Pharmaceutical Companies - U.S. Post-Marketing Requirements and Commitments

September 2026

Product	Due Date	Status	Description of Commitment or Requirement
(bedaquiline fumarate)	31-Aug-2023	Submitted	A confirmatory randomized double blind placebo controlled multicenter Phase 3 trial in subjects with sputum smear-positive pulmonary multidrug resistant tuberculosis (MDR-TB). This trial should assess long- term outcomes of failure or relapse or death at least 6 months after all MDR-TB treatment is completed.
(canagliflozin hemihydrate)	30-Jun-2024	Submitted	A 26-week, randomized double-blind, placebo-controlled study, followed by a 26-week double-blind, placebo- or active-controlled extension, to evaluate the efficacy and safety of canagliflozin compared to placebo in pediatric patients ages 10 to <18 years with type 2 diabetes mellitus, as add-on to metformin and as monotherapy.
PREZCOBIX ® PED®,PREZCOBIX ® PED® (cobicistat + darunavir ethanolate)	30-May-2025	Submitted	Evaluate the pharmacokinetics, safety, and antiviral activity (efficacy) of darunavir and cobicistat fixed dose combination (FDC) age-appropriate formulation in HIV-infected pediatric subjects 3 years to less than 6 years of age and weighing at least 15 kg. The safety and antiviral activity (efficacy) of darunavir and cobicistat FDC age-appropriate formulation in pediatric subjects should be evaluated for a minimum of 24 weeks. A clinical trial in children ages 3 years to less than 6 years may not be required if the dosing recommendation for the FDC age-appropriate formulation can be supported by pediatric trials already conducted with the individual drug products and if the age-appropriate FDC produces similar exposures as the individual components.
(fentanyl)	31-Dec-2016	Submitted	An observational study to develop and validate an algorithm using coded medical terminologies and other electronic healthcare data to identify opioid-related overdose and death.

Product	Due Date	Status	Description of Commitment or Requirement
(golimumab))	31-May-2030	Delayed	A prospective, multi-center, long-term, observational study of ulcerative colitis patients treated with SIMPONI®(golimumab) in a routine clinical setting, to assess the long-term safety of SIMPONI® (golimumab). The study's primary outcome should be the incidence of lymphoma. Design the study around a testable hypothesis to rule out a clinically meaningful increase in lymphoma above an estimated background risk in a suitable comparator. Secondary endpoints should be pre-specified and may include the incidence of other malignancies. Select and justify the choice of appropriate comparator population(s) and corresponding background rate(s) relative to SIMPONI® (golimumab)-exposed patients. Provide sample sizes and effect sizes that can be ruled out under various enrollment target scenarios and loss to follow-up assumptions. Patients should be enrolled over an initial 5-year period and then followed for a period of at least 10 years from the time of enrollment. Progress updates of patient accrual and a demographic summary should be provided in your annual reports. Safety data should be provided in periodic safety reports..
(infliximab)	1-Dec-2018	Submitted	A prospective, multi-center registry including 4000 adult psoriasis patients treated with commercial REMICADE® (infliximab) in the United States. This registry will characterize and assess the incidence of serious adverse events (including serious infection, 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 twice yearly for a period of at least 8 years with comprehensive annual reports provided to the agency. We will to 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: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.
(infliximab)	30-Jun-2018	Submitted	A safety and pharmacokinetic trial as a substudy of the DEVELOP registry to evaluate whether trough concentrations at the time of loss of clinical response can be used to identify pediatric UC and Crohn's disease patients who have low infliximab exposures and would benefit from a dose increase above that approved without increasing risk of serious adverse events.
(infliximab)	31-Dec-2045	Ongoing	A study to analyze samples from the pediatric inflammatory bowel disease (IBD) registry (DEVELOP) and the safety and pharmacokinetic trial as a substudy of the DEVELOP registry to determine the presence of anti-drug antibodies (ADA).
(infliximab)	30-Jun-2027	Ongoing	Conduct a registry of patients with pediatric Crohn's disease being treated with REMICADE® (infliximab) that will be established to obtain long-term clinical status and safety information. Information will be collected on patient demographics, disease characteristics, history of concomitant medications, dose and duration and frequency of REMICADE® (infliximab) administration, clinical status, adverse events including dysplasias and malignancies of all types, infections, autoimmune disease, assessment of immunogenicity, and potential effects of antibody formation. The age range should include patients ages 0 to 19 years. This registry will be designed so that detailed clinical status information is collected at registry entry and on a 6-month basis for at least 20 years. We commit to expand the currently existing Pediatric IBD Registry, and will actively encourage both patients and physicians to participate in the registry through an advertisement campaign, that includes a plan for proactive communication of associated risk. We also commit to recruiting at least 2,000 REMICADE® (infliximab)-treated pediatric Crohn's patients, which will provide an adequate number of patients to participate in the registry so that outcome measures will be collected and adequate risk assessment can be made. We will provide prompt risk communication for serious adverse events that are reported through the registry. The registry data will be analyzed at yearly intervals and the results will be submitted in annual reports for BB-IND 5389.

