Product	Description of the Commitment	Commitment Reference Number	Date Commitment Given (DD/MM/YYYY)	Commitment Due Date (including FDA Projected Completion Date) DD/MM/YYYY	Commitment Status (use drop-down list)	Commitment Fulfilment Date (DD/MM/YYYY)	Comments
Bydureon® (Exenatide)	A randomized and controlled paediatric 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 paediatric patients ages 10-17 years (inclusive).	PMR -1860-1	27-Jan-12	30-Jul-20	Delayed - Ongoing		
Bydureon® (Exenatide)	A medullary thyroid carcinoma case series registry of at least 15 years duration to systematically monitor the annual incidence of medullary thyroid 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) .	PMR -1860-5	27-Jan-12	30-Sep-28	On-going		
BYETTA (EXENATIDE)	Deferred paediatric study under PREA for the treatment of type 2 diabetes mellitus in paediatric patients ages 10 to 16 years (inclusive).	PMR -1559-1	28-Apr-05	31-Jan-20	On-going		
BYETTA (EXENATIDE) INJECTION	Deferred paediatric study under PREA for the treatment of type 2 diabetes mellitus in paediatric patients ages 10 to 16 years (inclusive).	PMR -1559-1	30-Oct-09	31-Jul-20	On-going		
Calquence	Submit the complete final report and datasets demonstrating clinical efficacy and safety from a randomized, double-blind, placebo-controlled, clinical trial of Calquence in combination with standard immunochemotherapy versus immunochemotherapy alone in patients with mantle cell lymphoma.	PMR-3291-1	30/10/2017	30/11/2024	Pending	30/11/2024	
Exenatide	A medullary thyroid carcinoma case series registry of at least 15 years duration to systematically monitor the annual incidence of medullary thyroid 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 (exenatide for injectable suspension).	PMR -1860-5	20-Oct-17	30-Sep-28	On-going		
Exenatide	A randomized and controlled paediatric 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 paediatric patients ages 10-17 years (inclusive).	PMR -1860-1	20-Oct-17	31-Jan-21	Delayed		

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Exenatide	A medullary thyroid carcinoma case series registry of at least 15 years duration to systematically monitor the annual incidence of medullary thyroid 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 (exenatide for injectable suspension).	PMR -1860-5	20-Oct-17	30-Sep-28	On-going		
Fasenra 30mg Solution for Injection	Conduct an open-label, pharmacokinetic and pharmacodynamics study of benralizumab in pediatric patients 6 to 11 years of age with a continued safety evaluation out to a minimum of 48 weeks. Doc ID-003711938 V4.0.	PMR 3287-1	31/10/2017	31/12/2022	On-going		
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.	125020 S-1668	29-Feb-12	31-Dec-18	Delayed		
FORXIGA	An enhanced pharmacovigilance study of ketoacidosis in patients treated with Dapaglifloxin. 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 specialised follow up to collect additional information on these cases.			31/12/2021	On-going		
FORXIGA	3199-1: Conduct a 26-week randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of the monotherapies saxagliptin and dapagliflozin for the treatment of pediatric patients ages 10 to < 18 years with type 2 diabetes mellitus, followed by a 26-week site- and subject-blinded safety extension period (weeks 26 to 52). Background therapy will consist of either metformin, insulin, or metformin plus insulin. A second randomization will take place at week 14, with uptitration of dose (saxagliptin may be increased from 2.5 mg to 5 mg; dapagliflozin from 5 mg to 10 mg) for approximately half of the subjects with a hemoglobin A1C greater than or equal to 7%.	PMR 3199-1	08/01/2014	30/04/2022	On-going		
Imfinzi (Durvalumab)	Submit the final report with datasets and labelling for the clinical trial entitled “A Phase III, Randomized, Open-label, Controlled, Multi-centre, Global Study of First-line MEDI4736 Monotherapy and MEDI4735 in Combination with Tremelimumab Versus Standard of Care Chemotherapy in Patients with Unresectable Stage IV Urothelial Cancer.”		01/05/2017	31/12/2020	Delayed		
Imfinzi (Durvalumab)	Conduct updated analyses of the duration of response for the patients with urothelial cancer who had received prior platinum-based therapy (N = 182) in the clinical trial entitled “A Phase 1-2 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of MEDI4736 in Subjects with Advanced Solid Tumours.” Present the median and updated information on the range of the duration of response for all patients, patients whose tumour have high PD-L1 staining, and patients whose tumours have low PD-L1 staining. Submit the final report with datasets and labelling.		01/05/2017	30/09/2020	Delayed		
Imfinzi (Durvalumab)	Submit the clinical report and datasets for the final analysis of overall survival and mature results for duration of response, for Study D4191C00001 (PACIFIC) to update the label.		16/02/2018	28/02/2023	On-going		

