

Performance in Delivering Clinical Research - Quarter 1 (2015/16)

All hosted, commercial clinical trials active between 01 July 2014 - 30 June 2015

| Trust Reference Code | Research Ethics Committee Reference Number | Name of Trial | Recruitment Target | Date Agreed to Recruit Target Number of Patients | Trial Status | Target Met Within Agreed Timeframe? | Comments |
|----------------------|--|---|--------------------------|--|-----------------------|-------------------------------------|--|
| C&W13/085 | 13/EE/0270 | A Global Registry to Evaluate Long-Term Effectiveness of Neurostimulation Therapy for Pain | 30 | 04/07/2016 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W14/079 | 14/EE/1063 | A Phase III, Open Label, Randomized Study of AZD9291 versus Platinum-Based Doublet Chemotherapy for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer whose Disease has Progressed with Previous Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy and whose Tumours harbour a T790M mutation within the Epidermal Growth Factor Receptor Gene | 2 | 31/08/2015 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W14/120 | 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. | 1 | 04/01/2016 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W14/126 | 14/YH/1269 | Open label evaluation of the population PK profile, safety, tolerability and efficacy of tapentadol IV solution for the treatment of post-surgical pain in children aged from birth to less than 2 years, including pre term neonates (KF5503-73). | 1 | 31/08/2016 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W14/131 | 14/NE/1099 | GA29103 - Phase III, randomised, multicentre, double blind, double dummy, study to evaluate the efficacy and safety of etrolizumab compared with infliximab in patients with moderate to severe active ulcerative colitis who are naive to TNF inhibitors | 4 | No date agreed with sponsor | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W13/081 | 14/LO/0565 | A Multicentre, Randomised, Placebo-controlled, Double-blind Study of the Efficacy, Safety, and Pharmacokinetics of Lubiprostone in Paediatric Subjects Aged = 6 Years to < 18 Years with Functional Constipation | 2 | 01/10/2015 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W15/002 | 15/WM/0050 | Efficacy and safety of ingenol mebutate gel 0.015% compared to diclofenac sodium gel 3% in subjects with actinic keratoses on the face or scalp. | 12 | 30/11/2015 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W15/023 | 14/NE/1100 | An open label, extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in etrolizumab phase III studies | No target set by sponsor | No date agreed with sponsor | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W15/052 | 14/WM/1210 | A Phase 3, randomized, active-controlled, open-label study to evaluate the efficacy, safety and tolerability of switching to a darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once-daily single-tablet regimen versus continuing the current regimen consisting of a boosted protease inhibitor (bPI) combined with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) in virologically-suppressed, human immunodeficiency virus type 1 (HIV-1) infected subjects. | 5 | 01/12/2017 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W15/053 | 13/EE/0214 | A Long-Term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Resistance Patterns of Subjects with Chronic Hepatitis C Who Have Been Previously Treated with MK-5172 in a Prior Clinical Trial. | 8 | 15/10/2018 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W15/059 | 15/LO/0495 | A phase 3b, randomised, double-blind, switch study to evaluate the safety and efficacy of emtricitabine / rilpivirine / tenofovir alafenamide (FTC/RPV/TAF) fixed dose combination (FDC) in HIV-1 positive subjects who are virologically suppressed on emtricitabine / rilpivirine / tenofovir disoproxil fumarate (FTC/RPV/TDF). | 5 | 22/06/2017 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W15/060 | 15/LO/0496 | GS-US-366-1160: A phase 3b, randomised, double-blind, study to evaluate switching from a regimen consisting of efavirenz / emtricitabine / tenofovir disoproxil fumarate (EFV/FTC/TDF) fixed dose combination (FDC) to emtricitabine / rilpivirine / tenofovir alafenamide (FTC/RPV/TAF) FDC in virologically. | 7 | 31/10/2016 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W15/064 | 15/LO/0438 | GS-US-337-1612: Open-label study to evaluate the safety and efficacy of ledipasvir / sofosbuvir (LDV/SOF) fixed-dose combination (FDC) for 6 weeks in subjects with acute genotype 1 or 4 hepatitis C virus (HCV) and chronic human immunodeficiency virus (HIV)-1 co-infection. | 5 | 29/04/2016 | Open | Not applicable | Trial remains open and therefore is still able to meet recruitment target. |
