## PERFORMANCE IN DELIVERING CLINICAL RESEARCH (Q3, 2016/17)

| Research Ethics Committee Reference Number | Name of Trial | Target Number Of Patients Agreed? | Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number) | Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number) | Target Date To Recruit Patients Agreed? | Date Agreed to recruit target number of patients | Total Number Of Patients Recruited At The Agreed Target Date | Date That The Trial Closed To Recruitment | Total Number Of Study Participants Recruited | Reason For Closure Of Trial | Comments |
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| 11/LO/2036 | A Phase I/II, Open-Label, Safety, Pharmacokinetic, and Preliminary Efficacy Study of Oral Rucaparib in Patients with gBRCA Mutation Ovarian Cancer or Other Solid Tumor | Number Agreed | 5 | 5 | Date Agreed | 18/08/2017 | 8 | 30/09/2016 | 8 | Recruitment Finished | Study recruited to time and target. |
| 12/LO/1981 | A Randomized, Multicenter, Open-Label Phase III Study To Evaluate The Efficacy And Safety Of Trastuzumab Emtansine Versus Trastuzumab As Adjuvant Therapy For Patients With Her2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologic | Number Agreed | 2 | 3 | Date Agreed | 01/03/2016 | 3 | 01/03/2016 | 14 | Recruitment Finished | Study recruited to time and target. |
| 13/EE/0444 | Maximizing CRT Delivery by using Multipolar Coronary Sinus Lead Acuity x4 | Number Agreed | 20 | 20 | Date Agreed | 31/12/2014 | 12 | 01/03/2016 | 12 | Recruitment Finished | Study was put on hold at site due to a protocol deviation then stopped recruiting globally. |
| 13/EM/0348 | Safety and Efficacy assessment of Monoprost? (unpreserved latanoprost) in comparison with Lumigan? 0.01 % and Lumigan? 0.03% UD, in patients with primary open angle glaucoma or ocular hypertension, stabilized by Lumigan? 0.01 % with ocular surface in | Number Agreed | 6 | 6 | Date Agreed | 31/08/2015 | 4 | 06/01/2016 | 4 | Recruitment Finished | Several patients were screened by the agreed date but were not eligible. |
| 13/LO/1557 | A Phase IV, Multicentre, Open label, Single Group Exploratory Study to Assess the Clinical Value of Enumeration of Circulating Tumour Cells (CTCs) to Predict Clinical Symptomatic Response and Progression Free Survival in Patients receiving Deep Subcu | Number Agreed | 5 | 5 | Date Agreed | 31/08/2016 | 7 | 30/07/2016 | 7 | Recruitment Finished | Study recruited to time and target. |
| 13/LO/1682 | A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rucaparib as Switch Maintenance Following Platinum-Based Chemotherapy in Patients with Platinum-Sensitive, High-Grade Serous or Endometrioid Epithelial Ovarian, Primary Peri | Number Agreed | 5 | 5 | Date Agreed | 31/12/2016 | 2 | 31/03/2016 | 2 | Recruitment Finished | A change in eligibility criteria meant fewer potential patients than originally anticipated. Several patients identified and screened but either declined to participate or were ineligible. |
| 13/LO/1758 | A Phase III, Randomized, PlaceboControlled, ParallelGroup, DoubleBlind Clinical Trial to Study the Efficacy and Safety of MK8931 (SCH 900931) in Subjects with Amnestic Mild Cognitive Impairment Due to Alzheimer's Disease (Prodromal AD). | Number Agreed | 10 | 10 | Date Agreed | 31/10/2016 | 10 | 24/10/2016 | 10 | Recruitment Finished | Study recruited to target. |
| 13/NW/0002 | Prospective, randomised, controlled investigation comparing the safety and performance of 032-11 Surgical Haemostat 2g Applicator with FLOSEAL® Hemostatic Matrix as an adjunctive haemostat in cardiac surgery and thoracic aortic surgery (VICTORY Study | Number Agreed | 20 | 20 | Date Agreed | 31/08/2016 | 5 | 02/12/2016 | 5 | Withdrawn By Sponsor | PI left Trust. |
| 14/EM/0130 | A Phase 3, Open-Label, Randomized Study of Quizartinib (AC220) Monotherapy vs. Salvage Chemotherapy in Subjects with FLT3-ITD Positive Acute Myeloid Leukemia (AML) Refractory to, or Relapsed after, First-Line Treatment with or without Hematopoietic S | Number Agreed | 2 | 2 | Date Agreed | 31/01/2017 | 0 | 31/10/2016 | 0 | Withdrawn By Sponsor | Very rare disease. |
