Janssen Pharmaceutical Companies
U.S. Post-Marketing Requirements and Commitments
July 2023

Product	Due Date	Status	Description of Commitment or Requirement
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.
DURAGESIC® (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.
EDURANT® (rilpivirine hydrochloride)	31-Jul-2023	Pending	Conduct a study in HIV-1 infected patients 2 to 12 years of age who are either treatment naïve with baseline HIV RNA <100,000 copies/mL or who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen at the time of enrollment, to assess the pharmacokinetics, safety and tolerability, and antiviral activity of rilpivirine. Study participants must be monitored for a minimum of 24 weeks to assess durability of antiviral response.
INVOKANA® (canagliflozin hemihydrate)	30-Jun-2024	Delayed	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.
RISPERDAL CONSTA® (risperidone)	31-Dec-2099	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
ULTRACET® (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.

DARZALEX (daratumumab)	31-Jan-2023	Submitted	Submit the final progression free survival, overall survival analysis, safety results and datasets with the final study report from the ongoing multicenter, randomized, phase 3 clinical trial (CANDOR) comparing daratumumab in combination with carfilzomib and dexamethasone to carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. The results from this report may inform product labeling. Final Protocol Submission: 09/2019 Trial Completion: 07/2022 Final Report Submission: 01/2023
DARZALEX (daratumumab)	31-Jul-2026	Ongoing	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
OLYSIO® (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.
OLYSIO® (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.

SIMPONI® (golimumab)	30-Jun-2025	Delayed	A study to evaluate the effectiveness and safety of SIMPONI® (golimumab) in pediatric patients 5 to 17 years of age with moderately to severely active ulcerative colitis. The study should be designed to establish that the dose regimen(s) of SIMPONI® (golimumab) identified in PMC#4 (pharmacokinetic pediatric UC study) are effective and safe for induction treatment, as well as for continued treatment after induction. Pharmacokinetic measurements should be conducted for exposure-response analysis. Collect serum samples for immunogenicity testing and conduct analyses of the impact of immunogenicity on pharmacokinetics, efficacy and safety.
SIMPONI® (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.
TOPAMAX (topiramate)	31-Oct-2023	Ongoing	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.
(amivantamab)	31-Oct-2021	Submitted	Submit EDI1001 final report for relevant patient population after 6 months of follow up post onset of response
(amivantamab)	31-Mar-2024	Ongoing	Submit NSC3001 Final Report
(amivantamab)	31-May-2024	Submitted	Submit a final report containing data from clinical trials enrolling a sufficient representation of Black or African American patients that is reflective of the U.S. population of patients with EGFR exon 20 insertion mutated NSCLC to further characterize the safety and efficacy of amivantamab-vmjw in Black or African American patients with EGFR exon 20 insertion mutated NSCLC

BALVERSA® (erdafitinib)	31-Mar-2023	Submitted	3561-5 Conduct a clinical pharmacokinetic study that evaluates the effect of repeated doses of erdafitinib (at steady-state) on the single dose pharmacokinetics of a probe substrate of OCT2 to determine appropriate dosing recommendations for OCT2 substrate when it is coadministered with erdafitinib. This study 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.
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.
BALVERSA® (erdafitinib)	31-Mar-2025	Delayed	3561-1 Submit the analysis, and datasets with the final report demonstrating clinical benefit of erdafitinib in patients with locally advanced and metastatic urothelial carcinoma with susceptible FGFR 3 or FGFR 2 genetic alterations from clinical trial BLC3001 entitled; "A Phase 3 Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations".
LEVAQUIN (levofloxacin hemihydrate)	31-Dec-2006	Submitted	Commitment to conduct post-marketing PK clinical trial in renally impaired patients
PREZCOBIX® (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.
PREZCOBIX® (cobicistat + darunavir ethanolate)	30-Sep-2024	Pending	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.

PREZCOBIX® (cobicistat + darunavir ethanolate)	30-Sep-2024	Pending	Evaluate the pharmacokinetics, safety, and antiviral activity (efficacy) of darunavir and cobicistat fixed dose combination (FDC) age-appropriate formulation in HIV-infected pediatric subjects 6 years to less than 12 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 6 years to less than 12 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.
SIRTURO® (bedaquiline fumarate)	31-Aug-2023	Ongoing	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.
SIRTURO® (bedaquiline fumarate)	*	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.
STELARA® (ustekinumab)	15-Dec-2020	Submitted	Provide data analyses from the Nordic Database Initiative regarding the occurrence of serious infection, tuberculosis, opportunistic infections, malignancy, hypersensitivity reactions, autoimmune disease, neurologic or demyelinating disease, cardiovascular, gastrointestinal or hematologic adverse events with exposure to ustekinumab.
STELARA® (ustekinumab)	15-Dec-2021	Submitted	Provide data analyses from the Pregnancy Research Initiative (study C0168T71).
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.

