# US Postmarketing Study Commitments (Updated June 2016)

| Compound Name | Description of Commitment | NDA Number | Date Commitment Given | FDA Projected Completion Date | Study Status | Notes |
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| **Arimidex** | Although not required to obtain pediatric exclusivity, we request that you make a commitment to monitor annually the participants until age 12 or until discontinuation of drug and that you submit information in your annual reports. The patients should be monitored with respect to the study endpoints and the drug safety parameters. | | As contained in Pediatric Written Request and reaffirmed in NDA submission September 2007 | Not Applicable | Ongoing | Not on FDA website. |
| **Bydureon® (Exenatide LAR)** | A randomized and controlled pediatric study under PREA to evaluate the safety, efficacy, and pharmacokinetics of BYDUREON (exenatide extended-release for injectable suspension) for the treatment of type 2 diabetes mellitus in pediatric patients ages 10-17 years (inclusive). | 22200 | 27-Jan-12 | 31-Jul-17 | Delayed | |
| **Bydureon® (Exenatide LAR)** | A medullary thyroid carcinoma case series registry of at least 15 years duration to systematically monitor the annual incidence of medullary thryroid carcinoma in the United States and to identify any increase related to the introduction of Bydureon (exenatide for injectable suspension) into the marketplace. This study will also establish a registry of incident cases of medullary thyroid carcinoma and characterize their medical histories related to diabetes and use of BYDUREON (exanatide for injectable suspension) . | 22200 | 27-Jan-12 | 30-Sep-28 | Ongoing | |

| Compound Name | Description of Commitment | NDA Number | Date Commitment Given | FDA Projected Completion Date | Study Status | Notes |
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| **Bydureon® (Exenatide LAR)** | A randomized, double blind, placebo-controlled trial evaluating the effect of Bydureon (exenatide extended-release for injectable suspension) on the incidence of major adverse cardiovascular events (MACE) in subjects with type 2 diabetes mellitus (T2DM). The trial must also assess adverse events of interest including the long-term effects of BYDUREON (exenatide extended-release for injectable suspension) on potential biomarkers of medullary thyroid carcinoma (e.g., serum calcitonin) as well as long-term effects on thyroid neoplasms, pancreatitis (including hemorrhagic and necrotizing forms), pancreatic cancer, serious injection site reactions (including nodules), allergic/hypersensitivity events, serious hypoglycemia, and renal disorders. | 22200 | 27-Jan-12 | 31-Dec-18 | Ongoing | |
| **Bydureon® (Exenatide LAR)** | A 2-year study in mice to determine the reversibility of C-cell hyperplasia, the potential of hyperplasia to progress to neoplasia, and GLP-1 receptor expression on C-cells after 6 months of treatment with exenatide for injectable suspension. | 22200 | 27-Jan-12 | 31-Mar-16 | Submitted | |
| **Bydureon Exanatide)** | A study to evaluate and compare GLP-1 receptor expression/density on human, rat, and mouse thyroid C-cells. This should include evaluation of mouse tissue from PMR 1860-2 following exenatide for injectable suspension treatment for 6 months as well as following 1.5 year recovery | 22200 | 27-Jan-12 | 30-Nov-15 | Submitted | Final report submitted to the FDA on Friday, May 27, 2016. |
| **Bydureon® (Exenatide LAR)** | A study to evaluate the dependence of the GLP-1 receptor for exenatide-induced C-cell hyperplasia and investigate the expression of growth regulatory genes in wild-type and GLP-1 receptor knock-out mice. | 22200 | 27-Jan-12 | 31-Dec-13 | Submitted | |