Product	Due Date	Status	Description of Commitment or Requirement
(infliximab)	31-Dec-2045	Ongoing	Expand the Pediatric IBD Registry (DEVELOP) to include pediatric patients with ulcerative colitis (UC) and indeterminate colitis (IC).
(levofloxacin hemihydrate)	31-Dec-2006	Submitted	Commitment to conduct post-marketing PK clinical trial in renally impaired patients
(paracetamol + tramadol hydrochloride)	15-May-2005	Submitted	Pediatric study commitment; final study report for TRAMAP-PEDS-001. Study TRAMAP-PEDS-001 compared the safety and clinical effectiveness of single doses of tramadol 75 mg/APAP 650 mg, tramadol 37.5 mg/APAP 325 mg, and placebo in pediatric participants, aged 8 to 17 years, with post-surgical pain. This study enrolled 150 participants at 20 study centers in the United States and Costa Rica.
(risperidone)	No Due Date	Submitted	Submit your plans for tracking medication errors and product complaints involving the new kits and clarify how you will address the challenges of differentiating reports for the new kits from reports involving the currently marketed kits
(simeprevir sodium)	31-Dec-2021	Terminated	A trial to evaluate the pharmacokinetics, safety and treatment response (using sustained virologic response) of OLYSIO™ (simeprevir) as a component of a combination antiviral treatment regimen in pediatric subjects 3 through 17 years of age with chronic hepatitis C.

Product	Due Date	Status	Description of Commitment or Requirement
(simeprevir sodium)	31-Jan-2025	Terminated	Collection of long-term safety data for subjects enrolled in the pediatric simeprevir safety, pharmacokinetic and efficacy trial. Data collected should include at least 3 years of follow-up in order to characterize the long-term safety of OLYSIO™ (simeprevir) in pediatric subjects, including growth assessment, sexual maturation and characterization of OLYSIO™ (simeprevir) resistance-associated substitutions in viral isolates from subjects failing therapy.
STELARA®®,STELARA®®,STELARA®®,STELARA®® (ustekinumab)	30-Dec-2022	Submitted	Establish a U.S.-based prospective, observational pregnancy exposure registry that compares the pregnancy and fetal outcomes of women exposed to STELARA® (ustekinumab) during pregnancy to an unexposed control population. Outcomes of the registry should include major and minor congenital anomalies, spontaneous abortions, stillbirths, elective terminations, adverse effects on immune system development, and other serious adverse pregnancy outcomes. These outcomes should be assessed throughout pregnancy. Infant outcomes should be assessed through at least the first year of life.
STELARA®®,STELARA®®,STELARA®®,STELARA®® (ustekinumab)	15-Dec-2021	Submitted	Provide data analyses from the Pregnancy Research Initiative (study C0168T71).
STELARA® (ustekinumab)	31-Aug-2030	Ongoing	Conduct a long-term, postmarketing, observational study to assess the long-term safety of STELARA (ustekinumab) versus other therapies used in the treatment of adults with moderate to severe Crohn's disease. The study's primary outcome is malignancy. Secondary outcomes include, but are not limited to, opportunistic infections (e.g., tuberculosis [TB]). Specify concise case definitions, and provide outcome validation for both primary and secondary outcomes. Describe and justify the choice of appropriate comparator population(s) and estimated background rate(s) relative to ustekinumab-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, with a pre-specified statistical analysis method. For the ustekinumab-exposed and comparator(s), the study drug initiation period should be clearly defined, including any exclusion and inclusion criteria. Ensure adequate number of patients with at least 18 months of ustekinumab exposure at the end of the study. Follow for a period of at least 7 years. (Draft Protocol Submission: February 2017 Final Protocol Submission: September 2017 Interim Report: December 2025 Study Completion: August 2029 Final Report Submission: August 2030)

Product	Due Date	Status	Description of Commitment or Requirement
STELARA® (ustekinumab)	31-Dec-2025	Submitted	Conduct a randomized, controlled, blinded, multicenter trial to evaluate the safety and efficacy of STELARA (ustekinumab) in pediatric patients 2 to 17 years of age with moderately to severely active Crohn's disease despite conventional therapy. (Draft Protocol Submission: December 2019 Final Protocol Submission: June 2020 Study Completion: February 2024 Final Report Submission: September 2024)
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	31-Jul-2027	Ongoing	Conduct a Pharmacokinetics (PK), Safety and Efficacy Study in pediatric subjects 6 years to less than18 years of age with moderate to severe plaque psoriasis (with a duration of exposure to guselkumab of at least one year).
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	30-Jun-2031	Delayed	A prospective, registry-based observational exposure cohort study that compares the maternal, fetal, and infant outcomes of women exposed to guselkumab during pregnancy to an unexposed control population
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	30-Jun-2031	Delayed	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 guselkumab during pregnancy compared to an unexposed control population

