Brighton & Sussex University Hospitals NHS Trust

Performance in Delivering Research

1st October 2012 to 30th September 2013

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
12/NE/0114	Symptom Effectiveness Study of VizAblate?? Intrauterine Ultrasound-Guided RF Ablation (IUUSgRFA) in the Ablation of Large Uterine Fibroids	8	No date agreed with sponsor	Suspended	N/A
12/LO/0062	Phase 3 Randomized Double-Blind Placebo-Controlled Study of Effects of Ranolazine on Major Adverse Cardiovascular Events in Subjects with a History of Chronic Angina Who Undergo Percutaneous Coronary Intervention with Incomplete Revascularization	20	01/11/2013	Open	N/A
12/LO/1188	A Study of HSP90 Inhibitor AT13387 Alone or in Combination with Abiraterone Acetate in the Treatment of Castration-Resistant Prostate Cancer (CRPC) no Longer Responding to Abiraterone	10	01/06/2014	Open	N/A
11/SC/0524	Phase 3b Randomized Open Label Study to Evaluate Switching from Regimens Consisting of a NNRTI plus Emtricitabine (FTC) and TDF to EVG/COBI/FTC/TDF in VirologicallySuppressed, HIV1 Infected Patients	5	No date agreed with sponsor	Closed - In Follow Up	Y
11/LO/1740	A multicenter, randomised, doubleblind,comparative trial of Maraviroc + Darunavir/Ritonavir versus Emtricitabine/Tenofovir + Darunavir/Ritonavir for the treatment of antiretroviral na?ve HIV infected patients with CCR5tropicHIV1	5	29/08/2012	Closed - Follow Up Complete	N
12/YH/0177	Ingenol Mebutate Gel, 0.015% Repeat Use for AKs on Face and Scalp	10	30/11/2012	Closed - In Follow Up	Y
12/SC/0429	A Phase II, multi-center, open-label, neoadjuvant, randomized study of weekly paclitaxel with or without LCL161 in patients with triple negative breast cancer	2	07/05/2014	Open	N/A
12/SC/0035	A 6-month safety and benefit study of inhaled fluticasone propionate/ salmeterol combination versus inhaled fluticasone propionate in the treatment of 6,200 paediatric subjects 4-11 years old with persistent asthma	2	31/08/2015	Open	N/A
12/SC/0098	A safety and efficacy study of inhaled fluticasone propionate/ salmeterol combination versus inhaled fluticasone propionate in the treatment of adolescent & adult subjects with persistent asthma	2	30/06/2016	Open	N/A
11/SC/0523	Phase 3b Randomized Open Label Study to Evaluate Switching from Regimens Consisting of a PI/r + FTC/TDF to EVG/COBI/FTC/TDF in Virologically Suppressed HIV 1 Infected Pts	5	14/12/2012	Closed - In Follow Up	N
12/EE/0176	Randomisd Ph 4 placebo-controlld comparative study to evaluate efficacy/safety of tapering MTX dosage vs maintaining dosage in severe active RA patients showing inadeq response to prior conventional DMARDs trtmt & initiatd RoActemra? in combo w/ MTX	5	01/04/2014	Open	N/A
11/WM/0050	A PHASE 3, MULTICENTER, OPEN-LABEL, EXTENSION STUDY TO ASSESS THE SAFETY AND TOLERABILITY OF EPRATUZUMAB TREATMENT IN SYSTEMIC LUPUS ERYTHEMATOSUS SUBJECTS	3	No date agreed with sponsor	Open	N/A
11/NW/0864	A Phase 1/2 Study to Assess the Safety and Efficacy of Lorvotuzumab Mertansine (IMGN901) in Combination with Carboplatin/Etoposide in Patients with Advanced Solid Tumors including Extensive Stage Small Cell Lung Cancer	3	31/01/2015	Open	N/A
12/LO/1156	A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs. Prednisone in Metastatic Castration-resistant Prostate Cancer Patients who have Received Prior Docetaxel and Prior Abiraterone or MDV3100	6	31/12/2013	Open	N/A
12/NE/0198	Multicentre Single-Blind Randomised Parallel-Group Study to Assess Short & Long-Term Efficacy of Certolizumab Pegol + Methotrexate Compared with Adalimumab + Methotrexate in Subjects with Moderate to Severe RA Responding Inadequately to Methotrexate	5	01/10/2013	Open	N/A

