Drug Product Name	Application Type & Description	Licence Number	Discipline	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	Commitment Fulfilment Date (DD/MM/YYYY)	Comments
Exenatide	209210 (Commitment No1)		Administrative	Test samples from clinical studies BCB118 and BCB120 for the presence of anti-GLP-1 and anti-glucagon antibodies using a similar assay used to test samples as described in report REST080154R1. Sample selection criteria will be submitted to and reviewed by the Agency prior to initiation of sample analysis.	PMR -3274-1	20-10-2017	31-05-2019	Fulfilled		FDA fulfilled the this PMC on 05/21/2020
XIGDUO	NDA 205649		Clinical	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		This PMR was issued on 24Apr2017 and replaced PMR 2121-2. Doc ID-003622499 v1.0
Kombiglyze XR	NDA		Clinical	PMR 1703-3: 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 extended release therapy at the time of randomization to add-on saxagliptin vs. add-on placebo		29/06/2015	30/06/2018	Released		Due to redesign of the pediatric trial the FDA *MAY* withdraw and release this PMR. If this happens we have requested that FDA change the due date to April 30, 2022. This was originally stated as: 'PMR 1703-2: A 52-week, randomized, double-blind, placebo-controlled study 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 XR therapy at the time of randomization to add-on saxagliptin vs. add-on placebo. As part of this study, you must evaluate whether pediatric patients can safely swallow the large metformin extended-release tablets.' but FDA released AZ from this PMR and released 1703-3 to remov the swallowability assessment. On 24 April 2017 FDA released AstraZeneca from this PMR and replaced it with a new PMR - PMR 3199-1, applicable to Onglyza, Kombiglyze XR, Farxiga, and Xigduo XR.
Onglyza	NDA		Clinical	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	30/06/2018	Released		Due to redesign of the pediatric trial the FDA *MAY* withdraw and release this PMR. If this happens we have requested that FDA change the due date to April 30, 2022. On 24 April 2017 FDA released AstraZeneca from this PMR and replaced it with a new PMR - PMR 3199-1, applicable to Onglyza, Kombiglyze XR, Farxiga, and Xigduo XR.

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Andexxa	BLA	BLA 125586	Clinical	Study-18-513: "A Phase 4 randomized trial of ANDEXXA in acute intracranial hemorrhage in patients receiving oral factor Xa inhibitors"	PMR Study 18 513	03-05-2018	28/02/2024, 31/07/2024	On going		Final Protocol Submission: April 17, 2018; Study Completion Date: October 31, 2022; Final Study Report Submission: April 30, 2023. Revised milestone (acknowledged by FDA 01 April 2021): Final Protocol Submission: April 17, 2018; Study Completion Date: February 28, 2024; Final Study Report Submission: July 31, 2024.
Bydureon BCise (exenatide)	NDA 209210	NDA 209210	Clinical	Conduct a simulated-use human factors (HF) validation study to demonstrate that the user interface has been designed to support that pediatric patients aged 10 years old to less than 18 years old can safely and effectively use Bydureon BCise for intended uses in intended use environments.	PMR 4114-1	22/07/2021	31-03-2023	Pending		The FDA approval letter for the Bydureon BCise NDA - BCB114 sNDA (NDA 209210/S-017) - received on 22/07/2021 - indicates this commitment. Draft Protocol Submission: December 2021 Final Protocol Submission: June 2022 Study Completion: December 2022 Final Report Submission: March 2023
Bydureon (exenatide)	NDA 022200	NDA 022200	Safety	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	27/01/2012	30-09-2028	On going		
Bydureon BCise (exenatide)	NDA 209210	NDA 209210	Safety	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	20/10/2017	30-09-2028	On going		
Farxiga	NDA 202293	NDA 202293	Clinical	D1690R00014: 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	Fulfilled	22/04/2022	Final Report in fullfillment of this PMR was submitted to FDA on 15Dec2021. Fullfillment letter issued on 22Apr22 See Doc ID-004865606

