AbbVie U.S. Postmarketing Commitments Table:

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
ANDROGEL (testosterone gel)	NDA 022309 and NDA 021015	PMR 3026-1: A randomized, double-blind, placebo-controlled clinical trial to evaluate the effect of testosterone replacement therapy on the incidence of major adverse cardiovascular events in men. We recommend that this trial also assess other important safety and efficacy outcomes associated with testosterone therapy.	February 09, 2015	Final Report Submission: June 30, 2023	Ongoing
CREON (pancrelipase)	NDA 20725	PMR 751-2: A 10 year, observational study to prospectively evaluate the incidence of fibrosing colonopathy in patients with cystic fibrosis treated with Creon (pancrelipase) Delayed- Release Capsules in the US and to assess potential risk factors for the event.	April 30, 2009	Final Report Submission: June 20, 2021	Ongoing
CREON (pancrelipase)	NDA 20725	PMR 751-3: A 10 year, observational study to prospectively evaluate the risk of transmission of selected porcine viruses in patients taking Creon (pancrelipase) Delayed-Release Capsules.	April 30, 2009	Final Report Submission: June 20, 2021	Ongoing
HUMIRA (adalimumab)	BLA 125057/114	PMC-1: Conduct Study Protocol P10-262, an 800-patient observational study, with inclusion of a reference group, of pediatric patients 4 to 17 years of age with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA).	February 21, 2008	Final Report Submission: December 31, 2021 Date Extended: December 31, 2024	Ongoing
HUMIRA	BLA	PMC-2: Conduct a prospective, multi-center	January 18,	Final Report	Ongoing

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
(adalimumab)	125057/110	registry including 5000 adult psoriasis patients treated with adalimumab in the United States. This registry will characterize and assess the incidence of serious adverse events (including serious infections, tuberculosis, opportunistic infections, malignancies, hypersensitivity reactions, autoimmune reactions and deaths) as well as other adverse events of interest in the study cohort. All enrolled study patients will be evaluated for a period of at least 10 years with comprehensive annual reports provided to the Agency. Collect data on the patient characteristics, demographics and drug exposure (including dose, duration and time to onset of adverse event). The collection of data will be via active surveillance methods and data will be validated by a review of medical records as per the guidance for industry titled *Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.*	2008	Submission: January 31, 2023	
HUMIRA (adalimumab)	BLA 125057/274	PMR 2418-2: Enhanced pharmacovigilance program for reports of malignancy in pediatric, adolescent, and young adult (≤ 30 years of age) patients treated with Humira (adalimumab), for a period of up to 10 years to collect data that will be analyzed to better define the risk of this serious adverse event. The enhanced pharmacovigilance program includes the following: 1) active query of reporters to	February 14, 2017	Final Report Submission: March 31, 2020	Ongoing

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		obtain additional clinical information related to malignancy diagnoses; 2) expedited reporting to FDA of all initial and follow-up reports of any malignancy in pediatric, adolescent, and young adult patients.			
HUMIRA (adalimumab)	BLA 125057/232	PMR-1: A study in inflammatory bowel disease (IBD) patients treated with Humira (adalimumab) in which you will bank tissue or blood samples (as appropriate) and then analyze them to identify genetic mutations and other biomarkers that predispose these patients to developing Hepatosplenic T-Cell Lymphoma (HSTCL).	September 28, 2012	Final Report Submission: September 30, 2020	Ongoing
HUMIRA (adalimumab)	BLA 125057/232	PMR-2: A multi-center observational study of Humira (adalimumab) in adults with moderately to severely active ulcerative colitis treated in a routine clinical setting, to assess the long-term safety as measured by the incidence of opportunistic infections and malignancies. Long-term effectiveness should be assessed as a secondary goal. The proposed study should follow patients for a period of at least 10 years from time of enrollment in order to ascertain adverse events with longer latency periods such as malignancies. The primary analysis is to summarize safety data for patients on adalimumab and patients on non-biologic immunomodulator therapy. The study should be adequately sized to sufficiently	September 28, 2012	Final Report Submission: December 31, 2029	Ongoing