Product	Due Date	Status	Description of Commitment or Requirement
TREMFYA®,TREMFYA®, TREMFYA®,TREMFYA®, TREMFYA®,TREMFYA®, TREMFYA®,TREMFYA®, TREMFYA®,TREMFYA®, TREMFYA® (guselkumab)	31-Dec-2031	Delayed	Conduct an observational study to assess the long-term safety of guselkumab compared to other therapies used in the treatment of adults with moderate-tosevere plaque psoriasis who are candidates for systemic therapy or phototherapy in the course of actual clinical care. The study's primary outcome is the long-term risk of 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
SPRAVATO™ (esketamine hydrochloride)	No Due Date	Submitted	Conduct a 3-year open-label safety study to characterize the long-term effects of esketamine on cognitive function and urinary symptoms. Ongoing trial TRD 3008 will be adapted to meet this requirement.
SPRAVATO™ (esketamine hydrochloride)	31-May-2021	Submitted	Conduct a 3-year open-label safety study to characterize the long-term effects of esketamine on cognitive function and urinary symptoms. Ongoing trial TRD 3008 will be adapted to meet this requirement.
SPRAVATO™ (esketamine hydrochloride)	30-Sep-2019	Submitted	Conduct a study to evaluate the efficacy of esketamine monotherapy for the treatment of treatment-resistant depression. The study design must be agreed to by the Division prior to initiating the study.
SPRAVATO™ (esketamine hydrochloride))	31-Jul-2024	Submitted	Conduct a study to evaluate the efficacy of esketamine monotherapy for the treatment of treatment-resistant depression. The study design must be agreed to by the Division prior to initiating the study.

Product	Due Date	Status	Description of Commitment or Requirement
BALVERSA®,BALVERSA®, BALVERSA®,BALVERSA™, BALVERSA™,BALVERSA™ (erdafitinib)	31-Mar-2023	Submitted	3561-3 Conduct a clinical pharmacokinetic trial that evaluates the effect of repeated doses of erdafitinib on the single dose pharmacokinetics of a sensitive CYP3A substrate (e.g., midazolam), to address the potential for excessive drug toxicity or decreased drug exposure, and to determine appropriate dosing recommendations when coadministering erdafitinib with a sensitive CYP3A substrate. This trial should be designed and conducted in accordance with FDA Draft Guidance for Industry: Clinical Drug Interaction Studies – Study Design, Data Analysis, and Clinical Implications. Submit the analysis and datasets with the final report.
BALVERSA®,BALVERSA®, BALVERSA®,BALVERSA™, BALVERSA™,BALVERSA™ (erdafitinib)	31-Aug-2023	Submitted	3561-4 Conduct a clinical pharmacokinetic trial that evaluates the effect of repeated doses of a strong inducer (e.g., rifampin) of CYP2C9 and CYP3A on the single dose pharmacokinetics of erdafitinib to assess the magnitude of decreased drug exposure and to determine appropriate dosing recommendations when erdafitinib is coadministered with CYP2C9 and CYP3A inducers. This trial should be designed and conducted in accordance with the FDA Draft Guidance for Industry: Clinical Drug Interaction Studies – Study Design, Data Analysis, and Clinical Implications. Submit the analysis and datasets with the final report.

Product	Due Date	Status	Description of Commitment or Requirement
STELARA® (ustekinumab)	31-Aug-2030	Ongoing	A long-term, postmarketing, observational study to assess the long-term safety of STELARA (ustekinumab) versus other therapies used in the treatment of adults with moderate to severe ulcerative colitis. The study's primary outcome is malignancy. Secondary outcomes include, but are not limited to, opportunistic infections (e.g., tuberculosis [TB]). Specify concise case definitions and provide outcome validation for both primary and secondary outcomes. Describe and justify the choice of appropriate comparator population(s) and estimated background rate(s) relative to ustekinumab-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, with a pre-specified statistical analysis method. For the ustekinumab-exposed and comparator(s), the study drug initiation period should be clearly defined, including any exclusion and inclusion criteria. Ensure adequate number of patients with at least 18 months of ustekinumab exposure at the end of the study. Follow for a period of at least 7 years. The ongoing observational study in patients with Crohn's disease with the same objectives, may be amended to also enroll patients with ulcerative colitis.
STELARA® (ustekinumab)	31-Oct-2025	Submitted	A one-year, randomized, controlled, blinded trial to evaluate the safety, efficacy, and pharmacokinetics of Stelara (ustekinumab) in pediatric patients 2 to 17 years of age with moderately to severely active ulcerative colitis.
STELARA® (ustekinumab)	30-Sep-2026	Ongoing	A multi-center, open-label extension study to evaluate the long-term safety of Stelara (ustekinumab) in pediatric patients 2 to 17 years of age with moderately to severely active ulcerative colitis who participated in PMC 3736-2.
(bedaquiline fumarate)	31-Dec-2020	Submitted	Develop a patient registry for bedaquiline-treated patients to assess incidence rates of serious adverse events, including death. The registry should capture the information listed below: a. Indication for use, including utilization of expert medical consultation. b. Minimum Inhibitory Concentration (MIC) data for baseline and any subsequent MDR-TB isolate (in patients who have relapsed/at end of treatment). c. Drug Utilization Data. d. Information on drug distribution mechanisms used. e. Information on how the drug was actually distributed to patients. f. Patient outcomes (clinical and microbiologic). g. Safety assessments in bedaquiline-treated patients, including deaths. h. Concomitant medications.