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Farxiga	NDA 202293	NDA 202293	Clinical	PMR 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%			30-04-2022	Delayed		The study completion and final report submission milestones were missed due to recruitment difficulties. The Final Report Submission milestone has been revised to January 2024. Original Final Report Due Date: 04/30/2022; Deferral Extension granted per FDA letter dated 07/28/2021.
Lokelma	NDA 207078		Clinical	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	30/06/2025	On going		The clinical protocol for study D9481C00001 (3373-1) was submitted 6 July 2018. The study has been initiated. FSI 2 April 2019. On 03Dec2021, FDA granted an extension for completion of the study until 31Dec2024 and Final Report Submission date to 30Jun2025.
Nexium	NDA - PREA commitment	NDA 021957	Clinical	Deferred paediatric study under PREA for the treatment of Gastroesophageal Reflux Disease (GERD): Maintenance of Healing of Erosive Esophagitis in paediatric patients ages birth to 11 years old.	PMR 59-1	20-10-2006	30-06-2008	Delayed		
Onglyza Kombiglyze XR Farxiga Xigduo XR	NDA	022350 200678 202293 205649	Clinical	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%.	PMR 3199-1	24/04/2017	31/07/2024	On going		Submit clinical protocols to IND 063634, with cross-reference letters to Onglyza NDA 022350, Kombiglyze XR NDA 200678, Farxiga NDA 202293, and Xigduo XR NDA 205649 Commitment: Doc ID-003622485 29 July 2021: Doc ID-004644652 V1.0 New dates for PMR 3199-1: Study Completion: January 2024 (revised date) Final Report Submission: July 2024 (deferral extension date) FDA agreed to the agree with your deferral extension request for this PREA PMR because of delays involving study participants, sites, and/or management.
XIGDUO	NDA 205649	NDA 205649	Clinical	D1690R00014 : 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	Fulfilled	22/04/2022	Final Report in fullfillment of this PMR was submitted to FDA on 15Dec2021. Fulfillment letter issued on 22Apr22. See CARA Doc ID-004865606.

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Fasenra 30mg Solution for Injection	BLA	761070	Clinical	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	31-03-2023	On going		Draft protocol submission date: Jun 2018 Final protocol submission date: Oct 2018 Study completion date (LSLV): Sept 2022 Final report submission date: Feb 2023 Draft Protocol submitted 29Jun2018 to IND (x-ref letter to BLA) Final Protocol submitted 31Oct2018 (x-ref letter to BLA) FDA acknowledgement (final protocol) 03Dec2018. Extension to delivery date: Doc ID-005002842
Saphnelo	BLA	761123	Clinical	Conduct a study to evaluate the safety, efficacy, and pharmacokinetics of anifrolumab-fnia plus background standard therapy in pediatric subjects ages 5 years to 17 years of age with active systemic lupus erythematosus (SLE). Final Protocol Submission: 03/2022 (PMR revised to 10/2022) Study Completion: 10/2026 Final Report Submission: 05/2027	4116-1	30/07/2021	31-05-2027	On going		The applicant requested a revised milestone because of the longer than anticipated development of the draft study design. A Revised milestone was acknowledged in a letter dated 04/12/2022. Request to modify PMR milestone date submitted 07 Mar 22
Saphnelo	BLA	761123	Clinical	Conduct a prospective pregnancy registry to evaluate the effects of Saphnelo (anifrolumab-fnia) on pregnancy and maternal and fetal/neonatal outcomes. This pregnancy registry study may be conducted as part of a multiple-product or disease-based pregnancy registry. Final Protocol Submission: 04/2022 (PMR revised to 08/2022) Interim Report: 04/2025 Study Completion: 04/2031 Final Report Submission: 04/2032	4116-2	30/07/2021	01-04-2032	On going		Request to modify PMR milestone date submitted 4 Feb 22
Saphnelo	BLA	761123	Clinical	Conduct a retrospective cohort study in a claims-based database to evaluate the effects of Saphnelo (anifrolumab-fnia) on pregnancy-related outcomes. The timetable you submitted on July 26, 2021, states that you will conduct this study according to the following schedule: Final Protocol Submission: 04/2022 (PMR revised to 08/2022) Study Completion: 04/2031 Final Report Submission: 04/2032	4116-3	30/07/2021	01-04-2032	On going		Request to modify PMR milestone date submitted 4 Feb 22