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| **BYETTA (EXENATIDE) INJ,SOL 0.25MG/ML** | Deferred pediatric study under PREA for the treatment of type 2 diabetes mellitus in pediatric patients ages 10 to 16 years (inclusive). | 21773 | 28-Apr-05 | 31-Dec-18 | Ongoing | |
| **BYETTA (EXENATIDE) INJ,SOL 0.25MG/ML** | A prospective observational cohort study to examine the incidence of pancreatic malignancy and thyroid neoplasm in patients with Type 2 diabetes mellitus initiated on Byetta compared to patients initiated on other antidiabetic agents | 21773 | 28-Apr-05 | 30-Sep-13 | Submitted | |
| **BYETTA (EXENATIDE) INJECTION** | Deferred pediatric study under PREA for the treatment of type 2 diabetes mellitus in pediatric patients ages 10 to 16 years (inclusive). | 21919 | 30-Oct-09 | 31-Dec-18 | Ongoing | |
| **BYETTA (EXENATIDE) INJECTION** | A prospective observational cohort study to examine the incidence of pancreatic malignancy and thyroid neoplasm in patients with Type 2 diabetes mellitus initiated on Byetta compared to patients initiated on other antidiabetic agents | 21919 | 31-Oct-09 | 30-Sep-13 | Submitted | |
| **Casodex** | Post-pediatric Exclusivity Commitment: All patients haven't reached adult height. Although not required at the time of pediatric exclusivity determination, we request that you monitor the study participants until final height is reached in all patients. To this end, submit the information in annual reports. Patients should be monitored with respect to above listed endpoints/assessments every 6 to 12 months. | | As contained in Pediatric Written Request and reaffirmed in NDA submission June 25, 2008 | | Not Applicable | Not on FDA website. |

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| **Daliresp®** | Conduct a controlled clinical trial to evaluate the efficacy of roflumilast as an add-on therapy to a long-acting beta agonist and inhaled corticosteroid fixed-dose combination therapy in the population of COPD patients for which roflumilast is indicated [severe COPD (FEV1 < 50% predicted) associated with chronic bronchitis and a history of exacerbations]. The design of the trial should be appropriate to demonstrate a clinically relevant beneficial effect of roflumilast as an add-on therapy compared to a long-acting beta agonist and inhaled corticosteroid fixed-dose combination treatment. | 22522 | 28-Feb-11 | 31-May-15 | Delayed | |
| **Farxiga® (Dapagliflozin)** | A 26-week randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of dapagliflozin for the treatment of pediatric subjects ages 10 to <18 years of age with type 2 diabetes mellitus (T2DM), as add-on to metformin or as monotherapy, followed by a 26-week double-blind, placebo- or active-controlled extension period (Week 26 to Week 52). At least 30% of randomized subjects will be 10 to 14 years of age and at least one-third and not more than two-thirds of subjects in both age subsets (10 to 14 years and 15 to <18 years) will be female. Secondary safety endpoints should include the effect of dapagliflozin on mineral and bone metabolism, and the effect of dapagliflozin on growth. | 202293 | 8-Jan-14 | 31-Aug-20 | Delayed | |
| **Farxiga® (Dapagliflozin)** | Conduct a study to evaluate dapagliflozin in an orthotopic rodent bladder tumor promotion model. | 202293 | 8-Jan-14 | 31-Aug-16 | Delayed | FDA determined "good cause" for the delay. |

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| **Farxiga® (Dapagliflozin)** | To assess the risk of bladder cancer associated with dapagliflozin, conduct adequate follow-up beyond completion of the cardiovascular outcomes trial (DECLARE) to observe a total of 66 events of bladder cancer, with 80% power to exclude a relative risk of 2.0 for dapagliflozin versus placebo, assuming a 2-sided alpha of 5%. | 202293 | 8-Jan-14 | 31-Dec-24 | Delayed | FDA determined "good cause" for the delay. |
| **Farxiga® (Dapagliflozin)** | Complete a randomized, multicenter, parallel, single-dose study to explore the pharmacokinetics (PK) and pharmacodynamics (PD) of dapagliflozin in children, 10 to 17 years of age with type 2 diabetes mellitus (T2DM) receiving one of the three dose levels of dapagliflozin over the range of 2.5 to 10 mg. At least 30% of randomized subjects in each dose group will be 10 - 15 years of age | 202293 | 8-Jan-14 | 28-Feb-16 | Fulfilled | |
| **Farxiga® (Dapagliflozin)** | An assessment and analysis of all foreign and domestic spontaneous reports of serious hepatic abnormalities and pregnancy outcomes in patients treated with dapagliflozin. The enhanced pharmacovigilance study should continue for 5 years. | 202293 | 8-Jan-14 | 31-Mar-20 | Ongoing | |