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		detect a doubling of the risk of lymphoma events in each treatment group. A secondary analysis is to summarize safety data for patients on adalimumab and patients on the combination of adalimumab and non-biologic immunomodulator therapy. In addition, the study is to document and evaluate effects of withdrawal and re- treatment with adalimumab and "switching" with other tumor necrosis factor (TNF)-blockers or biologics.			
HUMIRA (adalimumab)	BLA 125057/232	PMR-4: Utilizing a validated AAA assay as described in PMR #3, you should measure and analyze the immunogenicity profile based on post-dose patient samples from completed study M10-223, the trial conducted under PMR #5, the trial conducted under PMR #6, and the trial conducted under PMR #7.	September 28, 2012	Original Date: March 31, 2019 Date Extended: December 31, 2020	Delayed
HUMIRA (adalimumab)	BLA 125057/232	PMR-5: Conduct a trial in moderately to severely active ulcerative colitis patients to evaluate the safety of induction regimens of adalimumab at doses higher than 160/80 mg. In this trial, the efficacy of Humira (adalimumab) should also be assessed, both during induction treatment as well as during continued treatment after induction, and pharmacokinetic measurements should be conducted for exposure-response analysis. In this trial, collecting samples for immunogenicity testing (utilizing a validated	September 28, 2012	Original Date: March 31, 2019 Date Extended: December 31, 2020	Delayed

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		anti-adalimumab antibody assay as described in PMR #3 and conducting analyses of the impact of immunogenicity on safety, pharmacokinetics, and efficacy is important.			
HUMIRA (adalimumab)	BLA 125057/232	PMR-6: A safety and pharmacokinetic trial as a sub-study of the trial described in PMR #5 above to evaluate trough concentrations of adalimumab and antibody levels (utilizing a validated anti-adalimumab antibody assay as described in PMR #3) at the time of loss of clinical remission in patients whose physicians plan to escalate the dose (e.g., decrease the dosing interval to weekly or increase the dosage) in response to loss of remission. Trough concentrations will be evaluated to determine whether patients who have low adalimumab exposures benefit from dose escalation without increasing risk of serious adverse events.	September 28, 2012	Final Report Submission: March 31, 2019 Date Extended: December 31, 2020	Delayed
HUMIRA (adalimumab)	BLA 125057/232	PMR-7: Conduct a one-year, multi-center, randomized, double-blind placebo-controlled trial to evaluate the efficacy, safety and pharmacokinetics of adalimumab in pediatric patients 5 to 17 years of age with moderately to severely active ulcerative colitis. In this trial, the efficacy of adalimumab should be assessed during induction treatment as well as during continued treatment after induction, and pharmacokinetic measurements should be	September 28, 2012	Final Report Submission: December 31, 2019	Ongoing

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		conducted for exposure-response analysis. Also, collect samples for immunogenicity testing (utilizing a validated AAA assay as described in PMR #3) and conduct analyses of the impact of immunogenicity on pharmacokinetics, efficacy and safety.			
MARINOL (dronabinol)	NDA 018651	Pre and Post Natal development toxicology study in rats exposed to dronabinol to assess the risk of neurotoxicity.	July 1, 2016	Final Report Submission: September 30, 2019	Submitted
MAVYRET (glecaprevir, pibrentasvir)	NDA 209394	3246-1: Conduct a study to evaluate the pharmacokinetics, safety and treatment response (using sustained virologic response) of glecaprevir and pibrentasvir in pediatric subjects 3 through less than 18 years of age with chronic hepatitis C virus infection	August 03, 2017	Final Report Submission: January 31, 2023	Ongoing
MAVYRET (glecaprevir, pibrentasvir)	NDA 209394	PMC 3246-2: Submit the final SVR12 report and datasets, including drug resistance datasets, for the ongoing clinical trial M16-126, evaluating glecaprevir and pibrentasvir in patients with HCV genotype 5 or 6 infection.	August 03, 2017	Final Report Submission: March 31, 2019	Fulfilled
MAVYRET (glecaprevir, pibrentasvir)	NDA 209394	PMC 3246-3: Submit the final SVR12 study report and datasets for the ongoing trial M14-730 (EXPEDITION-2) to provide additional efficacy and safety data in HIV/HCV coinfected subjects receiving glecaprevir and pibrentasvir.	August 03, 2017	Final Report Submission: October 31, 2017	Fulfilled
MAVYRET (glecaprevir,	NDA 209394	PMC 3246-4: Conduct a study evaluating the efficacy of glecaprevir and pibrentasvir in	August 03, 2017	Final Report Submission:	Submitted