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TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	1-Jul-2027	Pending	Provide PK and safety information to support the pediatric assessment of guselkumab for the treatment of juvenile psoriatic arthritis (jPsA) in children 5 to 17 years of age.
PREZCOBIX ® PED®,PREZCOBIX ® PED® (cobicistat + darunavir ethanolate)	30-Nov-2021	Submitted	3632-1 Conduct a drug interaction trial to evaluate the effect of PREZCOBIX (darunavir and cobicistat) at steady state on the pharmacokinetics of dabigatran etexilate, a P-glycoprotein probe substrate.
SPRAVATO™ (esketamine hydrochloride)	30-Sep-2023	Submitted	Conduct double-blind, double-dummy, randomized, active- controlled dose -response efficacy and safety study in pediatric subjects with major depressive disorder ages 9 to <18
SPRAVATO™ (esketamine hydrochloride)	30-Sep-2026	Ongoing	Conduct double-blind, double-dummy, randomized, active- controlled study in pediatric subjects with major depressive disorder ages 9 to <18

Product	Due Date	Status	Description of Commitment or Requirement
SPRAVATO™ (esketamine hydrochloride)	30-Sep-2026	Pending	Conduct double-blind, double-dummy, randomized, active- controlled study in pediatric subjects with major depressive disorder ages 9 to <18
SPRAVATO™ (esketamine hydrochloride)	30-Sep-2026	Pending	Conduct open-label safety study in pediatrics subjects with major depressive disorder ages 9 to <18
DARZALEX FASPRO® (daratumumab + hyaluronidase)	28-Feb-2026	Submitted	Conduct clinical trials in newly diagnosed and relapsed/refractory AL amyloidosis to assess (1) all serious cardiovascular adverse events on study treatment; (2) all deaths on study treatment and; (3) the risk factors for cardiac toxicity and the adequacy of monitoring in at least 100 patients treated with daratumumab subcutaneous for at least 6 months. Data from clinical trials in patients with relapsed / refractory AL amyloidosis will be considered supportive. Characterize the incidence, clinical presentation, management and outcome of these events and identify those that represent major adverse cardiovascular events; namely nonfatal myocardial infarction, cardiac failure and arrhythmia, or fatal cardiovascular adverse events and events of sudden death. Also, identify hospitalizations for unstable angina, coronary revascularization procedures, and serious adverse events of heart failure. Include an evaluation of potential mitigation strategies for cardiac toxicity. The interim report should contain results from the first completed clinical trial. The timetable you submitted on January 13, 2021, states that you will conduct this study according to the following schedule: Draft Protocol Submission: 08/2021 Final Protocol Submission: 04/2022 Trial Completion: 08/2025 Interim Report Submission: 04/2024 Final Report Submission: 02/2026 Submit datasets with the final report.

Product	Due Date	Status	Description of Commitment or Requirement
(topiramate)	31-Oct-2023	Submitted	Conduct in vitro cardiac ion channel studies to determine Topamax's inhibitory profile on cardiac sodium channels using FDA recommended protocols and appropriate positive controls.
(ad26cov)	No Due Date	Submitted	Janssen Biotech, Inc. must submit to Investigational New Drug application (IND) number 22657 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER, beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes: • A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest. • A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval • Newly identified safety concerns in the interval; and • Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).
(ad26cov)	27-Apr-2021	Submitted	Janssen Biotech, Inc. will conduct post-authorization observational studies to evaluate the association between Janssen COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Janssen COVID-19 Vaccine under this EUA in the general U.S. population (18 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Janssen Biotech, Inc. will provide protocols and status update reports to the IND 22657 with agreed-upon study designs and milestone dates.

Product	Due Date	Status	Description of Commitment or Requirement
DARZALEX FASPRO® (daratumumab + hyaluronidase)	31-Jul-2026	Submitted	Conduct a prospective, observational single-arm study to assess the risk of severe (Grades 3-4) and fatal infusion-related reactions (IRRs) in patients treated with intravenous (IV) or sub-cutaneous (SC) daratumumab. Evaluate the incidence of severe and fatal IRRs, and collect information, including a full description of clinical features of the adverse reactions, to investigate associations and temporal relationships between the incidence and severity of IRRs and other potential associated risk factors. Specify case definitions, validation methods, and procedures for all study outcomes. Submit interim reports of the data collected from the study annually until the study is completed. Draft Protocol Submission: 12/2021 Final Protocol Submission: 06/2022 Interim Report Submission #1: 01/2024 Interim Report Submission #2: 01/2025 Study Completion: 01/2026 Final Report Submission: 07/2026
DARZALEX FASPRO® (daratumumab + hyaluronidase))	31-Jul-2026	Submitted	Submit a final report containing data from clinical trials, post-marketing reports, compassionate use/expanded access programs, real-world evidence, and other sources to further characterize the safety and efficacy of daratumumab (SC) in combination with pomalidomide and dexamethasone among U.S. racial and ethnic minority patients with multiple myeloma. Draft Analysis Submission: 02/2022 Final Analysis Submission: 06/2022 Study Completion: 07/2025 Final Report Submission: 01/2026
(daratumumab)	31-Jul-2026	Submitted	Conduct a prospective, observational single-arm study to assess the risk of severe (Grades 3-4) and fatal infusion-related reactions (IRRs) in patients treated with intravenous (IV) or sub-cutaneous (SC) daratumumab. Evaluate the incidence of severe and fatal IRRs, and collect information, including a full description of clinical features of the adverse reactions, to investigate associations and temporal relationships between the incidence and severity of IRRs and other potential associated risk factors. Specify case definitions, validation methods, and procedures for all study outcomes. Submit interim reports of the data collected from the study annually until the study is completed. Draft Protocol Submission: 12/2021 Final Protocol Submission: 06/2022 Interim Report Submission #1: 01/2024 Interim Report Submission #2: 01/2025 Study Completion: 01/2026 Final Report Submission: 07/2026