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| **Farxiga® (Dapagliflozin)** | A randomized, double-blind, placebo-controlled trial (the DECLARE trial) evaluating the effect of dapagliflozin on the incidence of major adverse cardiovascular events (MACE) in patients with type 2 diabetes mellitus. The primary objective of the trial should be to demonstrate that the upper bound of the 2-sided 95% confidence interval for the estimated risk ratio comparing the incidence of MACE (non-fatal myocardial infarction, non-fatal stroke, cardiovascular death) observed with dapagliflozin to that observed in the placebo group is less than 1.3. The long-term effects of dapagliflozin on the incidence of liver toxicity, bone fractures, nephrotoxicity/acute kidney injury, breast and bladder cancer, complicated genital infections, complicated urinary tract infections/pyelonoephritis/urosepsis, serious events related to hypovolemia and serious hypersensitivity reactions should also be assessed. The estimated glomerular filtration rate (eGFR) should also be monitored over time to assess for worsening of renal function. | 202293 | 8-Jan-14 | 30-Jun-20 | Ongoing | |
| **Farxiga® (Dapagliflozin)** | An enhanced pharmacovigilance study of ketoacidosis in patients treated with dapagliflozin. The study will include reports of ketoacidosis or diabetic ketoacidosis for a period of 5 years, and will include assessment and analysis of spontaneous reports of ketoacidosis in patients treated with dapagliflozin, with specialized follow-up to collect additional information on these cases. | 202293 | 8-Jan-14 | 31-Dec-21 | Pending | |
| **FluMist Quadrivalent (influenza vaccine live, intranasal** | To conduct an observational postmarketing case-control study of the effectiveness of FluMist Quadrivalent in children 2 years through 17 years of age to compare the effectiveness of vaccination with FluMist Quadrivalent to no vaccination and to vaccination with an inactivated influenza vaccine over four influenza seasons. | 125020 | 29-Feb-12 | 31-Dec-18 | Ongoing | |

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| **FluMist Quadrivalent (influenza vaccine live, intranasal)** | To conduct an observational postmarketing safety surveillance study of FluMist Quadrivalent in children 2 years through 8 years of age to evaluate rates of medically attended events in a minimum of 10,000 FluMist Quadrivalent recipients, compared to non-randomized comparison groups. | 125020 | 29-Feb-12 | 30-Jun-19 | Ongoing | |
| **Kombiglyze XR®** | Conduct a 52-week, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of saxagliptin vs. placebo, both as add-on therapy to metformin in pediatric patients with inadequate glycemic control on metformin alone. Approximately one-half of the patients must be on metformin extendedrelease therapy at the time of randomization to add-on saxagliptin vs. add-on placebo. | 200678 | 5-Nov-10 | 30-Jun-18 | Ongoing | |
| **Lynparza®** | Submit the progression-free survival (PFS) and overall survival (OS) analyses with datasets from clinical trial D0818C00002, SOLO-2, the ongoing randomized doubleblind, placebo-controlled, multi-center trial to assess the efficacy of olaparib maintenance monotherapy in relapsed high grade serous ovarian cancer (HGSOC) patients (including patients with primary peritoneal and/or fallopian tube cancer) or high grade endometrioid cancer with BRCA mutations (documented mutation in BRCA1 or BRCA2 that is predicted to be deleterious or suspected deleterious (known or predicted to be detrimental/lead to loss of function)) who have responded following platinum-based chemotherapy. | 206162 | 19-Dec-14 | 31-Mar-19 | Ongoing | |