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11/LO/1921	Randomized 2 arm open-label multicenter Phase 2 trial assessing efficacy & safety of pertuzumab given in combo w/trastuzumab & aromatase inhibitor in 1st line pts w/HER2+ & hormone receptor+ advanced (metastatic/locally advanced) breast cancer	5	29/01/2016	Open	N/A
12/EM/0389	Study NOG112264, a Phase II Study of Ozanezumab(GSK1223249) versus Placebo in the Treatment of Amyotrophic Lateral Sclerosis	2	No date agreed with sponsor	Closed - In Follow Up	Y
11/LO/1810	A prospective, single arm feasibility study to evaluate the safety and performance of the SMT? Embolic Deflection Device in patients undergoing Transcatheter Aortic Valve Replacement (TAVR): DEFLECT I SMT Embolic DEFLECTion CE Marke Trial	6	04/03/2013	Closed - In Follow Up	Y
11/AL/0167	CLINICAL INVESTIGATION OF A DES (MISTENT? SYSTEM) WITH SIROLIMUS AND A BIOABSORBABLE POLYMERFOR THE TREATMENT OF PATIENTS WITH DE NOVO LESIONS IN NATIVE CORONARY ARTERIES	8	21/07/2011	Closed - In Follow Up	N
10/H0808/137	GORE HELEX Septal Occluder and Antiplatelet Medical Management for Reduction of Recurrent stroke or Imaging-confirmed TIA in patients with Patent Foramen Ovale (PFO)	20	No date agreed with sponsor	Closed - In Follow Up	N
11/LO/0529	A prospective, single arm, multicenter clinical registry evaluating the change in migraine headaches in migraine with aura patients who undergo patent foramen ovale (PFO) closure with the Coherex FlatStent? EF PFO Closure System	No Target Agreed With Sponsor	No date agreed with sponsor	Withdrawn	N
12/EE/0201	GORE? Septal Occluder EU Clinical Evaluation: A Study to evaluate clinical success and performance in the treatment of transcatheter closure of Patent Foramen Ovale (PFO)	10	30/12/2013	Open	N/A
12/NI/0181	REPRISE II: REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus? Valve System ? Evaluation of Safety and Performance.	0	31/01/2019	Open	N/A
11/SC/0327	A Phase 3, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multi-centre Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Participants with Moderately to Severely Active Crohn?s Disease	6	15/09/2013	Closed - Follow Up Complete	N
11/SC/0326	Phase 3 Randomized Double-blind Placebo-controlled Parallel-group Multicenter Study to Evaluate Safety/Efficacy of Ustekinumab Induction Therapy in Subjects + Mod/Severe Active Crohn?s Disease Who Have Failed/Are Intolerant to TNF Antagonist Therapy	6	15/09/2013	Closed - Follow Up Complete	N
11/SC/0329	Phase 3 Randomized Double-blind Placebo-controlled Parallel-group Multicenter Study to Evaluate Safety/Efficacy of Ustekinumab Maintenance Therapy in Subjects w/ Mod/Severe Active Crohn?s Disease Who Failed/Are Intolerant to TNF Antagonist Therapy	12	01/10/2017	Open	N/A
11/LO/1498	PROTEAse inhibitor (DRV/rtv) in mono- or triple therapy in suppressed HIV-1 infected subjects.	10	31/01/2013	Closed - In Follow Up	Y
11/LO/1081	Open-Label Randomized Study Evaluating a Switch from 2 NRTI + any 3rd Agent to either A/R 1 Daily & Raltegravir 2 Daily or A/R 1 Daily & Tenofovir/Emtricitabine 1 Daily in Virologically Suppressed HIV-1 Infected Subjects + Safety/Tolerability Issues	5	01/03/2013	Closed - In Follow Up	Y
11/SC/0243	Safety/Efficacy of 240 mg BI 201335 once daily in combo + pegylated interferon alpha 2a & ribavirin for treatment of chronic HCV genotype 1 infection in HIV/HCV-co-infected patients	3	01/08/2015	Open	N/A
11/LO/0751	A Phase 3, Open-label Safety study of Cobicistat-containing Highly Active Antiretroviral Regimens in HIV-1 Infected Patients with Mild to Moderate Renal Impairment	5	01/11/2013	Open	Y