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Saphnelo	BLA	761123	Clinical	Perform a lactation study, milk only, in lactating women who have received Saphnelo (anifrolumab-fnia) to assess concentrations of anifrolumab-fnia in breast milk using a validated assay. A mother-infant pair study may be required in the future depending on the results of this milk-only study. The timetable you submitted on July 29, 2021, states that you will conduct this study according to the following schedule: Final Protocol Submission: 08/2022 Study Completion: 08/2025 Final Report Submission: 02/2026	4116-4	30/07/2021	28-02-2026	On going		
Lynparza Capsules 50 mg	SOLO-2	NDA 206162	Clinical	Submit the progression-free survival (PFS) and overall survival (OS) analyses with datasets from clinical trial D0818C00002, SOLO-2	2824-1	19-12-2014	31-03-2019	Fulfilled		This was fulfilled via the submission of NDA208558 which had the SOLO2 study as the pivotal registration study.
Imfinzi (Durvalumab)	BLA761069 (Commitment No2)	BLA761069	Clinical	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.	PMC:3205-02	01-05-2017	30-06-2018	Fulfilled	19-01-2022	Marked as missing commimtment, but submitted as part of IND. On-going IR with FDA to recify (seq 1280, 24th Sep 21). Fullfilment letter recieved dated 19Jan2022
Calquence	NDA	NDA 210259	Clinical	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	On going		
Imfinzi (Durvalumab)	BLA761069 S-2 (Commitment No1), Pacific	BLA 761069	Clinical	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.	PMC:3329-01	16-02-2018	28-02-2023	Submitted		CSR addendum 4 submitted, 5yr OS data

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Koselugo (selumetinib)	NDA 213756		Clinical	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		Approval Letter with PMRs: Doc ID-004264714
KOSELUGO (selumetinib)	NDA 213756		clinical	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		Approval Letter with PMRs: Doc ID-004264714
KOSELUGO (selumetinib)	NDA 213756		Clinical	Submit the final report and datasets from a pharmacokinetic trial in pediatric patients to confirm the effect of a low-fat meal on selumetinib exposure with the marketed capsule formulation and evaluate whether administration of selumetinib with food may alleviate gastrointestinal toxicities. Confirm appropriate dosing recommendation of selumetinib with a low-fat meal that maintains efficacy with acceptable safety.	3806-3	10-04-2020	30-04-2023	On going		Approval Letter with PMRs: Doc ID-004264714

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Lynparza Capsules 50 mg	SOLO-1	208558	Clinical	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.	3525-1 (S-6)	19-12-2018	31-05-2027	Pending		Commitment issued in NDA 208558/S-006
Lynparza tablets, 100 mg & 150 mg	SOLO-1	208558	Clinical	3525-1 -SOLO-1 OS Final Report OS Submission 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.	3525-1 (S-6)	19-12-2018	30-11-2027	Pending		Commitment issued in NDA 208558/S-006
Lynparza tablets, 100 mg & 150 mg	PAOLA-1	NDA 208558	Clinical	3819-1-D0817C00003 PAOLA PhIII (ESR) -Trial Completion 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 labeling.	3819-1 (S-13)	08-05-2020	31-03-2022	Fulfilled	10-11-2022	Commitment given in NDA 208558/S-013
Lynparza tablets, 100 mg & 150 mg	PAOLA-1	NDA 208558	Clinical	3819-1 D0817C00003 PAOLA PhIII (ESR) -Final Report Submission 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 labeling.	3819-1 (S-13)	08-05-2020	30-09-2022	Submitted	10-11-2022	Commitment given in NDA 208558/S-013