| 14/EM/0186 | A Randomized Controlled Phase 3 Study of Oral Pacritinib versus Best Available Therapy in Patients with Thrombocytopenia and Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis. | Number Agreed | 2 | 2 | Date Agreed | 14/08/2018 | 0 | 03/02/2016 | 0 | Recruitment Finished | Study closed early without recruitment. No patient satisfied the stringent entry criteria. |
| 14/EM/1059 | A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura | Number Agreed | 1 | 1 | Date Agreed | 30/09/2016 | 2 | 08/01/2016 | 2 | Recruitment Finished | Study recruited to time and target. |
| 14/EM/1060 | A Phase 3 Open Label Extension Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura | Number Agreed | 1 | 1 | Date Agreed | 30/09/2016 | 2 | 15/04/2016 | 2 | Recruitment Finished | Study recruited to time and target. |

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| 14/LO/0362 | Prospective, randomized, placebo-controlled, double-blind, multicenter, parallel-group, 24-week study to assess the efficacy, safety and tolerability of macitentan in subjects with inoperable chronic thromboembolic pulmonary hypertension | Number Agreed | 3 | 3 | Date Agreed | 28/07/2016 | 1 | 15/08/2016 | 1 | Withdrawn By Sponsor | Strict inclusion criteria. Sponsor eventually closed study. |
| 14/LO/0673 | A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study of Oral Ixazomib Citrate (MLN9708) Maintenance Therapy in Patients With Multiple Myeloma Following Autologous Stem Cell Transplant | Number Agreed | 7 | 7 | Date Agreed | 31/03/2018 | 5 | 03/02/2016 | 5 | Recruitment Finished | Rare disease study. |
| 14/LO/1053 | A Phase 3 Randomised double blind Active study Evaluating Momelotinib vs Ruxolitinib in subjects with primary Myelofibrosis (PMF) or Post-poly cythemia Vera or Post-essential Thrombocythemia Myelofibrosis ( Post-PV/ET MF) | Number Agreed | 2 | 2 | Date Agreed | 01/12/2017 | 3 | 24/02/2016 | 3 | Recruitment Finished | Study recruited to time and target. |
| 14/LO/1370 | Long Term, Multicenter, Single-arm, Open-label Extension Study of the MERIT-1 Study, to Assess the Safety, Tolerability and Efficacy of Macitentan in Subjects With Inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH) | Number Agreed | 1 | 1 | Date Agreed | 30/11/2016 | 1 | 01/04/2016 | 1 | Recruitment Finished | Study recruited to time and target. |
| 14/LO/2196 | A phase 2, double-blind, parallel group, randomised, placebo controlled, proof of concept study to assess the safety and efficacy of OBE001 after oral administration in pregnant women with threatened preterm labour | Number Agreed | 7 | 7 | Date Agreed | 04/01/2016 | 0 | 25/07/2016 | 0 | Recruitment Finished | UK-wide difficulty in finding eligible patients. |
| 14/NE/1072 | A PHASE II, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED BRONCHOSCOPY STUDY TO EVALUATE THE EFFECTS OF LEBRIKIZUMAB ON AIRWAY EOSINOPHILIC INFLAMMATION IN PATIENTS WITH UNCONTROLLED ASTHMA ON INHALED CORTICOSTEROIDS AND A SECOND CONTROLLER MEDICATION | Number Agreed | 4 | 4 | Date Agreed | 31/03/2016 | 0 | 31/03/2016 | 0 | Recruitment Finished | 5 patients failed screening; strict eligibility criteria made recruitment very challenging. |
| 14/NE/1109 | Cardiac Resynchronization Therapy Efficacy Enhancements (CRTee) | Number Agreed | 5 | 5 | Date Agreed | 01/01/2017 | 1 | 25/01/2016 | 1 | Recruitment Finished | Contracting delays. |
| 14/NE/1214 | A Randomized, Open-Label, Multicenter, Phase 3 Trial Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Investigator's Choice of Standard Chemotherapy in Subjects Receiving First Cytotoxic Chemotherapy for Metastatic or Advanced Non-Squamous | Number Agreed | 4 | 4 | Not Available / Not Agreed | | 7 | 30/06/2016 | 7 | Recruitment Finished | Study recruited to target. |