13/LO/0006	A Phase 3, Open-label Study to Investigate the Efficacy and Safety of Sofosbuvir plus Ribavirin in Chronic Genotype 1, 2, 3 and 4 Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) Co-infected Subjects	6	30/06/2013	Closed - In Follow Up	N
12/NW/0105	Phase III Randomized Double-Blind Placebo-Controlled Adaptive Design Study of Efficacy/Safety/Tolerability of Single Infusion of MK-3415 , MK-6072, and MK-3415A in Patients Receiving Antibiotic Therapy for Clostridium difficile Infection	1	14/02/2014	Open	N/A
11/H0903/1	Symptom Effectiveness Study of VizAblate? Intrauterine Ultrasound- Guided RF Ablation (IUUSgRFA) in the Ablation of Uterine Fibroids (FAST-EU)	5	01/06/2014	Open	N/A

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12/NI/0146	A Phase 3 Randomized, Double-Blind, Placebo-Controlled study of the safety and effectiveness of Immune Globulin Intravenous (Human), 10% solution (IVIG, 10%) for the treatment of mild to moderate Alzheimer's Disease (AD).	10	No date agreed with sponsor	Withdrawn	N
10/H1102/85	Protocol H8A-MC-LZAO Continued Efficacy and Safety Monitoring of Solanezumab, an Anti-Amyloid ? Antibody in Patients with Alzheimer?s Disease	20	13/06/2012	Closed - In Follow Up	N
11/LO/0537	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy of Natalizumab on Reducing Disability Progression in Subjects With Secondary Progressive Multiple Sclerosis	6	27/02/2015	Open	Y
10/H0711/11	Multicenter Double-blind Randomized Parallel-group Monotherapy Active-control Study to Determine Efficacy/Safety of DAC HYP versus Avonex (Interferon ? 1a) in Patients with Relapsing-Remitting Multiple Sclerosis	8	No date agreed with sponsor	Closed - In Follow Up	N
12/NW/0723	A multi-centre, open-label, long term safety extension of phase II studies ABE4869g and ABE4955g in patients with mild to moderate Alzheimer's Disease.	6	31/10/2013	Open	N/A
10/H0903/29	BIA-2093-311: Efficacy and safety of eslicarbazepine acetate (BIA 2-093) as monotherapy for patients with newly diagnosed partial-onset seizures: A double-blind, randomized, active-controlled, parallel-group, multicenter clinical study.	15	16/01/2013	Withdrawn	N
11/LO/1750	PHASE 3 RANDOMIZED MULTICENTER 2-ARM OPEN-LABEL TRIAL TO EVALUATE EFFICACY OF T-DM1 COMPARED WITH PHYSICIAN?S CHOICE TREATMENT IN PTS + HER2-POSITIVE METASTATIC BREAST CANCER WHO HAVE RECEIVED AT LEAST 2 PRIOR REGIMENS OF HER2-DIRECTED THERAPY	4	01/09/2013	Open	N/A
11/LO/1136	A Randomised, multi-centre cross-over study to evaluate patient preference and Health Care Professional (HCP) satisfaction with subcutaneous administration of trastuzumab in HER2 -positive early breast cancer (EBC)	5	01/02/2012	Closed - In Follow Up	N
11/LO/1381	A phase II double-blind placebo-controlled randomized study of GDC-0941 or GDC-0980 with Fulvestrant versus Fulvestrant in advanced or metastatic breast cancer in patients resistant to aromatase inhibitortherapy	5	31/01/2013	Closed - In Follow Up	Y
10/H0505/98	Amendment to Randomized double-blind Phase III trial of FOLF(HA)iri vs FOLFIRI for second or third line therapy in irinotecan-na?ve patients with metastatic colorectal cancer	10	No date agreed with sponsor	Withdrawn	N
13/LO/0033	Genentech GO28509-PEGGY: A PHASE II, randomized STUDY OF paclitaxel with GDC-0941 versus paclitaxel with placebo IN PATIENTS WITH LOCALLY RECURRENT OR METASTATIC BREAST CANCER	3	01/09/2014	Open	N/A
10/H0703/69	A RANDOMIZED, PHASE II, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY EVALUATING THE SAFETY AND EFFICACY OF ONARTUZUMAB AND/OR BEVACIZUMAB IN COMBINATION WITH PACLITAXEL IN PATIENTS WITH METASTATIC, TRIPLE-NEGATIVE BREAST CANCER	5	31/03/2013	Closed - In Follow Up	Y
09/H0724/39	Evaluation of Safety and Effectiveness of the Formula? PTX? Balloon-Expandable Stent for Renal Artery Stenosis	12	01/12/2013	Closed - In Follow Up	N