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Lynparza tablets, 100 mg & 150 mg	Prodigy	NDA 208558	Clinical	3826-1-Profound PMC study-Final Protocol Submission 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.	3826-1 (S14)	19/05/2020	30-09-2022	Fulfilled	07-09-2022	Commitment issued NDA 208558/S-014. Final protocol submission - Submitted
Lynparza tablets, 100 mg & 150 mg	Prodigy	NDA 208558	Clinical	3826-1-Profound PMC study--Interim Report 1 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.	3826-1 (S14)	19-05-2020	31/12/2024	Pending		Commitment issued NDA 208558/S-014

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Lynparza tablets, 100 mg & 150 mg	Prodigy	NDA 208558	Clinical	3826-1-Profound PMC study--Interim Report 2 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.	3826-1 (S14)	19-05-2020	31-12-2025	Pending		Commitment issued NDA 208558/S-014
Lynparza tablets, 100 mg & 150 mg	Prodigy	NDA 208558	Clinical	3826-1-Profound PMC study--Interim Report 3 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.	3826-1 (S14)	19-05-2020	31-12-2026	Pending		Commitment issued NDA 208558/S-014

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Lynparza tablets, 100 mg & 150 mg	Prodigy	NDA 208558	Clinical	3826-1-Profound PMC study--Interim Report 4 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.	3826-1 (S14)	19-05-2020	31-12-2027	Pending		Commitment issued NDA 208558/S-014
Lynparza tablets, 100 mg & 150 mg	Prodigy	NDA 208558	Clinical	3826-1-Profound PMC study-Trial Completion 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.	3826-1 (S14)	19/05/2020	31-12-2028	Pending		Commitment issued NDA 208558/S-014

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Lynparza tablets, 100 mg & 150 mg	Prodigy	NDA 208558	Clinical	3826-1-Profound PMC study--Final Report 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.	3826-1 (S14)	19-05-2020	31-12-2028	Pending		Commitment issued NDA 208558/S-014
LUMOXITI (moxetumomab pasudotox-tdfk)	BLA761104			PMC 3477-4 Submit updated limits for long term stability timepoints up to the 24-month timepoint for Drug Substance stored at 2 to 8°C. The limits will be established using the stability data from 5 Drug Substance Lots. A maximum of two lots in the years when the manufacturing occurs will be placed on stability at 2 to 8°C. A justification for the limits will be provided.	PMC 3477-4	13-09-2018	31-03-2026	On going		An update on the status of the PMC was provided to the FDA in the 2021 Annual Report. Ownership of the BLA was transferred back to AstraZeneca AB (AstraZeneca) from Innate Pharma Inc. The FDA reissued the BLA to AstraZeneca on 08 Feb 2022.
LUMOXITI (moxetumomab pasudotox-tdfk)	BLA761104		Clinical	"PMR 3477-1: Conduct a study to provide evidence characterizing 1) the safety of moxetumomab pasudotox in patient who are 65 years of age and older and 2) the safety of moxetumomab pasudotox in patients who have moderate renal impairment. Submit interim and complete final reports and data of adverse events, including outcomes, management and discussion of potential mitigating strategies, with data collection 2 years post-approval and 5-years post-approval respectively."	PMR 3477-1	13-09-2018	31-03-2024	On going		Ownership of the BLA was transferred back to AstraZeneca AB (AstraZeneca) from Innate Pharma Inc. The FDA reissued the BLA to AstraZeneca on 08 Feb 2022.