Pharmaceutical Companies - U.S. Post-Marketing Requirements and Commitments

September 2026

Product	Due Date	Status	Description of Commitment or Requirement
DARZALEX FASPRO® (daratumumab + hyaluronidase)	30-Jun-2026	Submitted	Conduct a prospective, observational single-arm study to assess the risk of severe (Grades 3-4) and fatal infusion-related reactions (IRRs) in patients treated with intravenous (IV) or sub-cutaneous (SC) daratumumab. Evaluate the incidence of severe and fatal IRRs, and collect information, including a full description of clinical features of the adverse reactions, to investigate associations and temporal relationships between the incidence and severity of IRRs and other potential associated risk factors. Specify case definitions, validation methods, and procedures for all study outcomes. Submit interim reports of the data collected from the study annually until the study is completed. Draft Protocol Submission: 12/2021 Final Protocol Submission: 06/2022 Interim Report Submission #1: 01/2024 Interim Report Submission #2: 01/2025 Study Completion: 01/2026 Final Report Submission: 07/2026
DARZALEX FASPRO® (daratumumab + hyaluronidase)	31-Aug-2026	Submitted	Conduct an integrated study analysis containing data from clinical trials, post-marketing reports, compassionate use/expanded access programs, real-world evidence, and other sources to further characterize the safety and efficacy of daratumumab (SC) in combination with carfilzomib and dexamethasone among U.S. racial and ethnic minority patients with multiple myeloma. Draft Analysis Submission: 07/2022 Final Analysis Submission: 11/2022 Study Completion: 02/2026 Final Report Submission: 08/2026
CARVYKTI™™,CARVYKTI® (ciltacabtagene autoleucel)	30-Jun-2042	Ongoing	A post-marketing, prospective, multi-center, observational study to assess the long-term safety of ciltacabtagene autoleucel and the risk of secondary malignancies occurring after treatment with ciltacabtagene autoleucel. The study will include at least 1500 adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; the enrolled patients will be followed for 15 years after product administration.
TECVAYLI™,TECVAYLI™,TECVAYLI®,TECVAYLI® (teclistamab)	31-Mar-2026	Submitted	Conduct a clinical trial to further characterize and determine the incidence of neurologic toxicities in patients receiving teclistamab, including immune effector cell-associated neurotoxicity syndrome, encephalopathy, peripheral neuropathy including Guillain-Barré syndrome, and motor dysfunction including Parkinsonism. This data may come from Study 64007957MMY3001 (MajesTEC-3) and other clinical trials across the teclistamab development program including long term follow-up from Study 64007957MMY1001 (MajesTEC-1). Include the incidence rates, time to onset, and outcomes in the final report. Also include investigation of associations and temporal relationships between the incidence and severity of neurologic adverse events and potential associated risk factors, such as age and comorbidities.

Product	Due Date	Status	Description of Commitment or Requirement
DARZALEX FASPRO® (daratumumab + hyaluronidase)	30-Jun-2026	Submitted	Conduct a clinical trial to assess the safety of daratumumab subcutaneous (SC) among U.S. racial and ethnic minorities including African American patients with AL amyloidosis given the higher pharmacokinetic (PK) exposure and hematologic toxicity rates (neutropenia, lymphopenia, thrombocytopenia and anemia). This study should characterize the exposure (including PK data), safety, and efficacy of daratumumab SC.
(talquetamab)	30-Sep-2027	Ongoing	Conduct a clinical trial to further characterize the serious risk of oral toxicity including severe stomatitis, mucositis, and weight loss, and potential mitigation measures, in patients receiving talquetamab 0.4 mg/kg weekly and talquetamab 0.8 mg/kg every two weeks. Evaluate incidence rates, time to onset, and outcomes including patient reported outcomes. Include investigation of associations and temporal relationships between incidence and severity of oral toxicity adverse events and other potential risk factors such as age, race and comorbidities, and impact of the mitigation measures evaluated. The study should enroll sufficient numbers of Black/African American patients to enable an evaluation of the serious risk of oral toxicity with talquetamab in this population.
(talquetamab)	31-Dec-2026	Ongoing	Conduct a randomized clinical trial that evaluates the clinical efficacy and safety of talquetamab in patients with relapsed or refractory multiple myeloma. Patients should be randomized to receive a talquetamab-based regimen compared to standard therapy for relapsed or refractory multiple myeloma. The primary endpoint should be progression-free survival and secondary endpoints should include overall survival and overall response rate. The trial should enroll sufficient numbers of racial and ethnic minority patients and older patients (ages 65-74 years and 75 years and above) to enable an evaluation of talquetamab in a study population that reflects the U.S. population of patients with multiple myeloma.
RYBREVANT®® (amivantamab)	30-Oct-2026	Ongoing	4597-1 Complete clinical trial PAPILLON (NCT04538664) and include the results of the final overall survival analysis, once the anticipated 210 death events have occurred, to further characterize the clinical benefit of amivantamab in combination with carboplatin and pemetrexed, for the first line treatment of adult patients with metastatic non-small cell lung cancer harboring epidermal growth factor receptor exon 20 insertion mutations.