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
pibrentasvir)		HCV genotype 1 infected subjects with prior treatment experience with an NS5A inhibitor plus sofosbuvir regimen.		June 30, 2019	
MAVYRET (glecaprevir, pibrentasvir)	NDA 209394	PMC 3246-5: Conduct a study to characterize the phenotypic effect of the following individual NS3/4A or NS5A substitutions on the cell culture anti-HCV activity of glecaprevir or pibrentasvir, respectively: genotype 1a NS3_I18V, NS3_N77S, NS3_V116A, NS3_I354V and NS4A_V23A, genotype 3a NS3_I366V, and genotype 1a NS5A_A61T.	August 03, 2017	Final Report Submission: March 31, 2018	Fulfilled
MAVYRET (glecaprevir, pibrentasvir)	NDA 209394	3719-1: Conduct a study to evaluate the pharmacokinetics, safety and treatment response (using sustained virologic response) of glecaprevir and pibrentasvir in pediatric subjects 3 through less than 12 years of age with chronic hepatitis C virus infection.	September 26, 2019	Final Report Submission: January 31, 2023	Ongoing
Orilissa (elagolix)	NDA 210450	PMR 3390-1: A prospective pregnancy registry to evaluate the effects of Orilissa on pregnancy and maternal and fetal/neonatal outcomes.	July 23, 2018	Final Report Submission: January 31, 2030	Ongoing
Orilissa (elagolix)	NDA 210450	PMR 3390-2: A pharmacoepidemiology surveillance study to evaluate the effects of Orilissa on pregnancy-related outcomes.	July 23, 2018	Final Report Submission: January 31, 2025	Ongoing
Orilissa (elagolix)	NDA 210450	PMR 3390-3: A drug-drug interaction trial to assess the pharmacokinetics, safety, and tolerability of the co-administration of a	July 23, 2018	Final Report Submission: April 30, 2020	Ongoing

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		combined oral contraceptive (containing ethinyl estradiol and levonorgestrel) with Orilissa 200 mg twice daily			
Orilissa (elagolix)	NDA 210450	PMC 3390-4: A randomized, controlled clinical trial to assess the effects of a combined hormonal contraceptive on the efficacy of Orilissa in women with moderate to severe pain associated with endometriosis. This trial will also assess the effects of Orilissa on the efficacy of the combined hormonal contraceptive, and safety with concomitant use of Orilissa and the combined hormonal contraceptive.	July 23, 2018	Final report Submission: February 28, 2023	Ongoing
Rinvoq (upadacitinib)	NDA 211675	3680-1: Conduct a multiple-dose pharmacokinetic study in children from 2 to less than 18 years of age with juvenile idiopathic arthritis (JIA)	August 16, 2019	February 28, 2021	Ongoing
Rinvoq (upadacitinib)	NDA 211675	3680-2: Conduct a randomized withdrawal, double-blind, placebo-controlled study to evaluate the efficacy and safety of upadacitinib in children from 2 to less than 18 years of age with polyarticular-course JIA	August 16, 2019	October 31, 2026	Pending
Skyrizi (risankizumab-rzaa) Injection	BLA 761105	3594-1: Conduct a pharmacokinetics (PK), safety and efficacy study in pediatric subjects 6 to <18 years of age with moderate to severe plaque psoriasis (with a duration of exposure to risankizumab of at least one year)	April 23, 2019	March 31, 2026	Pending
Skyrizi (risankizumab)	BLA 761105	3594-2: A prospective, registry based observational exposure cohort study that	April 23, 2019	June 30, 2033	Pending