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Imfinzi (Durvalumab)	Submit the updated overall survival (OS) results (based upon the protocol specified timing for the final analysis of OS) and datasets from clinical trial CASPIAN titled, "A Phase III, Randomized, Multicenter, Open-Label, Comparative Study to Determine the Efficacy of Durvalumab or Durvalumab and Tremelimumab in Combination With Platinum-Based Chemotherapy for the First-Line Treatment in Patients With Extensive Disease Small-Cell Lung Cancer" to further characterize survival differences at late time points. The updated analysis should include patients from the durvalumab in combination with etoposide and either carboplatin or cisplatin arm and etoposide with either carboplatin or cisplatin arm.	3815-1	27/03/2020	31/10/2020	On-going		
Kombiglyze XR	3199-1: Conduct a 26-week randomised, double-blind, placebo-controllled study to evaluate the efficacy and safety of the monotherapies saxagliptin and dapagliflozin for the treatment of pediatric patients aged 10 to <18 years of age with type 2 diabetes mellitus, followed by a 26-week site- and subject-blinded safety extension period (weeks 26-52). Background therapy will consist of either metformin, insulin or metformin plus insulin. A second randomisation will take place at week 14, with up-titration of dose (saxagliptin may be increased from 2.5mg to 5mg; dapagliflozin from 5mg to 10mg) for approximately half of the subjects with a heamaglin A1C greater then or equal to 7%.	PMR 3199-1		30/04/2022			
KOSELUGO (selumetinib)	Characterize and evaluate the long-term safety effects and any potential for serious adverse risks of selumetinib on the growth and development of pediatric patients. Submit the complete final report and long-term follow-up data from pediatric patients enrolled on SPRINT and ongoing or completed studies of selumetinib. All patients must be evaluated for growth and development milestones annually for at least 7 years from initiation of selumetinib. Evaluations must include: growth as measured by weight, height, height velocity, height standard deviation scores (SDS), age at thelarche (females), age at adrenarche (males), age at menarche (females), and Tanner Stage progression. Descriptive statistics (including mean and standard deviation values) of on study data for growth velocity must be presented. Growth velocity during the trial should be compared with growth velocity at baseline (if pre-baseline data are available). Provide analyses of height and weight data that assess measures of central tendency and outlier analyses using height and weight z-scores.	3806-1	10/04/2020	30/03/2026	On-going		

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KOSELUGO (selumetinib)	Characterize and evaluate the long-term safety effects and any potential for specific serious adverse risks of selumetinib in pediatric patients. Submit the complete final report and long-term follow-up safety data (minimum of 7 years) from pediatric patients enrolled on SPRINT and all other ongoing or completed studies of selumetinib to include an analysis of the following toxicities in pediatric patients: ocular toxicity (including but not limited to retinal pigment epithelial detachment and retinal vein occlusion), cardiac toxicity (including but not limited to ventricular dysfunction), muscle toxicity (including but not limited to rhabdomyolysis and symptomatic and asymptomatic CPK elevation), serious gastrointestinal toxicity (including but not limited to colitis, ileus, intestinal obstruction, and intestinal perforation), and serious dermatologic toxicity.	3806-2	10/04/2020	30/03/2026	On-going		
Lokelma	Conduct a two-part study with an acute and maintenance phase to evaluate the safety, tolerability, and pharmacodynamic effects of Lokelma (sodium zirconium cyclosilicate) in paediatric patients 0 to 17 years of age with hyperkalaemia.	Doc ID-003872782; Committment No1	18/05/2018	31/12/2021	On-going		
Lynparza 50mg Capsules	2824-3: 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 patients treated 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		19/12/2014	30/06/2020	Delayed		
Lynparza tablets, 100 mg & 150 mg	3238-1 OPINION PFS and molecular characteristics, final report, labeling, and datasets (Trial completion).		17/08/2018	31/12/2020	Pending		
Lynparza tablets, 100 mg & 150 mg	Submit the progression-free survival (PFS) and molecular charactersitics (patient and tumour) final report, labelling and datasetsfrom Clinical Trial D0816C00020, entitled "OPINION - A Phase IIIb, single-arm, open-label, multi-centre study of Olaparib maintenance monotherapy in platinum sensitive relapsed non-Germaline BRCA mutated ovarian cancer patients who are in complete or partial response following platinum based chemotherapy.		17/08/2018	30/06/2021	On-going		
Lynparza tablets, 100 mg & 150 mg	3238-2 SOLO-3 ORR & DOR with data sets (Final report submission). Submit the overall response rate (ORR) and duration of response (DOR) analyses with datasets from clinical trial D0816C00010 (SOLO-3), entitled " A randomised trial establishing the superiority of Olaparib over physician's choice sinle agent chemotherapy in the treatment of platinum sensitive relapsed ovarian cancer in patients carrying deleterious or suspected deleterious germaline BRCA1/2 mutations"		17/08/2018	31/08/2019	Delayed		