Product	Due Date	Status	Description of Commitment or Requirement
RYBREVANT®® (amivantamab)	29-Dec-2028	Ongoing	4597-2 Conduct an integrated analysis containing data from clinical trials and other data sources, such as real-world evidence and post-marketing clinical trial reports, to further characterize the efficacy and safety of amivantamab in combination with carboplatin and pemetrexed in patients ages 75 years and older, Black or African American patients, and patients of Latino ethnicity, diagnosed with metastatic NSCLC harboring EGFR exon 20 insertion mutations.
CARVYKTI™™,CARVYKTI® (ciltacabtagene autoleucel)	29-Feb-2032	Ongoing	Submit the final overall survival report and datasets for the CARTITUDE NCT04181827 clinical trial, titled “A Phase 3 Study Comparing JNJ-68284528, a Chimeric Antigen Receptor T (CAR T) Cell Therapy Directed Against B-cell Maturation Antigen (BCMA), versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in Participants With Relapsed and Lenalidomide-Refractory Multiple Myeloma".

Product	Due Date	Status	Description of Commitment or Requirement
RYBREVANT®® (amivantamab)	29-Jun-2029	Ongoing	Conduct an integrated analysis containing data from clinical trials and other data sources such as post-marketing reports, real-world evidence and other sources to further characterize the safety and efficacy of amivantamab in combination with lazertinib in patients who- are Black or African American diagnosed with metastatic NSCLC harboring EGFR exon 19 deletions or exon 21 L858R substitution mutations.
RYBREVANT®® (amivantamab)	31-Dec-2024	Submitted	Conduct comprehensive safety analyses from clinical studies that further characterize the known serious risk of venous thromboembolic events (VTEs) in patients treated with amivantamab intravenously (IV) and patients treated with amivantamab subcutaneously (SC), in combination with lazertinib. Provide the incidence, timing, and outcome of VTEs by grade in patients who did not receive prophylactic anticoagulation, who received prophylactic anticoagulation for the initial 4 months of study therapy only, who continued prophylactic anticoagulation beyond 4 months of study therapy, and who required initiation of treatment-level anticoagulation. Monitor patients for VTEs throughout study therapy until treatment discontinuation.

Product	Due Date	Status	Description of Commitment or Requirement
LAZCLUZE™,LAZCLUZE™ (lazertinib mesylate monohydrate)	31-Dec-2024	Submitted	Conduct comprehensive safety analyses from clinical studies that further characterize the known serious risk of venous thromboembolic events (VTEs) in patients treated with amivantamab intravenously (IV) and patients treated with amivantamab subcutaneously (SC), in combination with lazertinib. Provide the incidence, timing, and outcome of VTEs by grade in patients who did not receive prophylactic anticoagulation, who received prophylactic anticoagulation for the initial 4 months of study therapy only, who continued prophylactic anticoagulation beyond 4 months of study therapy, and who required initiation of treatment-level anticoagulation. Monitor patients for VTEs throughout study therapy until treatment discontinuation.
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	31-Jan-2029	Ongoing	Conduct a one-year, randomized, open-label induction, double-blind maintenance, parallel-group, multicenter study to assess the pharmacokinetics, safety, and efficacy of Tremfya (guselkumab) in pediatric patients 2 to <18 years of age with moderately to severely active ulcerative colitis. Final Protocol Submission: 04/2025 Study Completion: 07/2028 Final Report Submission: 01/2029