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Tagrisso	Label supplement (ASTRIS PMC)	NDA 208065	Clinical	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	28-09-2016	01-06-2022	Fulfilled	12-12-2022	16/11/17: AstraZeneca proposed to provide the summary report based on the outputs (Tables, Figures and Listings [TFLs]) specified in the ASTRIS study SAP v4.0 (Section 5.1, Supplementary Analysis to support an FDA Post Marketing Commitment) based on the second planned interim analysis for patients in cohort 2 (174 patients with an EGFR T790M mutation identified by cobas® EGFR plasma test only). At the time of the first interim analysis (November 2016) data from patients tested on plasma using the cobas® EGFR mutation test was too immature, both in terms of patient numbers and duration of follow-up, to meet the requirements of this PMC. The second interim analysis for the ASTRIS study will occur in November 2017 with a study final analysis planned for November 2019. USPI section 2.1 updates based on the second interim analysis will be submitted to the NDA as a Prior Approval Supplement by June 2018. 20/12/17: AstraZeneca has submitted the request for a Type C Meeting to discuss and reach agreement on the proposal for the specific information and datasets to be included in the data package to fulfill PMC 3119-1. 24/01/18: AZ has cancelled the Type C Meeting scheduled for February. Timelines to submitting a new request are pending team discussion. 05/04/18: Type C Meeting held with FDA to discuss

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Tagrisso	ADAURA	NDA 208065	Clinical	3992-1 Submit the final study report including datasets from the clinical trial ADAURA, titled, “A Phase III, Double-blind, Randomized, PlaceboControlled Multi-center, study to assess the efficacy and safety of AZD9291 versus Placebo, in Patients with Epidermal Growth Factor Receptor Mutation Positive Stage IB – IIIA Non small Cell Lung Carcinoma, following Complete Tumor Resection With or Without Adjuvant Chemotherapy (ADAURA)” to provide additional long-term efficacy and safety data that may inform product labeling. The interim studyreport will contain exploratory DFS analysis and safety data, including datasets (OS analysis will be included only if approximately 94 events in Stage II-IIIA population have been reached). The final study report will contain the final OS analysis (approximately 94 events in StageII-IIIA population have been reached) and safety data including datasets and will contain safety data analyses once follow-up is obtained for all patients who have received osimertinib for three years. The timetable you submitted on December 16, 2020, states that you will conduct this study according to the following schedule: Final Protocol Submission: 07/2020 (completed) Interim Report Submission: 10/2022Trial Completion: 01/2024 Final Report Submission: 06/2024 A final submitted protocol is one that the FDA has reviewed and commented upon, and you have revised as needed to meet the goal of the study or clinical trial.	3992-1	18-12-2020	01-06-2024	On going		Final Protocol Submission: 07/2020 (completed) Interim Report Submission: 10/2022 (completed) Trial Completion: 01/2024 Final Report Submission: 06/2024
Lynparza tablets, 100 mg & 150 mg	OlympiA	NDA 208558	Clinical	Conduct analyses of clinical trial data to characterize the safety and pharmacokinetics of olaparib across a diverse population. To support a comparative assessment across all U.S. race and ethnic populations, ensure that racial and ethnic minorities are sufficiently represented in the analysis. Include a tabular summary of the available pharmacokinetic data by each racial and ethnic group. Provide the specific racial ethnic group as well as the geographic location of each patient.	4248-1	11-03-2022	31-07-2024	Fulfilled	01-12-2023	Draft Protocol Submission (Analysis Plan): 01/2023 Final Protocol Submission (Analysis Plan): 07/2023 Study Completion: 01/2024 Final Report Submission: 07/2024
FluMist	BLA	125020/STN 1668	Clinical	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	29-02-2012	31-12-2018	Delayed		Study enrolment suspended for the 2016-2017, 2017-2018, 2018-2019, 2019-2020, 2020-2021, 2021-2022, 2022-2023 influenza seasons. Due to the ongoing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (novelcoronavirus-2019, [COVID-19]) pandemic and the fact that supply of the influenza vaccine to the US will not be at levels to conduct a test negative case-control study, the study will not be conducted as per earlier planned timelines

