

Clatterbridge Cancer Centre Performance in Initiating Research (PII) Q4 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
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/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 Sq NSCLC	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	Yes	12/10/2015	Yes	Target achieved
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	Yes	01/10/2015	Yes	Target achieved
15/LO/0897	W029637 - A phase III, open-label, randomized study of MPDL3280A (Anti-PD-L1 antibody) in combination with bevacizumab versus sunitinib in patients with untreated advanced renal cell carcinoma	02/10/2015	09/10/2015	Yes	21/10/2015	Yes	Target achieved
15/LO/0159	SELPAC Uveal Melanoma Study	30/10/2015	30/10/2015	Yes	10/11/2015	Yes	Target achieved
13/LO/1481	MARS2: A study to determine if it is feasible to recruit into a randomised trial comparing (extended) pleurectomy decortication versus no pleurectomy decortication in the multimodality management of patients with malignant pleural mesothelioma	20/11/2015	20/11/2015	Yes	21/12/2015	Yes	Target achieved
15/EE/0385	NEPTUNE Lung: A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First Line Treatment of Patients with Advanced or Metastatic Non Small-Cell Lung Cancer (NSCLC)	23/12/2015	23/12/2015	Yes	07/01/2016	Yes	Target achieved

15/NE/0149	CANC - 3928 - CONDOR: A Phase II, Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy, Tremelimumab Monotherapy, and MEDI4736 in Combination with Tremelimumab in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	01/10/2015	09/10/2015	Yes	13/11/2015	Yes	Target achieved
15/SC/0431	CANC - 4032 Ramucirumab plus BSC vs placebo plus BSC as 2nd line treatment in HCC (JVDE)	03/02/2016	11/02/2016	Yes	17/03/2016	Yes	Target achieved
15/EM/0305	CANC - 4278 - GTx-024 in Advanced, AR+ TNBC	16/02/2016	16/02/2016	No		Within 70 days	Within 70 day target - to be updated Q1 2016/17
14/EE/1200	CANC - 3417 - A Phase III Randomized Trial of MK-3475 (Pembrolizumab) versus Standard Treatment in Subjects with Recurrent or Metastatic Head and Neck Cancer	17/02/2016	17/02/2016	No		Within 70 days	Within 70 day target - to be updated Q1 2016/17
15/EM/0546	KESTREL: MEDI4736 or in combo with Tremelimumab vs SOC in 1st line SCCHN cancer	24/02/2016	24/02/2016	No		Within 70 days	Within 70 day target - to be updated Q1 2016/17
15/NW/0690	MK-3475 054: Adjuvant immunotherapy with anti-PD-1 monoclonal antibody Pembrolizumab (MK-3475) versus placebo after complete resection of high-risk Stage III melanoma: A randomized, double-blind Phase 3 trial of the EORTC Melanoma Group	25/02/2016	25/02/2016	No		Within 70 days	Within 70 day target - to be updated Q1 2016/17
15/SC/0676	ANNOUNCE - A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial of Doxorubicin plus Olaratumab versus Doxorubicin plus Placebo in Patients with Advanced or Metastatic Soft Tissue Sarcoma	07/03/2016	07/03/2016	No		Within 70 days	Within 70 day target - to be updated Q1 2016/17
15/LO/1612	DANUBE: A Phase III, Randomized, Open-label, Controlled, Multi-Center, Global Study of First-Line MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of Care Chemotherapy in Patients with Unresectable Stage IV Urothelial Bladder Cancer	10/03/2016	10/03/2016	No		Within 70 days	Within 70 day target - to be updated Q1 2016/17
15/WS/0121	Javelin Lung 200: EMR100070004:Phase III study of avelumab vs docetaxel in NSCLC	23/03/2016	23/03/2016	No		Within 70 days	Within 70 day target - to be updated Q1 2016/17
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. Short recruitment window, study closed to recruitment 23/10/2015.
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	Yes	10/11/2015	No	Rare patient group. 3 Patients consented within the 70 day target but were ineligible on screening tests and central pathology review. Study now closed to recruitment.

14/LO/1426	NCRN - 2960 - Unresected Stage IIIB - IVM1a Melanoma Treated with Talimogene Laherparepvec	01/07/2015	02/07/2015	Yes	24/11/2015	No	Rare disease group. 1 Patient approached within the 70 day target but was ineligible on further screening.
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	Yes	29/09/2015	No	Study not activated until 17/08/2015. Patient consented within 70 days of study activation 29/09/2015. Complex screening procedures and strict eligibility criteria.
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		No	Study still awaiting activation to recruit by sponsor.
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	Yes	18/12/2015	No	Rare group of patients.
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 (RAINFALL)	24/09/2015	30/09/2015	Yes	14/12/2015	No	Study not activated to recruit until 23/10/2015. Strict eligibility criteria. Although no eligible patients were seen within the 70 day target, in Q3 15-16 4 patients were approached; 2 declined as they wanted standard of care treatment, 1 ineligible on screening investigations and 1 awaiting a decision. Q4 15/16 update: 4 patients have now been recruited.
14/SC/1156	JAVA P: A phase II study of Cabazitaxel chemotherapy in relapsed locally advanced and/or metastatic carcinoma of the penis.	27/11/2015	27/11/2015	No		No	Rare disease group.
15/SC/0291	MPDL3280A in solid tumours: An open label, multicohort, phase II study of MPDL3280A in advanced solid tumours	30/11/2015	01/12/2015	No		No	Difficult study to recruit as complex study design and global availability of slots within each cohort.
15/NW/0431	Janssen Bladder: A Phase II, 2-Arm MultiCenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects with Metastatic or Surgically Unresectable Urothelial Cancer with FGFR Genomic Alterations	21/10/2015	22/10/2015	No		No	Rare patient group and strict eligibility criteria for randomisation. Several patients have consented to the molecular screening and are either not eligible or awaiting an outcome.
15/WM/0011	Alligator - ADC-1013 First-in-Human study	27/10/2015	09/11/2015	No		No	First in Human study, strict eligibility criteria and rare patient group. Low recruitment target.
15/SC/0289	AMG-319: A Cancer Research UK randomised, double blind, placebo controlled, Phase IIa trial of AMG-319 given orally as a neoadjuvant therapy in patients with human papillomavirus (HPV) negative head and neck squamous cell carcinoma (HNSCC)	19/11/2015	20/11/2015	No		No	Sponsor delayed study activation. Site initiation cancelled by Sponsor on 22/12/2015

15/YH/0388	CLDK378A2112 Food Effect: A multi-center, randomized open label study to assess the systemic exposure, efficacy, and safety of 450 mg ceritinib taken with a low-fat meal and 600 mg ceritinib taken with a low-fat meal as compared with that of 750 mg ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lung cancer (NSCLC)	23/12/2015	23/12/2015	No		No	Very rare mutation group. Low recruitment target of 2. 2 patients were approached in Q3-4 15/16. Sponsor delay with SIV and PI availability.
14/SC/0171	Add-Aspirin Trial: A phase III, double blind, placebo controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours	18/01/2016	22/01/2016	No		No	Study put on hold by Sponsor due to drug availability. Study still awaiting 'green light' from Sponsor - Sponsor delay.