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Lynparza tablets, 100 mg & 150 mg	3238-3 SOLO-2 OS (Trial completion) Submit the overall survival (OS) analyses with datasets from clinical trial D0818C00002, SOLO-2, the on-going randomised double-blind, placebo-controlled, multi-centre trial to assess the efficacy of Olaparib maintenance monotherapy in relpased high grade serious 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 the following platinum-based chemotherapy.		17/08/2018	31/12/2019	Delayed		
Lynparza tablets, 100 mg & 150 mg	3238-3 SOLO-2 OS (Final report submission) Submit the final overall survival analysis and datasets with the final report for Trial D081FC0001, titled "A Phase III, randomised, double-blind, placebo-controlled multicentred study of maintenance Olaparib monotherapy in patients with gBRCA mutated metastatic pancreatic cancer whose disease has not progressed on first line platinum based chemtherapy. (POLO)" that may inform product labelling.		17/08/2017	30/06/2020	Pending		
Lynparza tablets, 100 mg & 150 mg	3525-1 -SOLO-1 OS (Trial completion) Submit the final overall survival (OS) analysis with datasets from clinical trial D0818C00001 (SOLO-1), the ongoing phase 3, randomized, double-blind, placebo-controlled, multicenter trial of olaparib maintenance monotherapy in patients with BRCA mutated advanced (FIGO Stage III-IV) ovarian cancer following first-line platinum-based chemotherapy.		19/12/2018	31/05/2027	Pending		
Lynparza tablets, 100 mg & 150 mg	3525-1 -SOLO-1 OS (Final report submission)		19/12/2018	30/11/2027	Pending		
Lynparza tablets, 100 mg & 150 mg	3521-2 - PAOLA PFS (final protocol) Submit the final report of progression-free survival (PFS) with analyses and datasets from patients with tumour BRCA-mutated advanced epithelial ovarian, fallopian tube, and primary peritoneal cancer on the ongoing clinical trial entitled, “A Randomized, Double-Blind, Phase III Trial of Olaparib vs. Placebo in Patients with Advanced FIGO Stage IIIB – IV High Grade Serous or Endometrioid Ovarian, Fallopian Tube, or Peritoneal Cancer treated with standard First-Line Treatment, Combining Platinum-Taxane Chemotherapy and Bevacizumab Concurrent with Chemotherapy and in Maintenance (PAOLA-1).		19/12/2018	30/09/2019	Pending		

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Lynparza tablets, 100 mg & 150 mg	3525-3: Complete the analytical and clinical validation study that uses SOLO1 clinical trial data that is adequate to support labeling of an in vitro diagnostic device that demonstrates the device is essential for the safe and effective use of olaparib maintenance monotherapy in patients with advanced (FIGO Stage III-IV) ovarian cancer with deleterious BRCA aberrations detected in tissue specimens following first-line platinum-based chemotherapy. Reference- Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products: Draft Guidance for Industry 12/2018.			30/06/2019	Pending		
Lynparza tablets, 100 mg & 150 mg	Submit the final overall survival analysis and datasets with the final report from the Randomized, Double-blind, Phase III Trial of Olaparib vs. Placebo in Patients with Advanced FIGO Stage IIIB-IV High Grade Serous or Endometrioid Ovarian, Fallopian Tube, or Peritoneal Cancer treated with standard First Line Treatment, (PAOLA-1), that may inform product labelling.	3819-1	08/05/2020	01/09/2022	Pending		
Nexium	Deferred paediatric 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 paediatric patients ages birth to 11 years old.	PMR 59-1	20/10/2006	30/06/2008	Delayed	31/05/2024	
Onglyza	PMR 1493-1: A randomized and controlled pediatric study under PREA to evaluate efficacy, safety, and pharmacokinetics of saxagliptin for the treatment of T2DM in pediatric patients ages 10 to 16 years.		31/07/2009	The final report submission date is 30 June 2018			
Onglyza	3199-1: Conduct a 26-week randomised, double-blind, placebo-controllled study to evaluate the efficacy and safety of the monotherapies saxagliptin and dapagliflozin for the treatment of pediatric patients aged 10 to <18 years of age with type 2 diabetes mellitus, followed by a 26-week site- and subject-blinded safety extension period (weeks 26-52). Background therapy will consist of either metformin, insulin or metformin plus insulin. A second randomisation will take place at week 14, with up-titration of dose (saxagliptin may be increased from 2.5mg to 5mg; dapagliflozin from 5mg to 10mg) for approximately half of the subjects with a heamaglin A1C greater then or equal to 7%.	PMR 3199-1		30/04/2022			