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		compares the maternal, fetal, and infant outcomes of women exposed to risankizumab during pregnancy to an unexposed control population. The registry will detect and record major and minor congenital malformations, spontaneous abortions, stillbirths, elective terminations, small for gestational age, and any other adverse pregnancy outcomes. These outcomes will be assessed throughout pregnancy. Infant outcomes, including neonatal deaths, infections in the first 6 months of life, and effects on postnatal growth and development, will be assessed through at least the first year of life.			
Skyrizi (risankizumab-rzaa) Injection	BLA 761105	3594-3: Conduct a retrospective cohort study using claims or electronic medical record data or a case control study to assess adverse pregnancy outcomes such as major congenital malformations, spontaneous abortions, stillbirths, small for gestational age, neonatal deaths, and infant infections in women exposed to risankizumab during pregnancy compared to an unexposed control population.	April 23, 2019	October 31, 2030	Pending
Skyrizi (risankizumab-rzaa) Injection	BLA 761105	3594-4: Conduct an observational study to assess the long-term safety of risankizumab compared to other therapies used in the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy in the course	April 23, 2019	January 31, 2034	Pending

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		of actual clinical care. The study's primary outcome is long-term malignancy. Secondary outcomes include, but are not limited to, serious infections, tuberculosis, opportunistic infections, hypersensitivity reactions, autoimmune disease, neurologic or demyelinating disease, cardiovascular, gastrointestinal and hematologic adverse events. Describe and justify the choice of appropriate comparator population(s) and estimated background rate(s) relative to risankizumab-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, a clinically meaningful increase in malignancy risk above the comparator background rate(s), with a prespecified statistical analysis method. Specify concise case definitions and validation algorithms for both primary and secondary outcomes. For the risankizumab-exposed and comparator(s) cohorts, clearly define the study drug initiation period and any exclusion and inclusion criteria. Enroll patients over an initial 4-year period and follow for a minimum of 8 years from the time of enrollment.			
Skyrizi (risankizumab-	BLA 761105	3594-5: To perform a leachable study to evaluate the drug product in the final container	April 23, 2019	June 30, 2020	Pending

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
rzaa) Injection		closure system through the end of shelf-life when stored under the recommended conditions. Testing should be performed at regular intervals and should include appropriate methods to detect, identify, and quantify organic non-volatile (e.g. HPLC-UV-MS), volatile (e.g. headspace GC-MS) and semi-volatile (e.g. GC-MS) species and metals (e.g. ICP-MS). Study results will be updated annually in the BLA Annual report. The complete data and risk evaluation for potential impact of leachables on product safety and quality will be submitted to the BLA.			
TECHNIVIE (ombitasvir, paritaprevir, and ritonavir)	NDA 207931	2934-1: Evaluate the safety and treatment response (using sustained virologic response as the primary endpoint) of TECHNIVIE (ombitasvir, paritaprevir, and ritonavir) in a cohort of pediatric subjects 3 to less than 18 years of age with chronic genotype 4 hepatitis C virus infection.	July 24, 2015	Original Date: August 31, 2019 Date Extended: August 31, 2022	Ongoing
VENCLEXTA (venetoclax)	NDA 208573	PMR 3068-2: Evaluate the effect of hepatic impairment on the pharmacokinetics and safety of VENCLEXTA (venetoclax) compared to subjects with normal hepatic function. Submit a complete final report with all supporting datasets for trial M15-342 entitled, “A Study to Evaluate the Safety and Pharmacokinetics of a Single Dose of Venetoclax in Female Subjects with Mild, Moderate, or Severe Hepatic	April 11, 2016	Original Date: December 31, 2017 Date Extended: October 31, 2018	Fulfilled

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		Impairment."			
VENCLEXTA (venetoclax)	NDA 208573	PMC 3426-1: Provide updated efficacy information from Study M14-032 to characterize longer-term efficacy of venetoclax monotherapy in patients with previously treated chronic lymphocytic leukemia (CLL). Data will include independent review committee-assessed and investigator-assessed duration of response for all 127 patients with CLL with a shared cut-off date of March 30, 2018. Include a written summary and associated derived and tabulated datasets.	June 08, 2018	Final Report Submission: December 31, 2018	Fulfilled
VENCLEXTA (venetoclax)	NDA 208573	PMC 3426-2: Provide updated efficacy information from Study M12-175 to characterize longer-term efficacy of venetoclax monotherapy in patients with previously treated chronic lymphocytic leukemia (CLL) and small lymphocyte lymphoma (SLL). Data will include independent review committee-assessed and investigator-assessed duration of response for all 67 patients with CLL or SLL treated at the 400 mg dose, with a shared cut-off date of March 30, 2018. Include a written summary and associated derived and tabulated datasets.	June 08, 2018	Final Report Submission: February 28, 2019	Fulfilled
VENCLEXTA (venetoclax)	NDA 208573	PMR 3545-1: Submit the complete final study report and data that verifies and isolates the clinical efficacy and safety from trial M16-043, a randomized, double-blind,	November 21, 2018	Final report submission: January 31, 2020	Submitted