TECVAYLI™ (teclistamab)	30-Jun-2024	Ongoing	Complete the MajesTEC-1 trial (Study 64007957MMY1001) to obtain the overall response rate and duration of response in enrolled patients with relapsed or refractory multiple myeloma who have received at least 3 prior lines of therapy including a proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody to further characterize efficacy of teclistamab monotherapy in this population.
TECVAYLI™ (teclistamab)	31-Mar-2026	Ongoing	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.
TECVAYLI™ (teclistamab)	31-Mar-2026	Ongoing	Conduct a randomized clinical trial in patients with relapsed or refractory multiple myeloma. The trial should enroll sufficient numbers of racial and ethnic minority patients and older patients (ages 65-74 and 75 and above) to enable an evaluation of teclistamab in a study population that better reflects the U.S. population of patients with multiple myeloma. Patients should be randomized to receive a teclistamab-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, overall response rate, and duration of response.
PONVORY™ (ponesimod)	31-Mar-2024	Ongoing	4024-4 Conduct a drug-drug interaction trial to evaluate the impact of strong PXR agonists on the pharmacokinetics of Ponvory (ponesimod). The timetable you submitted on March 5, 2021, states that you will conduct this trial according to the following schedule: Draft Protocol Submission: 06-Aug-2021 Final Protocol Submission: 03/2022 Trial Completion: 03/2023 Final Report Submission: 03/2024

PONVORY™ (ponesimod)	31-Aug-2028	Pending	4024-1 Conduct a two-part study of Ponvory (ponesimod) in pediatric patients with relapsing forms of multiple sclerosis (RMS) at least 10 years and less than 18 years of age. Part A is an open-label study of the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of Ponvory (ponesimod) in pediatric patients. Part A will include two cohorts, one with body weights less than 40 kg, and the other with body weights 40 kg or more. The objective of Part A is to determine titration and maintenance doses of Ponvory (ponesimod) that will result in PK and PD effects that are comparable to those of the 14-day titration administered to adult patients. Part B is a randomized, blinded, non-inferiority trial with an appropriate active comparator. Timetable: Final Protocol Submission: 03/2022 Study Completion: 11/2027 Final Report Submission: 08/2028 The status of this postmarketing study must be reported annually.
PONVORY™ (ponesimod)	31-Dec-2034	Pending	4024-2 Prospective pregnancy exposure registry cohort analyses in the United States that compare the maternal, fetal, and infant outcomes of women with multiple sclerosis exposed to Ponvory (ponesimod) during pregnancy with two unexposed control populations: one consisting of women with multiple sclerosis who have not been exposed to Ponvory (ponesimod) before or during pregnancy and the other consisting of women without multiple sclerosis. The registry will identify and record pregnancy complications, major and minor congenital malformations, spontaneous abortions, stillbirths, elective terminations, preterm births, small-forgestational-age births, and any other adverse outcomes, including postnatal growth and development. 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. Timetable: Draft Protocol Submission: 03/2022 Final Protocol Submission: 12/2022 Annual Interim Report Submissions: 12/2023, 12/2024, 12/2025, 12/2026, 12/2027, 12/2028, 12/2029, 12/2030, 12/2031, 12/2032 Study Completion: 12/2033 Final Report Submission: 12/2034

PONVORY™ (ponesimod)	31-Dec-2034	Pending	4024-3 A pregnancy outcomes study using a different study design than provided for in PMR 4024-2 (for example, a retrospective cohort study using claims or electronic medical record data with outcome validation or a case-control study) to assess major congenital malformations, spontaneous abortions, stillbirths, preterm births, and small-for-gestational-age births in women exposed to Ponvory (ponesimod) during pregnancy compared to an unexposed control population. Timetable: Draft Protocol Submission: 03/2022 Final Protocol Submission: 12/2022 Annual Interim Report Submissions: 12/2023, 12/2024, 12/2025, 12/2026, 12/2027, 12/2028, 12/2029, 12/2030, 12/2031, 12/2032 Study Completion: 12/2033 Final Report Submission: 12/2034
REMICADE® (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.
REMICADE® (infliximab)	01-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.
REMICADE® (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.
REMICADE® (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).
REMICADE® (infliximab)	31-Dec-2045	Ongoing	Expand the Pediatric IBD Registry (DEVELOP) to include pediatric patients with ulcerative colitis (UC) and indeterminate colitis (IC).
TREMFYA (guselkumab)	30-Apr-2024	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 (guselkumab)	30-Apr-2024	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.
TREMFYA (guselkumab)	31-Dec-2025	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
TREMFYA (guselkumab)	31-Dec-2026	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 (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