| 14/NW/1354 | A Single Arm, Open-label, Long-term Efficacy and Safety Study of Romiplostim in Thrombocytopenic Pediatric Subjects With Immune Thrombocytopenia (ITP) | Number Agreed | 5 | 5 | Date Agreed | 28/02/2017 | 6 | 02/08/2016 | 6 | Recruitment Finished | Study recruited to time and target. |
| 14/SC/0032 | PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS | Range Agreed | 12 | 50 | Date Agreed | 27/07/2017 | 13 | 22/07/2016 | 13 | Recruitment Finished | Study recruited to time and target. |
| 14/SC/0033 | PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS | Number Agreed | 5 | 5 | Date Agreed | 07/07/2016 | 13 | 26/01/2016 | 13 | Recruitment Finished | Study recruited to time and target. |
| 14/SC/1014 | A Randomized, DoubleBlind, 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 FirstLine Chemothera | Number Agreed | 2 | 2 | Date Agreed | 26/01/2016 | 2 | 08/01/2016 | 4 | Recruitment Finished | Study recruited to time and target. |
| 14/SC/1059 | A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy | Range Agreed | 5 | 10 | Not Available / Not Agreed | | 0 | 14/09/2016 | 0 | Withdrawn By Sponsor | Sponsor withdrew study. |
| 14/SW/0091 | Randomized, DoubleBlind, Multicenter, Phase 3 Study Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Previously Untreated Advanced or Metastatic Squamous NonSmall Cell Lung Cancer (NSCLC) | Number Agreed | 6 | 6 | Date Agreed | 31/03/2016 | 6 | 12/02/2016 | 6 | Recruitment Finished | Study recruited to time and target. |

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| 14/SW/0115 | Safety and Efficacy of the Veniti Vici? Venous Stent System (Veniti Inc.) when Used to Treat Clinically Significant Chronic Non-malignant Obstruction of the Iliofemoral Venous Segment Subtitle: A Study Looking at the Veniti Vici? Venous Stent Syste | Number Agreed | 12 | 12 | Date Agreed | 31/03/2017 | 1 | 28/10/2016 | 1 | Withdrawn By Sponsor | Late amendments to study which then fully recruited globally. |
| 14/WM/0170 | A Phase 3, Randomized Study To Evaluate the Efficacy of Momelotinib versus Best Available Therapy in Anemic or Thrombocytopenic Subjects with Primary Myelofibrosis, Post-polycythemia Vera Myelofibrosis, or Post-essential Thrombocythemia Myelofibrosis | Number Agreed | 2 | 2 | Date Agreed | 01/10/2020 | 3 | 14/01/2016 | 3 | Recruitment Finished | Study recruited to time and target. |
| 14/WM/1202 | A Phase 1b, Randomized, Double-Blind (Sponsor Open), Placebo-Controlled Study To Evaluate The Safety, Tolerability, Pharmacokinetics, And Pharmacodynamics Of Pf-04447943, Co-Administered With And Without Hydroxyurea, In Subjects With Stable Sickle Ce | Number Agreed | 5 | 5 | Date Agreed | 22/10/2015 | 1 | 31/05/2016 | 1 | Withdrawn By Sponsor | Rare disease study. |
| 14/WS/1105 | A Multicenter, Randomized, Open-Label Study to Assess the Impact of Natalizumab versus Fingolimod on Central Nervous System Tissue Damage and Recovery in Active Relapsing Remitting Multiple Sclerosis Subjects | Number Agreed | 20 | 20 | Date Agreed | 25/01/2016 | 0 | 19/11/2016 | 0 | Withdrawn By Sponsor | Contracting delays. Sponsor then closed study. |
| 14/YH/1234 | A phase III, doubleblind, randomised study to assess the efficacy and safety of AZD9291 versus a standard of care Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor as firstline treatment in patients with Epidermal Growth Factor Receptor Muta | Number Agreed | 1 | 2 | Date Agreed | 28/02/2016 | 0 | 28/02/2016 | 0 | Recruitment Finished | Sponsor delays with activation of site, equipment provision. |
| 15/EE/0350 | A Phase III, randomised, double blind, placebo-controlled, parallel group, efficacy, safety and tolerability trial of once daily, oral doses of Empagliflozin as Adjunctive to insulin therapy over 26 weeks in patients with Type 1 Diabetes Mellitus | Number Agreed | 5 | 5 | Date Agreed | 31/12/2016 | 1 | 31/12/2016 | 1 | Recruitment Finished | Study team absences. |