Product	Due Date	Status	Description of Commitment or Requirement
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	31-Aug-2030	Ongoing	. Conduct a long-term extension study to evaluate the long-term safety of Tremfya (guselkumab) in patients 2 to <18 years of age with moderately to severely active ulcerative colitis who participated in postmarketing requirement 4696-1. This Study can be conducted as a part of postmarketing requirement 4696-1. Final Protocol Submission: 04/2025 Study Completion: 02/2030 Final Report Submission: 08/2030
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	31-Mar-2031	Ongoing	4696-3 Complete the treatment and evaluation of subjects enrolled in the ongoing CNTO1959UCO3001 (QUASAR), CNTO1959UCO3004 (ASTRO), CNTO1959CRD3001 (GALAXI), and CNTO1959CRD3004 (GRAVITI) studies. Follow subjects in these studies for 5 years unless a safety signal is identified that indicates the potential risks of such continued long-term treatment outweigh the benefits. Evaluation of subjects should continue through the end of the trial when achievable. Adverse events (including, but not limited to, malignancy, serious infection, tuberculosis, opportunistic infections, hypersensitivity reactions, autoimmune disease, neurologic or demyelinating disease, cardiovascular, gastrointestinal [including hepatic] or hematologic adverse events) will continue to be collected throughout the long-term extensions. Final Protocol Submission: 09/2025 Study Completion: 03/2030 Final Report Submission: 03/2031

Product	Due Date	Status	Description of Commitment or Requirement
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	30-Jun-2031	Ongoing	. Collect data from prospective pregnancy exposure registry/registries, preferably disease-based multiproduct pregnancy registry/registries, using a registry-based cohort study design to compare the maternal, fetal, and infant outcomes of women with inflammatory bowel disease exposed to guselkumab during pregnancy with unexposed comparator population(s). Align the U.S. protocol with protocols(s) outside the U.S. to reach the target sample size, if applicable. The registry will identify and record pregnancy complications, major and minor congenital malformations, spontaneous abortion, stillbirths, pregnancy terminations, preterm births, small-for-gestational-age births, and any other adverse outcomes, including postnatal growth and development. These outcomes will be assessed throughout pregnancy. Infant outcomes, including effects on postnatal growth and development, will be assessed through at least the first year of life. Final Protocol Submission: 09/2025 Study Completion: 06/2030 Final Report Submission: 06/2031
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	30-Jun-2031	Ongoing	Conduct a retrospective cohort study using claims or electronic medical record data or a case control study with confirmation based upon review of data from medical records to assess adverse pregnancy outcomes such as major congenital malformations, spontaneous abortions, stillbirths, small-for-gestational-age births, neonatal deaths, and infant infections in women exposed to guselkumab regardless of indication during pregnancy compared to an unexposed control population. Final Protocol Submission: 09/2025 Study Completion: 06/2030 Final Report Submission: 06/2031

Product	Due Date	Status	Description of Commitment or Requirement
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	30-Sep-2028	Ongoing	. Perform a lactation study (milk only) in lactating women who have received guselkumab, regardless of indication, to measure concentrations of guselkumab in breast milk using a validated assay. Draft Protocol Submission: 09/2025 Final Protocol Submission: 03/2026 Study Completion: 09/2027 Final Report Submission: 09/2028
RYBREVANT®® (amivantamab)	29-jun-2026	Submitted	Complete clinical trial MARIPOSA-2 (NCT04988295) and include the results of the final overall survival analysis, once the anticipated 400 death events have occurred in all three arms of the trial, to further characterize the clinical benefit of amivantamab in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.

Product	Due Date	Status	Description of Commitment or Requirement
RYBREVANT®® (amivantamab)	29-jun-2026	Submitted	Complete clinical trial MARIPOSA-2 (NCT04988295) and include the results of the final overall survival analysis, once the anticipated 400 death events have occurred in all three arms of the trial, to further characterize the clinical benefit of amivantamab in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
RYBREVANT®® (amivantamab)	29-jun-2029	Ongoing	Conduct an integrated analysis containing data from clinical trials and other data sources such as post-marketing reports, real-world evidence and other sources to further characterize the safety and efficacy of amivantamab in combination with carboplatin and pemetrexed in Black or African American patients diagnosed with metastatic NSCLC harboring EGFR exon 19 deletions or exon 21 L858R substitution mutations.
LAZCLUZE™,LAZCLUZE™ (lazertinib mesylate monohydrate)	*29-Jun-2029	Ongoing	Conduct an integrated analysis containing data from clinical trials and other data sources such as post-marketing reports, real-world evidence and other sources to further characterize the safety and efficacy of amivantamab in combination with lazertinib in patients who-are Black or African American diagnosed with metastatic NSCLC harboring EGFR exon 19 deletions or exon 21 L858R substitution mutations.
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	*31-Dec-2029	Ongoing	Conduct a one-year, randomized, open-label induction, double-blind maintenance, parallel-group, multicenter study to assess the pharmacokinetics, safety, and efficacy of Tremfya (guselkumab) in pediatric patients 2 to <18 years of age with moderately to severely active Crohn's disease. Final Protocol Submission: 09/2025 Study Completion: 06/2029 Final Report Submission: 12/2029
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	*31-Aug-2031	Ongoing	Conduct a long-term extension study to evaluate the long-term safety of Tremfya (guselkumab) in patients 2 to <18 years of age with moderately to severely active Crohn's disease who participated in postmarketing requirement 4798-1. This Study can be conducted as a part of postmarketing requirement 4798-1. Final Protocol Submission: 09/2025 Study Completion: 02/2031 Final Report Submission: 08/2031
TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA®,TREMFYA® (guselkumab)	*31-Dec-2038	Submitted	Conduct an observational study to assess the incidence of severe acute liver injury in in adults with inflammatory bowel disease who are exposed to Tremfya (guselkumab), relative to other therapies used to treat inflammatory bowel disease. Compare rates (per person-time) or risks (proportion of patients with a minimum amount of follow-up). Describe and justify the choice of appropriate comparator population(s). Specify concise case definition for severe liver injury and validation of algorithm(s) to identify severe liver injury in the proposed data source. For the Tremfya (guselkumab)-exposed and comparator(s) cohorts, clearly define the study drug initiation period and any exclusion and inclusion criteria. Ensure that the data source allows for average follow-up for at least 1 year. Specify a minimum sample size and justify the precision of the estimate achievable with the proposed study. Draft Protocol Submission: 12/2025 Final Protocol Submission: 06/2026 Interim/Other: 06/2032