| C&W11/075 | 11/SC/0329 | A Phase 3, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multi-centre Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects with Moderately to Severely Active Crohn's Disease | 5 | No date agreed with sponsor | Closed - in follow up | Yes | Trial remained in follow up during this reporting period. 5 patients were screened, of which 5 patients were enrolled. |
| C&W12/016 | 11/LO/1974 | A Multicenter, controlled, Open-Label Extension (OLE) Study To Assess the Long-Term Safety and Efficacy of AMG 145 | 2 | 19/03/2013 | Closed - in follow up | No | Trial remained in follow up during this reporting period. 1 patient was screened, of which 1 patient was enrolled. |
| C&W12/092 | 12/LO/1434 | Lung Volume Reduction Coil Treatment in Patients with Emphysema (RENEW) Study | 8 | 30/10/2014 | Closed - in follow up | Yes | Trial remained in follow up during this reporting report. |
| C&W13/015 | 11/LO/1455 | Gilead HCV Registry 0122 Responders | 8 | 01/10/2016 | Closed - in follow up | No | Trial remained in follow up during this reporting period. It was not possible to achieve the recruitment target, as only those patients enrolled to an earlier trial with a positive response to treatment were eligible. When the recruitment target was originally set for this trial, it was not possible to ascertain how many patients would be positive responders and therefore an arbitrary target was set, based upon the target for the earlier trial. |
| C&W13/016 | 11/LO/1456 | A Long Term Follow-up Registry Study of Subjects Who Did Not Achieve a Sustained Virologic Response in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection | 5 | 01/10/2016 | Closed - in follow up | No | Trial remained in follow up during this reporting period. It was not possible to achieve the recruitment target, as only those patients enrolled to an earlier trial with a sustained virologic response to treatment were eligible. When the recruitment target was originally set for this trial, it was not possible to ascertain how many patients would be sustained virologic responders and therefore an arbitrary target was set, based upon the target for the earlier trial. |

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| C&W13/039 | 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 (GS-US-292-0112) | 5 | 01/02/2016 | Closed - in follow up | No | Trial remained in follow up during this reporting period. 3 patients were screened, of which 1 patient was enrolled. |
| C&W13/044 | 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 (GS-US-292-0109) | 5 | 22/01/2016 | Closed - in follow up | Yes | Trial remained in follow up during this reporting period. 9 patients were screened, of which 8 patients were recruited. |
| C&W13/050 | 13/LO/0572 | A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Treatment- Naive Adults (GS-US-292-0104) | 10 | 22/01/2016 | Closed - in follow up | No | Trial remained in follow up during this reporting period. 8 patients were screened, of which 6 patients were enrolled. |
| C&W13/052 | 13/LO/0574 | A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Treatment- Naive Adults (GS-US-292-0111) | 10 | 22/01/2016 | Closed - in follow up | No | Trial remained in follow up during this reporting period. 12 patients were screened, of which 9 patients were enrolled. |
| C&W13/068 | 13/EE/0241 | Secukinumab In patients with moderate to severe active, chronic plaque psoriasis who have failed on TNFa antaGoNists: A clinical Trial Evaluating Treatment REsults (SIGNATURE) | 2 | 16/01/2015 | Closed - in follow up | Yes | Trial remained in follow up during this reporting period. 3 patients were screened, of which 2 patients were enrolled. |
| C&W14/063 | 14/LO/0667 | A Phase III Open-Label Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK-5172/MK-8742 in Treatment-Naive Subjects with Chronic HCV GT1, GT4, GT5, and GT6 Infection who are Co-Infected with HIV | 9 | 11/05/2015 | Closed - in follow up | No | Trial remained in follow up during this reporting period. 13 patients were screened, of which 8 patients were enrolled. Due to sponsor closing recruitment sooner than anticipated, enrollment of a further 1 patient was not possible. |