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Zomig Nasal Spray	NDA	NDA 21450	Clinical	PMR 2921-3: Conduct a randomized, adequately controlled safety and efficacy study of Zomig (zolmitriptan) Nasal Spray in pediatric patients with migraine ages 6 years to 11 years old followed by an evaluation of long-term safety in an open label extension of that study. The long-term safety evaluation 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 portion of the study.	PMR 2921-3	09-03-2017	30-01-2022	Not fulfilled	11-09-2022	On 09-Nov-2022, FDA has provided defferal extension and released new PMR 2921-3 with recommendation of conducting new efficacy study. Commitment due date: Nov-2023 This NDA 21450 was transffered to Amneal with effective date of 29-Dec-2022 and as a new MAH, Amneal would take care of further commitment fulfillment. The CSR has been submitted on 12/01/2022 and under assessment with US FDA. We have received Information Request for the same.
Tezspire	NDA	761224	Clinical	PMR 4188-1: Conduct a PK/safety study in children 5-11 years of age with asthma requiring daily controller medication	PMR 4188-1		31-05-2024	Pending		Study is completed - CSR to be finalized in early March and submitted to FDA
Tezspire	NDA	761224	Clinical	PMR 4188-2: Conduct a 52-week efficacy and safety study in children 5 to < 12 years of age with severe asthma.	PMR 4188-2		30-09-2028	Pending		The study has not been initiated, but it does not meet the criterion for delayed.
Tezspire	NDA	761224	Clinical	PMR 4188-3: Conduct an efficacy, safety, and PK study in children 2 years to < 5 years of age with severe asthma with a continued safety evaluation out to a minimum of 52 weeks.	PMR 4188-3		30-09-2036	Pending		The study has not been initiated, but it does not meet the criterion for delayed.
Saphnelo	BLA	761123	Clinical	Conduct a prospective pregnancy registry to evaluate the effects of Saphnelo (anifrolumab-fnia) on pregnancy and maternal and fetal/neonatal outcomes. This pregnancy registry study may be conducted as part of a multiple-product or disease-based pregnancy registry. Final Report Submission: 04/2032	4116-2	30/07/2021	30/04/2032	Pending		
Saphnelo	BLA	761123	Clinical	Conduct a retrospective cohort study in a claims-based database to evaluate the effects of Saphnelo (anifrolumab-fnia) on pregnancy-related outcomes. The timetable you submitted on July 26, 2021, states that you will conduct this study according to the following schedule: Final Protocol Submission: 04/2022 (PMR revised to 08/2022) - complete	4116-3	30/07/2021	31/08/2022	Pending		
Saphnelo	BLA	761123	Clinical	Conduct a retrospective cohort study in a claims-based database to evaluate the effects of Saphnelo (anifrolumab-fnia) on pregnancy-related outcomes. The timetable you submitted on July 26, 2021, states that you will conduct this study according to the following schedule: Study Completion: 04/2031	4116-3	30/07/2021	30/04/2031	Pending		
Saphnelo	BLA	761123	Clinical	Conduct a retrospective cohort study in a claims-based database to evaluate the effects of Saphnelo (anifrolumab-fnia) on pregnancy-related outcomes. The timetable you submitted on July 26, 2021, states that you will conduct this study according to the following schedule: Final Report Submission: 04/2032	4116-3	30/07/2021	30/04/2032	Pending		