| 15/EE/0464 | A phase 3, Placebo-Controlled, Randomized, Double-Blind, Multi-Center Study of LJPC-501 in Patients with Catecholamine-Resistant Hypotension (CRH) | Number Agreed | 3 | 3 | Date Agreed | 30/09/2016 | 0 | 01/12/2016 | 0 | Withdrawn By Sponsor | Study team screened several patients but none suitable. |
| 15/EM/0487 | A Randomized, Open-Label, Active-Controlled, Multicenter Study to Compare Efficacy and Safety of ABT-493/ABT-530 to Sofosbuvir Co-Administered with Daclatasvir in Adults with Chronic Hepatitis C Virus Genotype 3 Infection (ENDURANCE-3) | Number Agreed | 4 | 4 | Date Agreed | 30/04/2016 | 8 | 27/04/2016 | 8 | Recruitment Finished | Study recruited to time and target. |
| 15/ES/0184 | A Phase 3, Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 12 Weeks in Direct-Acting Antiviral-Experienced Subjects with Chron | Range Agreed | 3 | 5 | Date Agreed | 01/05/2016 | 2 | 25/03/2016 | 2 | Recruitment Finished | Sponsor closed recruitment early - globally fast recruitment. |
| 15/ES/0185 | A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS9857 Fixed-Dose Combination for 8 Weeks Compared to Sofosbuvir/Velpatasvir for 12 Weeks in Direct-Acting Antiviral-Na?ve S | Number Agreed | 7 | 7 | Date Agreed | 30/04/2016 | 3 | 18/03/2016 | 3 | Recruitment Finished | Sponsor closed recruitment early - globally fast recruitment. |
| 15/ES/0192 | A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 12 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks in Direct-Acting Antiviral-Experienced S | Number Agreed | 3 | 3 | Date Agreed | 30/04/2016 | 3 | 25/03/2016 | 3 | Recruitment Finished | Study recruited to time and target. |
| 15/LO/0140 | CLEANER Assessment of efficacy and safety for a new wound dressing URGO 310 3166 in the local treatment of venous or mixed leg ulcers: a European, randomised clinical trial. | Number Agreed | 4 | 4 | Date Agreed | 31/08/2016 | 4 | 31/05/2016 | 4 | Withdrawn By Sponsor | Study recruited to time and target. |
| 15/LO/0691 | 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 o | Number Agreed | 4 | 4 | Date Agreed | 15/04/2016 | 4 | 06/07/2016 | 6 | Recruitment Finished | Study recruited to time and target. |

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| 15/LO/0743 | A phase I, randomised, double-blind, placebo-controlled, multi-centre, ascending-dose trial to evaluate the safety, tolerability and immunogenicity of Vaccine FP-02.2 in HBeAg-negative hepatitis B patients as an add-on treatment to entecavir or tenof | Number Agreed | 12 | 12 | Not Available / Not Agreed | | 12 | 31/01/2016 | 12 | Recruitment Finished | Study recruited to target. |
| 15/LO/0863 | AG348-C-003: A Phase 2, Open Label, Randomized, Dose Ranging, Safety, Efficacy, Pharmacokinetic and Pharmacodynamic Study of AG-348 in Adult Patients with Pyruvate Kinase Deficiency. | Number Agreed | 5 | 5 | Date Agreed | 18/08/2017 | 8 | 30/09/2016 | 8 | Recruitment Finished | Study recruited to time and target. |
| 15/LO/0881 | A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA? Once-Daily in Treatment-Na?ve HIV-1 Infected Subjects | Number Agreed | 5 | 5 | Date Agreed | 31/01/2016 | 0 | 08/01/2016 | 0 | Withdrawn By Sponsor | Sponsor closed study early - no eligible patients were seen. |
| 15/LO/0940 | A Phase 3, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Idelalisib in Combination with Obinutuzumab Compared to Chlorambucil in Combination with Obinutuzumab for Previously Untreated Chronic Lymphocytic Leukemia | Number Agreed | 4 | 4 | Not Available / Not Agreed | | 0 | 14/03/2016 | 0 | Withdrawn By Sponsor | Study terminated early by sponsor due to a change in the risk profile of the study drug. |
| 15/LO/1228 | An Open-Label Study to Evaluate the Safety and Efficacy of Ombitasvir/Paritaprevir/Ritonavir with or without Dasabuvir in Adults with Genotype 1a or Genotype 4 Chronic Hepatitis C Virus (HCV) Infection, with Severe Renal Impairment or End-Stage Renal | Number Agreed | 4 | 4 | Date Agreed | 30/06/2016 | 2 | 29/02/2016 | 2 | Recruitment Finished | Several patients were screened by the agreed date but were not eligible. |