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| **Lynparza®** | Submit the progression-free survival (PFS) and overall survival (OS) analyses with datasets from clinical trial D0816C00010, a randomized trial establishing the superiority of olaparib over physician's choice single-agent chemotherapy in the treatment of platinum sensitive relapsed ovarian cancer in patients carrying deleterious or suspected deleterious germline BRCA1/2 mutations. | 206162 | 19-Dec-14 | 30-Jun-20 | Ongoing | |
| **Lynparza®** | Collect and analyze all cases of acute myelogenous leukemia/ myelodysplastic syndrome identified in patients treated with Lynparza (olaparib) on an annual basis. These interim reports should summarize all cases identified up until that reporting date (new cases and those reported in previous years), and should include patientstreated with Lynparza on clinical trials and outside of clinical trials (including spontaneous safety reports) to provide an accurate assessment of the long-term incidence and risk of AML/MDS. | 206162 | 19-Dec-14 | 30-Jun-20 | Ongoing | On 6 May 2016, AstraZeneca sent a request to the FDA for change of date of all future reports. |
| **Lynparza®** | Submit the final report for trial D0816C00006 entitled, "An Open-label, Non-randomized, Multicenter, Comparative, and Phase 1 Study of the Pharmacokinetics, Safety and Tolerability of Olaparib Following a Single Oral 300 mg Dose to Patients with Advanced Solid Tumors and Normal Renal Function or Renal Impairment." | 206162 | 19-Dec-14 | 30-Nov-16 | Ongoing | |
| **Lynparza®** | Submit the final report for trial D0816C00005 entitled, "An Open-label, Non-randomized, Multicenter, Comparative, Phase 1 Study to Determine the Pharmacokinetics, Safety and Tolerability of Olaparib Following a Single Oral 300 mg Dose to Patients with Advanced Solid Tumors and Normal Hepatic Function or Mild or Moderate Hepatic Impairment." | 206162 | 19-Dec-14 | 30-Nov-16 | Delayed | FDA determined "good cause" for the delay. |

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| **Lynparza®** | Conduct a stability study with the process validation batches (minimum of 3): ICH primary stability testing to the submitted NDA specifications (acceptance criteria, analytical method) for the commercial product, including polymorph content up to end of expiry. | 206162 | 19-Dec-14 | | Ongoing | Not on FDA website. |
| **Movantik™** | A post-marketing, observational epidemiologic study comparing MOVANTIK (naloxegol) to other treatments of opioid induced constipation in patients with chronic non-cancer pain. The study's primary outcome is a composite of major adverse cardiovascular events (MACE): cardiovascular (CV) death, nonfatal myocardial infarction, and nonfatal stroke. Secondary outcomes include, but are not limited to, CV death, nonfatal myocardial infarction, and nonfatal stroke separately. Specify concise case definitions and validation algorithms for the primary and secondary outcomes. Justify the choice of appropriate comparator population(s) and estimated background rate(s) relative to MOVANTIK (naloxegol)-exposed patients; clearly define the primary comparator population for the primary objective. Design the study around a testable hypothesis to assess, with sufficient sample size and power, MACE risk among MOVANTIK (naloxegol) users relative to comparator(s) considering important potential confounders including lifestyle risk factors and over the counter (OTC) medications with potential for cardiovascular effects, with a pre-specified statistical analysis method. For the MOVANTIK (naloxegol)-exposed and comparator(s), clearly define the new user clean period, including any exclusion and inclusion criteria. Ensure an adequate number of patients with at least 12 months of MOVANTIK (naloxegol) exposure at the end of the study. | 204760 | 16-Sep-14 | 31-Dec-23 | Pending | |
| **Movantik™** | An in vitro study to evaluate the time-dependent/mechanism-based inhibition potential of naloxegol on the hepatic CYP2C8 enzyme. | 204760 | 16-Sep-14 | 30-Apr-15 | Fulfilled | |