Product	Due Date	Status	Description of Commitment or Requirement
IMAAVY ™™ (nipocalimab)	31-Oct-2036	Pending	4833-1: Conduct a worldwide descriptive study that collects prospective and retrospective data in women exposed to Imaavy (nipocalimab) during pregnancy and lactation to assess risk of pregnancy and maternal complications, adverse effects on the developing fetus and neonate, and adverse effects on the infant. Infant outcomes will be assessed through at least the first year of life. The minimum number of patients will be specified in the protocol. The protocol must be agreed upon with the Agency.
INLEXZO™ (gemcitabine hydrochloride)	30-Jun-2028	Ongoing	Complete the ongoing clinical trial SunRISe-1 (NCT05243550) to further characterize the clinical benefit of TAR-200 for the treatment of patients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. Provide updated duration of response (DOR) data for all patients with current ongoing response in the final trial report after all of the patients who have current ongoing responses have either experienced recurrence of high-grade NMIBC, progression, death, or been lost to followup, for up to 48 months after the first instillation
DARZALEX FASPRO® (daratumumab + hyaluronidase)	28-Feb-2030	Ongoing	Conduct an integrated analysis of data from clinical trials, and other sources such as post-marketing reports, to further characterize the efficacy and safety of daratumumab and hyaluronidase in a pooled population that includes a sufficient representation of racial and ethnic populations that are reflective of the U.S. population with high-risk smoldering multiple myeloma and allow for an interpretation of the data in these subgroups. Draft Protocol Submission: 02/2026 Final Protocol Submission: 06/2026 Trial Completion: 08/2029 Final Report Submission: 02/2030
Akeega™,Akeega™,Akeega®,Akeega® (abiraterone acetate + niraparib tosylate monohydrate)	30-Jun-2028	Ongoing	Complete the trial AMPLITUDE (NCT04497844), which is an ongoing phase 3, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of niraparib in combination with abiraterone acetate in patients with homologous recombination repair gene-mutated metastatic castration-sensitive prostate cancer, to obtain the trial's final overall survival (OS) analysis.

Product	Due Date	Status	Description of Commitment or Requirement
Akeega™,Akeega™,Akeega®,Akeega® (abiraterone acetate + niraparib tosylate monohydrate)	31-Mar-2027	Submitted	Conduct an analytical and clinical validation study using clinical trial data, adequate to support the availability of an in vitro diagnostic device using tissue samples that is essential to the safe and effective use of niraparib and abiraterone acetate (AKEEGA) for patients diagnosed with metastatic castration-sensitive prostate cancer (mCSPC), whose tumors harbor BRCA2 mutations.
ICOTYDE™ (icotrokinra)	30-Sep-2030	Ongoing	Conduct a trial to evaluate the safety and pharmacokinetics of icotrokinra in pediatric subjects 4 years to less than 12 years of age with moderate to severe psoriasis who are candidates for systemic therapy or phototherapy. Evaluate a sufficient number of subjects exposed to icotrokinra at the highest proposed dosage for a minimum of 26 weeks to evaluate for safety and pharmacokinetics of icotrokinra in pediatric subjects 4 years to less than 12 years of age with moderate to severe psoriasis who are candidates for systemic therapy or phototherapy. Draft Protocol Submission: 10/2026 Final Protocol Submission: 03/2027 Study Completion: 03/2030 Final Report Submission: 09/2030

Product	Due Date	Status	Description of Commitment or Requirement
ICOTYDE™ (icotrokinra)	30-Sep-2029	Ongoing	Conduct a worldwide, as applicable, descriptive study that collects prospective and retrospective data in women exposed to Icotyde (icotrokinra) during pregnancy to assess risk of pregnancy and maternal complications, and adverse effects on the developing fetus, neonate, and infant. Assess infant outcomes up to the first year of life. The minimum number of patients will be specified in the protocol. Draft Protocol Submission: 12/2026 Final Protocol Submission: 06/2027 Study Completion: 03/2037 Final Report Submission: 09/2037
ICOTYDE™ (icotrokinra)	30-Sep-2029	Ongoing	Perform a lactation study in lactating women who have received icotrokinra to measure concentrations of icotrokinra in breast milk using a validated assay. Assess the effects on the breastfed infant, if available, based on study population.