activate CCC until the partner Trust gave NHS permission for the study.
14/WM/1055	NCRN - 3246: Masitinib/Placebo + FOLFIRI in Metastatic Colorectal Cancer	06/02/2015	17/02/2015	No		No	Study has not yet been activated to recruit
14/EM/0089	BRAVO: 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.	03/02/2015	18/02/2015	Yes	01/04/2015	Yes	Target achieved
14/NW/1110	REECUR: International randomised controlled trial of chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma	17/02/2015	24/02/2015	No		No	Rare disease group
14/LO/1385	REASURE (Radium-223: Evaluation of Activity and SURrogate REsponse)	24/02/2015	25/02/2015	Yes	12/06/2015	No	Sponsor delayed activating our site due to Sponsor staff availability issues. CCC was activated in April 2015 and the first patient was recruited within 4 weeks of activation.
14/LO/1788	GO29294 AntiPDL1 Bladder Cancer : 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	11/03/2015	17/03/2015	Yes	18/03/2015	Yes	Target achieved
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	12/03/2015	24/03/2015	Yes	25/03/2015	Yes	Target achieved

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	11/05/2015	13/05/2015	No		No	1 patient consented on 15/05/2015 within the 70 day target but was ineligible on full screening.
14/SW/1164	HAWK: A Phase II, Multi-Centre, single-arm, global study of MEDI4736 Monotherapy in patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN)	15/06/2015	18/06/2015	No		No	Rare patient group. 3 Patients consented within 70 day target but were ineligible on screening tests and central pathology review.
14/LO/1426	NCRN - 2960 - Unresected Stage IIIB - IVM1a Melanoma Treated with Talmogene Laherparepvec	01/07/2015	02/07/2015	No		No	Rare disease group. 1 Patient approached but was ineligible on further screening.
15/LO/0165	Janssen Prostate: A Phase 3 Randomized, Placebo-controlled Double-blind Study of JNJ-56021927 in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects with Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)	17/07/2015	20/07/2015	Yes	01/09/2015	Yes	Target achieved
15/LO/0236	A Phase II Clinical Trial of Pembrolizumab (MK-3475) in Subjects with Advanced/Unresectable or Metastatic Urothelial Cancer	17/07/2015	21/07/2015	No		No	Study not activated until 17/08/2015
15/LO/0691	Checkmate 171: An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy in Subjects with Advanced or Metastatic Squamous Cell (Sq) Non-Small Cell Lung Cancer(NSCLC) who Have Received at Least Two Prior Systemic Regimens for the Treatment of Stage IIIB/IV SqNSCLC CheckMate 171: CHECKpoint pathway and nivolumab clinical Trial Evaluation 171	21/07/2015	22/07/2015	Yes	28/07/2015	Yes	Target achieved
13/LO/0066	TAX-TORC: A phase 1 multi-centre trial of the combination of AZD2014 (dual mTORC1 and mTORC2 inhibitor) and weekly Paclitaxel in patients with solid tumours	10/08/2015	21/08/2015	No		Within 70 Days	Within 70 day period, to be updated in Q3 report
12/LO/0864	FIESTA: FGFR Inhibition for Epithelial Solid Tumours: a Phase Ib trial of AZD4547 in combination with gemcitabine and cisplatin	28/08/2015	02/09/2015	No		Within 70 Days	Within 70 day period, to be updated in Q3 report
14/LO/2182	TS103: A Phase III Clinical Trial of Intra-arterial TheraSphere? in the Treatment of Patients with Unresectable Hepatocellular Carcinoma (HCC)	02/09/2015	03/09/2015	No		Within 70 Days	Within 70 day period, to be updated in Q3 report
14/WA/1118	PATHOS: Phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer	07/09/2015	24/09/2015	No		Within 70 Days	Within 70 day period, to be updated in Q3 report

15/LO/0448	RAINFALL: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Capecitabine and Cisplatin With or Without Ramucirumab as First-line Therapy in Patients With Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma.	24/09/2015	30/09/2015	No		Within 70 Days	Within 70 day period, to be updated in Q3 report
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