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| **Esomeprazole Magnesium** | Deferred pediatric study under PREA for the treatment of Gastroesophageal Reflux Disease (GERD): Healing of Erosive Esophagitis, Maintenance of Healing of Erosive Esophagitis, Symptomatic Gastroesophageal Reflux Disease in pediatric patients ages birth to 11 years old. | 21957 | 20-Oct-06 | 30-Jun-08 | Delayed | |
| **Onglyza®** | Deferred randomized and controlled pediatric study under PREA to evaluate efficacy, safety, and pharmacokinetics of saxagliptin for the treatment of type 2 diabetes mellitus in pediatric patients ages 10 to 16 years. | 22350 | 31-Jul-09 | 30-Jun-18 | Ongoing | |
| **Onglyza®** | A randomized, double-blind, controlled trial evaluating the effect of saxagliptin on the incidence of major adverse cardiovascular events in patients with type 2 diabetes mellitus. | 22350 | 31-Jul-09 | 31-Jan-16 | Fulfilled | |
| **Symbicort** | Agree to validate the test results shown on the certificate of analysis (C of A) for the excipient HFA 227 propellant either annually or every 10th batch (whichever is more frequent). | | | | Ongoing | Not on FDA website. |
| **Symbicort** | Conduct the following study: A randomized, double-blind, 26-week, active-controlled clinical trial comparing Symbicort (budesonide and formoterol fumarate dihydrate) Inhalation Aerosol with budesonide HFA to evaluate the risk of serious asthma outcomes (hospitalizations, intubation, death) in 11,700 adult and adolescent patients 12 years of age and older with persistent asthma. | 21929 | 14-Apr-11 | 30-Jun-17 | Submitted | |

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| **Symbicort** | Conduct pediatric studies required under PREA:<br>Study 1: Phase 2 study of the efficacy and safety of budesonide 160 µg dose (80 µg × 2 inhalations bid) compared with placebo in children 6 to <12 years of age.<br>Study 2: Phase 2 study for formoterol dose - a single-dose, placebo-controlled and active-controlled efficacy and safety study using a crossover design in pediatric patients (ages 6 to <12 years) to determine the appropriate dose(s) of formoterol.<br>Study 3: Phase 3 study - a double-blind, 3-arm, parallel-group, 12-week study of 2 doses of SYMBICORT pMDI (1 dose of the budesonide component and 2 doses of the formoterol component, carried forward from the budesonide and formoterol Phase 2 studies) compared with the corresponding dose of budesonide monotherapy to determine the efficacy and safety of SYMBICORT pMDI in pediatric patients (ages 6 to <12 years). | 21929 | Original pediatric requirement given on 21 July 2006 | 30-Sep-16 | Delayed | |
| **Tagrisso (osimertinib)** | Conduct and submit the results of at least one multicenter, randomized clinical trial establishing the superiority of osimertinib over available therapy as determined by progression-free or overall survival in patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) | 208065 | 13-Nov-15 | 31-Jul-17 | Pending | |

| Compound Name | Description of Commitment | NDA Number | Date Commitment Given | FDA Projected Completion Date | Study Status | Notes |
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| **Tagrisso (osimertinib)** | Complete a pharmacokinetic trial to determine an appropriate dose of osimertinib in patients with mild to moderate hepatic impairment in accordance with the FDA Guidance for Industry entitled "Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling." found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072123.pdf. | 208065 | 13-Nov-15 | 31-May-19 | Pending | |
| **Tagrisso (osimertinib)** | Complete a clinical trial to evaluate the effect of a strong CYP3A4 inducer on the pharmacokinetics of osimertinib in accordance with the FDA draft Guidance for Industry entitled "Drug Interaction Studies – Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations" found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292362.pdf | 208065 | 13-Nov-15 | 31-Dec-15 | Submitted | |
| **Tagrisso (osimertinib)** | Complete a clinical trial to evaluate the effect of repeated doses of osimertinib on the pharmacokinetics of a probe substrate of CYP3A4 in accordance with the FDA draft Guidance for Industry entitled "Drug Interaction Studies – Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations" found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292362.pdf. | 208065 | 13-Nov-15 | 31-Dec-15 | Submitted | |