STELARA (ustekinumab)	30-Sep-2024	Ongoing	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)
STELARA (ustekinumab)	28-Feb-2025	Ongoing	A clinical trial to assess whether ustekinumab alters the metabolism or pharmacokinetics of cytochrome P450 (CYP) substrates in UC patients treated with ustekinumab (e.g., using a cocktail of relevant CYP probe drugs). The ongoing trial in patients with Crohn's disease with the same objectives, may be amended to also enroll patients with ulcerative colitis. Conduct a clinical trial to assess whether STELARA (ustekinumab) alters the metabolism or pharmacokinetics of cytochrome P450 (CYP) substrates in Crohn's disease (CD) patients treated with ustekinumab (e.g., using a cocktail of relevant CYP probe drugs). (Final Protocol Submission: March 2017 Trial Completion: September 2019 Final Report Submission: March 2020)
STELARA (ustekinumab)	30-Sep-2025	Ongoing	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.
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-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)
DARZALEX FASPRO (daratumumab + hyaluronidase)	31-Dec-2023	Ongoing	Submit an integrated final report containing data from sources such as clinical trials, registries, post marketing reports and real-world data to inform the efficacy and safety of the regimen of daratumumab and hyaluronidase in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients with multiple myeloma who are eligible for autologous stem cell transplant. The study report should include, but not necessarily be limited to, safety data, including the incidence and rates of neutropenia, infection, stem cell collection and transplantation, and data regarding response rates. The results from this study may inform product labeling. The timetable you submitted on September 29, 2020, states that you will conduct this study according to the following schedule: Study Completion: 06/2023 Final Report Submission: 12/2023

DARZALEX FASPRO (daratumumab + hyaluronidase)	30-Jun-2024	Ongoing	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. Draft Protocol Submission: 06/2021 Final Protocol Submission: 12/2021 Trial Completion: 12/2023 Final Report Submission: 06/2024
DARZALEX FASPRO (daratumumab + hyaluronidase)	30-Jun-2025	Ongoing	Submit the final study report and datasets from a randomized clinical trial to verify and further characterize the clinical benefit and safety of daratumumab subcutaneous for the treatment of patients with AL amyloidosis. This submission should include the final analysis and datasets of progression free survival or overall survival results. Draft Protocol Submission: 10/2017 Final Protocol Submission: 10/2017 Trial Completion: 12/2024 Final Report Submission: 06/2025
DARZALEX FASPRO (daratumumab + hyaluronidase)	01-Jan-2026	Ongoing	Conduct a clinical study to further characterize the exposure of daratumumab (D) subcutaneous (SC), the increased risk of severe and serious adverse events, including severe neutropenia, and efficacy among U.S. racial and ethnic minority patients with relapsed or refractory multiple myeloma. Include an assessment of the PK, PD, safety, and efficacy of daratumumab SC in combination with other agents including pomalidomide and dexamethasone (Pd) in U.S. racial and ethnic minority patients including Black and Asian patients with relapsed or refractory multiple myeloma in the final study report. The population pharmacokinetic and exposure-response analyses for both efficacy and safety should be updated. Draft Protocol Submission: 12/2021 Final Protocol Submission: 03/2022 Study Completion: 07/2025 Final Report Submission: 01/2026

DARZALEX FASPRO (daratumumab + hyaluronidase)	31-Jan-2026	Ongoing	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
DARZALEX FASPRO (daratumumab + hyaluronidase)	28-Feb-2026	Ongoing	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.

DARZALEX FASPRO (daratumumab + hyaluronidase)	31-Jul-2026	Ongoing	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	Ongoing	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
Janssen COVID-19 Vaccine (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.

Janssen COVID-19 Vaccine (ad26cov)	31-Dec-2099	Ongoing	All descriptive printed matter, advertising, and promotional material relating to the use of the Janssen COVID-19 Vaccine clearly and conspicuously shall state that: • This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and • The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.
Janssen COVID-19 Vaccine (ad26cov)	31-Dec-2099	Ongoing	All descriptive printed matter, advertising, and promotional material, relating to the use of the Janssen COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.
Janssen COVID-19 Vaccine (ad26cov)	31-Dec-2099	Ongoing	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).
Janssen COVID-19 Vaccine (ad26cov)	31-Dec-2099	Ongoing	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.

Janssen COVID-19 Vaccine (ad26cov)	31-Dec-2099	Ongoing	Janssen Biotech, Inc. will report to Vaccine Adverse Event Reporting System (VAERS): • Serious adverse events (irrespective of attribution to vaccination); • Cases of Multisystem Inflammatory Syndrome in adults; and • Cases of COVID-19 that result in hospitalization or death, that are reported to Janssen Biotech, Inc. These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Janssen Biotech, Inc.
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	30-Sep-2026	Ongoing	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	Ongoing	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	30-Sep-2026	Pending	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	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		Conduct open-label safety study in pediatrics subjects with major depressive disorder ages 9 to <18
SPRAVATO™ (esketamine hydrochloride	30-Sep-2026	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.