09/H1306/104	Randomised double blind placebo-controlled pivotal study to evaluate efficacy and safety of rPhleum in adult and adolescent patients suffering from rhinoconjunctivitis +/- controlled Asthma	10	01/08/2010	Closed - In Follow Up	Y
11/WM/0048	A PHASE 3, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTRE STUDY OF THE EFFICACY AND SAFETY OF FOUR 12-WEEK TREATMENT CYCLES (48 WEEKS TOTAL) OF EPRATUZUMAB IN SYSTEMIC LUPUS ERYTHEMATOSUS SUBJECTS WITH MODERATE TO SEVERE DISEASE (EMBODY 1)	3	01/06/2014	Open	N/A
11/NW/0200	A Phase 2b dose ranging study to evaluate the efficacy and safety of sifalimumab in sdult subjects with systemic lupus erythematosus	5	05/10/2012	Closed - In Follow Up	Y

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12/SC/0469	A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of SAR236553/REGN727 in Patients With Heterozygous Familial Hypercholesterolemia Not Adequately Controlled With Their Lipid-Modifying Therapy	6	No date agreed with sponsor	Closed - In Follow Up	N
09/H0406/110	A multicenter randomized double-blind parallel group active-controlled study to evaluate efficacy/safety of LCZ696 compared to enalapril on morbidity & mortality in patients with chronic heart failure & reduced ejection fraction	6	25/06/2011	Closed - In Follow Up	N
11/NW/0338	Clinical Outcomes Study to compare effect of Fluticasone Furorate/Vilanterol Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate COPD and a history of or at increased risk for cardiovascular disease.	8	03/03/2014	In set up	N/A
12/SW/0378	Effect of Bivalirudin on Aortic Valve Intervention outcomes 2/3	20		In set up	N/A
13/LO/0129	A Phase 4 Cross-Sectional Study of Bone Mineral Density in HIV-1 Infected Subjects	6	31/05/2014	In set up	N/A
13/LO/0572	Phase 3 Randomized Double-Blind Study to Evaluate Safety/Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide VS Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1+ Antiretroviral Treatment-Naive Adults	10	No date agreed with sponsor	Open	N/A
13/LO/0574	Phase 3 Randomized Double-Blind Study to Evaluate Safety/Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide vs Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1+ Antiretroviral Treatment-Naive Adults	10	No date agreed with sponsor	Open	N/A
13/LO/0821	A Phase 3 Open-label Safety Study of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Single-Tablet Regimen in HIV-1 Positive Patients with Mild to Moderate Renal Impairment	5	31/12/2013	Open	N/A
13/LO/0830	Phase 3 open label study evaluating efficacy/safety of pegylated interferon lambda-1a, in combination + ribavirin and daclatasvir, for treatment of chronic HCV infection + treatment na?ve genotypes 1, 2, 3 or 4 in subjects co-infected + HIV	5	31/10/2014	Open	N/A
13/NW/0002	Prospective, randomised, controlled investigation comparing the safety and performance of 032-11 Surgical Haemostat 2g Applicator with FLOSEAL? Haemostatic Matrix as an adjunctive haemostat in cardiac surgery and thoracic aortic surgery	34	28/02/2014	Open	N/A
13/NW/0316	Phase 4 trial comparing cumulative incidence of SCC after treatment + ingenol mebutate & imiquimod for multiple actinic keratoses on face &scalp. A multi-centre, randomised, two-arm, open label, active-controlled, parallel group, 36-month trial.	8	31/05/2015	Open	N/A
13/SC/0279	A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically Suppressed, HIV1 Positive Subjects.	No Target Agreed With Sponsor	No date agreed with sponsor	Open	N/A
10/H0715/57	Phase 3 efficacy and safety study of oral MDV3100 in chemo na?ve patients with progressive metastatic prostate cancer who have failed androgen deprivation therapy	10	01/09/2012	Closed - In Follow Up	N