| Compound Name | Description of Commitment | NDA Number | Date Commitment Given | FDA Projected Completion Date | Study Status | Notes |
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| **Tagrisso (osimertinib)** | Complete a clinical trial to evaluate the effect of repeated doses of osimertinib on the pharmacokinetics of a probe substrate of breast cancer resistant protein (BCRP) in accordance with the FDA draft Guidance for Industry entitled "Drug Interaction Studies – Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations" found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292362.pdf. | 208065 | 13-Nov-15 | 31-Dec-15 | Submitted | |
| **Tudorza Pressair (aclidinium bromide)** | Conduct a randomized, controlled trial to evaluate the risk of major adverse cardiac events with aclidinium bromide in patients with COPD. | 202450 | 23-Jul-12 | 30-Jun-18 | Ongoing | |
| **Xigduo™ (Dapagliflozin and Metformin)** | A study to evaluate whether pediatric patients with type 2 diabetes mellitus or healthy pediatric subjects ages 10 to 17 years (inclusive) can safely swallow Xigduo XR(dapagliflozin and metformin HCl extended-release) tablets. The study should evaluate tablets that are at least as large as the largest Xigduo XR tablet (dapagliflozin and metformin HCl extended-release). Placebo tablets should be used if the study population consists of healthy subjects. | 205649 | 29-Oct-14 | 31-Oct-18 | Released | Per FDA letter dated 06/30/2015, this PMR has been released. |
| **Xigduo™ (Dapagliflozin and Metformin)** | An enhanced pharmacovigilance study of ketoacidosis in patients treated with dapagliflozin. The study will include reports of ketoacidosis or diabetic ketoacidosis for a period of 5 years, and will include assessment and analysis of spontaneous reports of ketoacidosis in patients treated with dapagliflozin, with specialized follow-up to collect additional information on these cases. | 205649 | 29-Oct-14; S-3 | 31-Dec-21 | Pending | |

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| **Zomig® Nasal Spray** | Conduct a juvenile rat toxicology study to identify the unexpected serious risk of adverse effects of zolmitriptan on postnatal growth and development. The study should utilize animals of an age range and stage(s) of development that are comparable to the intended pediatric population; the duration of dosing should cover the intended length of treatment in the pediatric population. In addition to the usual toxicological parameters, this study must evaluate effects of zolmitriptan on growth, reproductive development, and neurological and neurobehavioral development. | 21450 | 12-Jun-15 | 31-May-18 | Pending | |
| **Zomig® Nasal Spray** | Conduct a controlled efficacy and pharmacokinetics (PK) study in children ages > or equal to 6 years to 11 years with migraine that includes sparse PK samples throughout the efficacy study. Conduct a long-term open-label safety study in pediatric patients with migraine ages > or equal to 6 years to 11 years. The long-term safety study must provide a descriptive analysis of safety data in at least 50 pediatric patients exposed for at least 6 months, treating on average at least one migraine attack per month, at doses evaluated in the efficacy study. | 21450 | 12-Jun-15 | 31-May-21 | Pending | |
| **Zurampic (Lesinurad)** | A randomized, controlled, clinical trial to evaluate the safety of lesinurad 200mg on a background of concomitant xanthine oxidase inhibitor, with respect to renal function and renal adverse events, in gout patients who have not achieved target serum uric acid with a xanthine oxidase inhibitor alone. Enrollment should be enriched with patients with moderate renal impairment (creatinine clearance 30 to 60 mL/min). The minimum treatment duration should be 2 years. The trial must also include an assessment of cardiovascular (CV) safety based on an independent adjudication of prospectively defined and collected CV events. | 207988 | 22-Dec-15 | 31-Dec-25 | Pending | |