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		placebo-controlled Phase 3 study of venetoclax co-administered with low-dose cytarabine versus low-dose cytarabine in treatment naïve patients with acute myeloid leukemia who are precluded from receiving standard chemotherapy due to age > 75 years or comorbidities. The primary endpoint will be overall survival. An interim analysis of overall survival will be performed and included in the interim analysis submission or the final study report.			
VENCLEXTA (venetoclax)	NDA 208573	PMR 3545-2: Submit the complete final study report and data that verifies and isolates the clinical efficacy and safety from trial M15-656, a randomized, double-blind, placebo-controlled Phase 3 study of venetoclax in combination with azacitidine versus azacitidine in treatment naïve patients with acute myeloid leukemia who are precluded from receiving standard chemotherapy due to age > 75 years or comorbidities. The primary endpoint will be overall survival. Interim analysis of response rates and overall survival will be performed and included in the interim analysis submission or the final study report.	November 21, 2018	Final report submission: January 31, 2021	Ongoing
VIEKIRA PAK (dasabuvir/ombitasvir/paritap	NDA 206619	2830-1: Evaluate the pharmacokinetics, safety and treatment response (using sustained virologic response as the primary endpoint) of ombitasvir, paritaprevir, ritonavir, dasabuvir	December 19, 2014	Original Date: August 31, 2019	Ongoing

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
revir and ritonavir)		(Viekira Pak) in pediatric subjects 3 to less than 18 years of age with chronic hepatitis C virus infection.		Date Extended: August 31, 2022	
VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir and ritonavir)	NDA 206619	2830-2: Collect and analyze long-term safety data for subjects enrolled in the pediatric ombitasvir, paritaprevir, ritonavir, dasabuvir (Viekira Pak™) pharmacokinetic, safety, and antiviral efficacy study(ies). Data collected should include at least 3 years of follow-up in order to characterize the durability of response to ombitasvir, paritaprevir, ritonavir, dasabuvir (Viekira Pak™) and the long-term safety including growth assessment, sexual maturation, and characterization of resistance associated substitutions in viral isolates from subjects failing therapy.	December 19, 2014	Original Date: August 31, 2022 Date Extended: August 31, 2025	Ongoing
VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir and ritonavir)	NDA 206619	PMR 2830-5: Conduct an observational study to investigate the safety and efficacy of ombitasvir, paritaprevir, ritonavir, dasabuvir (Viekira Pak™) in a sufficient number of Blacks/African Americans with and without cirrhosis compared to whites/Caucasians.	December 19, 2014	Final Report Submission: December 31, 2020	Fulfilled
VIEKIRA XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir)	NDA 208624	3107-1 Evaluate the pharmacokinetics, safety and treatment response (using sustained virologic response as the primary endpoint) of ombitasvir, paritaprevir, ritonavir, dasabuvir (VIEKIRA XR™) in pediatric patients greater than 3 years of age with chronic hepatitis C virus infection, who weigh at least 42 kg and	July 22, 2016	Final Report Submission: August 31, 2022	Ongoing

Name of Product	NDA/BLA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
		are able to swallow tablets.			
ZEMPLAR (paricalcitol)	NDA 21606/S-004	PMR 2144-1: Deferred pediatric study under PREA to determine the safety of Zemplar (paricalcitol) for the treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 5 in pediatric patients ages 0 to 9 years receiving peritoneal dialysis or hemodialysis.	June 29, 2009	Original Date: April 30, 2012 Date Extended: May 31, 2020	Pending

Note: The PMC Summary Table includes all active U.S. postmarketing commitments and requirements as of September 30, 2019.