| C&W14/062 | 14/SC/0225 | A Phase 3, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV 1 Positive Subjects who are Virologically Suppressed on Regimens containing FTC/TDF (GS-US-311-1089) | 8 | 15/06/2016 | Closed - in follow up | No | Trial remained in follow up during this reporting period. 7 patients were screened, of which 6 patients were enrolled and due to sponsor closing recruitment sooner than anticipated, enrollment of a further 2 patients was not possible. |
| C&W14/083 | 14/LO/1288 | A multiple dose, open label, pivotal, 4- period, 2-treatment, 2-sequence full replicative cross-over study to assess the bioequivalence (BE) of TEVA's generic once daily nevirapine 400 mg prolonged-release (PR) formulation compared with the approved reference product Viramune® 400mg prolonged-release tablets under fasted conditions in HIV-1 infected patients | 46 | 01/05/2015 | Closed - in follow up | Yes | Trial remained in follow up during this reporting period. 46 patients were screened, of which 46 patients were enrolled. |
| C&W14/092 | 14/LO/1513 | A Randomized, Open Label, Phase 4 Study Evaluating the Renal Effect of Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/ Tenofovir DF or Efavirenz/ Emtricitabine/ Tenofovir DF) compared to Ritonavir boosted Atazanavir plus Abacavir/ Lamivudine in Antiretroviral Treatment-naive HIV-1 Infected Adults with eGFR =70 mL/min | 3 | 04/06/2015 | Closed - in follow up | Yes | Trial remained in follow up during this reporting period. 13 patients were screened, of which 13 patients were enrolled. |
| HHG09004NI | 09/H1102/54 | An International, Multicentre, Prospective Observational study of the safety of maraviroc used with optimized background therapy in treatment-experienced HIV-1 infected patients | 5 | No date agreed with sponsor | Closed - follow up complete | Yes | Last patient last visit took place 01/10/2014, with site having not met recruitment target. 44 patients were screened, of which 44 patients were enrolled. |
| C&W10/046 | 09/S501/68 | A Randomised Multicenter, Open-Label, Phase 3 Study of Gemcitabine-Cisplatin Chemotherapy Plus IMC-11F8 Versus Gemcitabine-Cisplatin Chemotherapy Alone in the First-Line Treatment of Patients with Squamous Stage IIb or IV Non-Small Cell Lung Cancer (NSCLC) | 4 | 31/01/2013 | Closed - follow up complete | No | Last patient last visit took place 24/11/2014, with site having not met recruitment target. 2 patients were screened, of which 1 patient was enrolled. |
| C&W10/103 | 10/H0706/69 | A Phase III, randomised, double blind study of the safety and efficacy of GSK1349572 50 mg once daily to raltegravir 400 mg twice daily both administered with fixed-dose dual nucleoside reverse transcriptase inhibitor therapy over 96 weeks in HIV-1 infected antiretroviral therapy naive adult subjects. | 10 | 31/01/2013 | Closed - follow up complete | No | Last patient last visit took place 31/03/2015, with site having not met recruitment target. 13 patients were screened, of which 9 patients were enrolled. |
| C&W11/044 | 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 | 31/07/2013 | Closed - follow up complete | Yes | Last patient last visit took place 07/10/2014, with site having met recruitment target. 11 patients were screened, of which 7 were enrolled. |
| C&W11/052 | 11/LO/0785 | A Multi-Centre, Randomised, Blinded, Placebo-Controlled Study to Evaluate the Safety of Maraviroc in Combination with Other Antiretroviral Agents in HIV-1 Infected Subjects Co-Infected With Hepatitis C and / or Hepatitis B Virus | 2 | 30/09/2013 | Closed - follow up complete | Yes | Last patient last visit took place 02/03/2015, with site having met recruitment target. 2 patients were screened, of which 2 patients were enrolled. |
| C&W11/100 | 11/LO/1034 | A randomised, prospective study, assessing changes in cerebral function in treatment naive HIV-1 infected subjects commencing either boosted atazanavir with Truvada or boosted drunavir with maraviroc and Kivexa | 7 | No date agreed with sponsor | Closed - follow up complete | No | Last patient last visit took place 25/09/2014, with site having met recruitment target. 6 patients were screened, of which 3 were enrolled. |