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Saphnelo	BLA	761123	Clinical	Perform a lactation study, milk only, in lactating women who have received Saphnelo (anifrolumab-fnia) to assess concentrations of anifrolumab-fnia in breast milk using a validated assay. A mother-infant pair study may be required in the future depending on the results of this milk-only study. The timetable you submitted on July 29, 2021, states that you will conduct this study according to the following schedule: Final Protocol Submission: 08/2022 - (PMR Revised to 04/2023) -SDC submitted 08/2022	4116-4	30/07/2021	30/04/2023	Pending		
Saphnelo	BLA	761123	Clinical	Perform a lactation study, milk only, in lactating women who have received Saphnelo (anifrolumab-fnia) to assess concentrations of anifrolumab-fnia in breast milk using a validated assay. A mother-infant pair study may be required in the future depending on the results of this milk-only study. The timetable you submitted on July 29, 2021, states that you will conduct this study according to the following schedule: Study Completion: 08/2025	4116-4	30/07/2021	31/08/2025	Pending		
Saphnelo	BLA	761123	Clinical	Perform a lactation study, milk only, in lactating women who have received Saphnelo (anifrolumab-fnia) to assess concentrations of anifrolumab-fnia in breast milk using a validated assay. A mother-infant pair study may be required in the future depending on the results of this milk-only study. The timetable you submitted on July 29, 2021, states that you will conduct this study according to the following schedule: Final Report Submission: 02/2026	4116-4	30/07/2021	28/02/2026	Pending		
Imjudo (Tremelimumab)	BLA	US License No. 2059 BLA 761289	Clinical	REQUIRED PEDIATRIC ASSESSMENTS PMR 4333-1: Conduct Study D419EC00001 (A Phase I/II, open-label, multicenter study to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of tremelimumab in combination with durvalumab in pediatric patients) to further characterize the safety, pharmacokinetics, and efficacy of tremelimumab in combination with durvalumab in patients from birth to <18 years of age with relapsed/refractory malignant solid tumors or a relapsed/refractory hematological malignancy including lymphomas for whom no standard treatment is available. Include at least 12 patients in the dose escalation cohort and at least 45 evaluable patients in the dose expansion cohort. Trial Completion:02 /2024 Final Report Submission: 12 /2024	PMR 4333-1	21-10-2022	31-12-2024	Pending		

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Imjudo (Tremelimumab)	BLA	US License No. 2059 BLA 761289	Clinical	POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B PMC 4333-2: Conduct a study, Study 2, to evaluate the efficacy and safety of tremelimumab used in combination with durvalumab in children from birth to less than 18 years of age with a pediatric solid tumor, to further characterize the efficacy and safety of tremelimumab in combination with durvalumab in pediatric solid tumors The timetable you submitted on September 30, 2022, states that you will conduct this study according to the following schedule: Draft Protocol Submission: 12/2024 Final Protocol Submission: 06 /2025 Study Completion: 06 /2030 Final Report Submission: 04 /2031	PMC 4333-2	31-10-2022	04-04-1931	Pending		
Imjudo (Tremelimumab)	BLA	US License No. 2059 BLA 761289	Clinical	PMC 4333-3: Conduct a study, Study 3, to evaluate the efficacy and safety of tremelimumab in combination with durvalumab in children from birth to less than 18 years of age with a pediatric hematological malignancy, to further characterize the efficacy and safety of tremelimumab in combination with durvalumab in pediatric hematologic malignancies. The timetable you submitted on September 30, 2022, states that you will conduct this study according to the following schedule: Draft Protocol Submission: 12/2024 Final Protocol Submission: 06 /2025 Study Completion: 06 /2030 Final Report Submission: 04 /2031	PMC 4333-3	31-10-2022	01-04-2031	Pending		

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Imjudo (Tremelimumab)	BLA	US License No. 2059 BLA 761289	CMC	4333-4 To perform a shipping validation study under real time shipping conditions (i.e., temperature, mode of transport, shipping duration, and shipping containers and packing representative of the minimum and maximum load) using a representative commercial tremelimumab drug product lot in the final commercial container closure and packaging systems to evaluate the ability of the shipping containers to maintain the recommended temperature and to evaluate the impact of shipping from the AstraZeneca Sweden labeling and packaging site to the US Distribution Center on the physical integrity and product quality of tremelimumab drug product. The shipping validation data will be submitted in accordance with 21 CFR 601.12. The timetable you submitted on August 9, 2022, states that you will conduct this study according to the following schedule: Final Report Submission: 12/31/2023	PMC 4333-4	31-10-2022		ongoing		
Imjudo (Tremelimumab)	BLA	US License No. 2059 BLA 761289	CMC	4333-5 Implement pressure monitoring upstream the sterile filter using the pressure validated by the microbial retention study. The timetable you submitted on May 31, 2022, states that you will conduct this study according to the following schedule: Final Report Submission: 12/31/2023 Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this BLA	PMC 4333-5	31-10-2022		ongoing		