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Onglyza, Kombiglyze XR, Farxiga, and Xigduo XR	Your deferred pediatric study required under section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81(b)(2)(vii) and section 505B(a)(3)(C) of the FDCA. This required study is listed below. 3199-1 Conduct a 26-week randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of the monotherapies saxagliptin and dapagliflozin for the treatment of pediatric patients ages 10 to < 18 years with type 2 diabetes mellitus, followed by a 26-week site- and subject-blinded safety extension period (weeks 26 to 52). Background therapy will consist of either metformin, insulin, or metformin plus insulin. A second randomization will take place at week 14, with uptitration of dose (saxagliptin may be increased from 2.5 mg to 5 mg; dapagliflozin from 5 mg to 10 mg) for approximately half of the subjects with a hemoglobin A1C greater than or equal to 7%.	Not assigned yet	24/04/2017	Study Completion: December 2021 Final Report Submission: April 2022	On-going		
Tagrisso	3119-1: Provide data on overall response rate with osimertinib from one or more “realworld” cohorts of a minimum of 100 patients who have been selected for treatment on the basis of an EGFR T790M mutation positive result from plasma (ctDNA) using the cobas® EGFR Mutation Test v2. Provide tissue EGFR T790M status on these patients, where available. Study D5160C00022 (ASTRIS).	3119-1	28-Sep-16	01-Jun-22	Delayed		
Tagrisso	3195-1: Submit the clinical report and datasets for the final analysis of overall survival for Trial D5160C00003 (AURA3), “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 Tumors harbor a T790M mutation within the Epidermal Growth Factor Receptor Gene”, to update the label with mature overall survival data. Study D5160C00003 (AURA3).	3195-1	30-Mar-17	01-Jun-20	Delayed		
Tagrisso	3381-1: Submit the clinical report and datasets for the final analysis of overall survival, as well as updated duration of response data, for Study FLAURA (Protocol D5160C00007), “A Phase III, Double-Blind, Randomized Study to Assess the Efficacy and Safety of AZD9291 versus a Standard of Care Epidermal Growth Factor Receptor-Tyrosine Kinase Inhibitor as First-Line Treatment in Patients with Epidermal Growth Factor Receptor Mutation Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer,” to update the label with mature duration of response and overall survival data. Study/trial completion is June 2019; final report submisison is December 2019	3381-1	18-Apr-18	December 2019		23/05/2020	
Tudorza and Daliresp				31/08/2017	Pending		

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XIGDUO XR	D1690R00014 (includes Xigduo XR): 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.	PMR 3006-1	25/09/2015	31/12/2021	On-going		
XIGDUO XR	3199-1: Conduct a 26-week randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of the monotherapies saxagliptin and dapagliflozin for the treatment of pediatric patients ages 10 to < 18 years with type 2 diabetes mellitus, followed by a 26-week site- and subject-blinded safety extension period (weeks 26 to 52). Background therapy will consist of either metformin, insulin, or metformin plus insulin. A second randomization will take place at week 14, with uptitration of dose (saxagliptin may be increased from 2.5 mg to 5 mg; dapagliflozin from 5 mg to 10 mg) for approximately half of the subjects with a hemoglobin A1C greater than or equal to 7%.	PMR 3199-1		30/04/2022	On-going		
Lynparza tablets, 100 mg & 150 mg	Submit the final overall survival analysis and datasets with the final report for Trial D081FC0001, titled “A Phase III, Randomized, Double Blind, Placebo Controlled, Multicentre Study of Maintenance Olaparib Monotherapy in Patients with gBRCA Mutated Metastatic Pancreatic Cancer whose Disease Has Not Progressed on First Line Platinum Based Chemotherapy (POLO)” that may inform product labeling.	3778-1	27/12/2019	01/06/2021	Pending		

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Lynparza tablets, 100 mg & 150 mg	Submit the final report from a study evaluating the response (overall response rate in patients with measurable disease, prostate specific antigen response (measurable and non-measurable disease), CTC conversion (measurable and non-measurable disease)) and duration of responses to olaparib in patients with metastatic castration-resistant prostate cancer who have progressed on a new hormonal agent and had somatic or germline mutations in homologous recombination repair (HRR) genes that were present in five or fewer patients among the HRR genes evaluated in Cohort B of the PROfound trial. HRR mutation should be determined based on an FDA-approved assay and the study will evaluate at least five patients per HRR gene. Provide annual updates on patient enrollment and responses in the interim reports. Annual updates and the final report should include information regarding the assay used to identify each HRR mutation. The timetable you submitted on May 11, 2020, states that you will conduct this study according to the following schedule: Draft Protocol Submission: 03/2021 Final Protocol Submission: 09/2022 Interim Report #1: 12/2024 Interim Report #2: 12/2025 Interim Report #3: 12/2026 Interim Report #4: 12/2027 Trial Completion: 12/2028 Final Report Submission: 12/2028	3826-1	19/05/2020	01/12/2028	Pending		