| C&W12/017 | 11/SC/0523 | A Phase 3b Randomized, Open Label Study to Evaluate Switching from Regimens Consisting of a Ritonavirboosted Protease Inhibitor (PI/r) plus Emtricitabine/Tenofovir Fixed-Dose Combination (FTC/TDF) to the Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate Single-Tablet Regimen (EVG/COBI/FTC/TDF) in Virologically Suppressed, HIV 1 Infected Patients | 8 | 01/03/2013 | Closed - follow up complete | Yes | Last patient last visit took place 14/10/2014, with site having met recruitment target. 15 patients were screened, of which 8 patients were enrolled. |
| C&W12/018 | 11/SC/0524 | A Phase 3b Randomized, Open-Label Study to Evaluate Switching from Regimens Consisting of a Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI) plus Emtricitabine (FTC) and Tenofovir DF (TDF) to the Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate Single-Tablet Regimen (EVG/COBI/FTC/TDF) in Virologically-Suppressed, HIV-1 Infected Patients | 8 | 01/03/2013 | Closed - follow up complete | Yes | Last patient last visit took place 05/11/2014, with site having met recruitment target. 13 patients were screened, of which 9 patients were enrolled. |
| C&W13/013 | 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 | 5 | 15/07/2014 | Closed - follow up complete | Yes | Last patient last visit took place 01/07/2014, with site having met recruitment target. |
| C&W13/026 | 13/LO/0425 | A Randomized, Double-Blind, Controlled Study to Evaluate the Efficacy and Safety of the Combination of ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 With and Without Ribavirin (RBV) in Treatment-Naive Adults with Genotype 1a Chronic Hepatitis C Virus (HCV) Infection (PEARL-IV) | 5 | 01/11/2014 | Closed - follow up complete | No | Last patient last visit took place 29/07/2014, with site not having met recruitment target. |
| C&W13/057 | 13/LO/0830 | Phase 3 open label study evaluating the efficacy and safety of pegylated interferon lambda-1a, in combination with ribavirin and daclatasvir, for treatment of chronic HCV infection with treatment naive genotypes 1, 2, 3 or 4 in subjects co-infected with HIV | 5 | 15/02/2015 | Closed - follow up complete | No | Last patient last visit took place 29/09/2014, with site having not met recruitment target. 4 patients were recruited, and due to sponsor closing recruitment sooner than anticipated, recruitment of a further 1 patient was not possible. |
| C&W13/075 | 13/EE/0276 | A Phase 3B Randomized, Open-Label Multi-Center Trial Assessing Sofosbuvir + Ribavirin for 16 or 24 Weeks and Sofosbuvir + Pegylated Interferon + Ribavirin for 12 Weeks in Subjects with Genotype 2 or 3 Chronic HCV Infection (GS-US-334-0153) | 5 | 21/05/2014 | Closed - follow up complete | No | Last patient last visit took place 23/10/2014 with site having not met recruitment target. 3 patients were screened, of which 3 patients were enrolled. |

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| C&W14/066 | 14/LO/0803 | Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Pharmacodynamics, Safety and Pharmacokinetics of BMS-955176 (Double-Blinded) and BMS-955176 with Atazanavir +/- Ritonavir (Open-Labeled) in HIV-1 Infected Subjects | 22 | 23/12/2014 | Closed - follow up complete | No | Last patient last visit took place 16/10/2014, with site having not met recruitment target. 6 patients were screened, of which 4 were enrolled. |
| C&W14/098 | 14/LO/1381 | A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Reformulated Raltegravir 1200 mg Once Daily Versus Raltegravir 400 mg Twice Daily, Each in Combination With TRUVADA™, in Treatment-Naive HIV-1 Infected Subjects | 5 | 30/03/2017 | Closed - follow up complete | No | Last patient last visit took place 04/03/2015, with site not having met recruitment target. 2 patients were screened, of which 2 were enrolled. |
| C&W13/073 | 13/LO/1290 | A Follow-up Study to Assess Resistance and Durability of Response to AbbVie Direct-Acting Antiviral Agent (DAA) Therapy in Subjects Who Participated in Phase 2 or 3 Clinical Studies for the Treatment of Chronic Hepatitis C Virus (HCV) Infection | 3 | 08/11/2016 | Withdrawn | No | Trial closed by sponsor due to a change in development pipeline within sponsor company. Trial is a roll over trial, and sponsor decided to close the trial on 02/04/2014, prior to any patients rolling over on to the trial at site. As such, sponsor did not expect any recruitment at site. |