US Postmarketing Requirements

Public

Status as of 09-Jan-2023

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
BELSOMRA	suvorexant	NDA 204569 US	31-Jul-2023	Not Applicable	Ongoing		PMR 3790-1	Conduct a lactation study in lactating women who have received therapeutic doses of suvorexant using a validated assay to assess concentrations of suvorexant in breast milk. Final Report Submission.
BRIDION	sugammadex sodium	NDA 022225 US	31-Aug-2023	Not Applicable	Ongoing		PMR 3003-9	A randomized, controlled trial evaluating the efficacy, safety, and pharmacokinetics of BRIDION injection when used to reverse neuromuscular blockade induced by either rocuronium or vecuronium must be conducted in pediatric patients ages birth to less than 2 years old. Final Report Submission
DELSTRIGO	doravirine (+) lamivudine (+) tenofovir disoproxil fumarate	NDA 210807 US	31-Jan-2022	Not Applicable	Fulfilled	FDA acknowledged fulfillment on 27-Jan-2022	PMR 3416-1	Conduct a study to evaluate the pharmacokinetics, safety, and antiviral activity (efficacy) of doravirine/lamivudine/tenofovir disoproxil fumarate fixed dose combination (FDC) product in HIV-1 infected pediatric subjects less than 18 years of age and weighing at least 35 kg. Subjects must be followed for a minimum of 24 weeks to assess the safety and antiviral activity of doravirine/lamivudine/tenofovir disoproxil fumarate FDC product. A clinical trial in pediatric subjects weighing at least 35 kg may not be required if dosing recommendation for the FDC tablets can be supported by pediatric trials already conducted with the individual drug products. Final Report Submission
DELSTRIGO	doravirine (+) lamivudine (+) tenofovir disoproxil fumarate	NDA 210807 US	31-May-2024	Not Applicable	Ongoing		PMR 3416-2	Conduct a study to evaluate the pharmacokinetics, safety, and antiviral activity (efficacy) of doravirine/lamivudine/tenofovir disoproxil fumarate fixed dose combination (FDC) product in HIV-1 infected pediatric subjects age 2 years and older, and weighing less than 35 kg. The study participants must be followed for a minimum of 24 weeks to assess the safety and antiviral activity of the FDC product, doravirine/lamivudine/tenofovir disoproxil fumarate. A clinical trial in pediatric subjects 2 years and older and weighing less than 35 kg may not be required if dosing recommendation for the FDC tablets can be supported by pediatric trials conducted with the individual drug products. Final Report Submission
EMEND	fosaprepitant dimeglumine	NDA 022023 US	30-Sep-2021	Not Applicable	Fulfilled	FDA acknowledged 02-MAY-2022 fulfillment date	PMR 3361-1	Conduct a trial to evaluate the safety of multiple cycles of intravenous administration of fosaprepitant daily for three consecutive days for the prevention of chemotherapy-induced nausea and vomiting in pediatric patients 6 months to 17 years of age. Final Report Submission
EMEND for Injection	fosaprepitant dimeglumine	NDA 022023 US	30-Sep-2021	Not Applicable	Fulfilled	FDA acknowledged 02-MAY-2022 fulfillment date	PMR 3361-1	Conduct a trial to evaluate the safety of multiple cycles of intravenous administration of fosaprepitant daily for three consecutive days for the prevention of chemotherapy-induced nausea and vomiting in pediatric patients 6 months to 17 years of age. Final Report Submission
ERVEBO	Ebola Zaire Vaccine (rVSV delta G-ZEBOV-GP, live)	BLA 125690 US	30-Jun-2021	30-Jun-2022	Submitted	FDA deferral extension granted on 16-Apr-2021	PMR 1	Deferred study V920-016 to evaluate the safety and immunogenicity of ERVEBO in children 12 months through 17 years of age. Final Report Submission

US Postmarketing Requirements

Public

Status as of 09-Jan-2023

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
GARDASIL®9	Human Papillomavirus 9-valent Vaccine, Recombinant	BLA 125508 US	30-Sep-2026	Not Applicable	Ongoing		PMR 1	To conduct Study V503-049 to evaluate the efficacy of a three-dose regimen of GARDASIL®9 in the prevention of oral persistent infection with HPV types 16, 18, 31, 33, 45, 52 or 58 in men 20 through 45 years of age. Final Report Submission.
IVEMEND	fosaprepitant dimeglumine	NDA 022023 US	30-Sep-2021	Not Applicable	Fulfilled	FDA acknowledged 02-MAY-2022 fulfillment date	PMR 3361-1	Conduct a trial to evaluate the safety of multiple cycles of intravenous administration of fosaprepitant daily for three consecutive days for the prevention of chemotherapy-induced nausea and vomiting in pediatric patients 6 months to 17 years of age. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Jul-2019	31-Mar-2024	Released	Released by FDA on 04-Feb-2022	PMR 3258-1	Conduct and submit the results of one or more randomized trials to verify and describe the clinical benefit of pembrolizumab over standard therapy based on a clinically meaningful improvement in overall survival in patients with PD-L1 positive, microsatellite stable/mismatch repair (MMR) proficient metastatic gastric or gastroesophageal junction adenocarcinoma. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Oct-2019	31-Oct-2023	Ongoing	FDA deferral extension granted on 08-October-2019.	PMR 3492-1	Conduct and submit the results of one or more randomized trials to verify and describe the clinical benefit of pembrolizumab as compared to available therapy in patients with locally advanced, unresectable or metastatic hepatocellular carcinoma as demonstrated by an improvement in overall survival or a large improvement in progression-free survival that is clinically meaningful. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Aug-2021	Not Applicable	Submitted		PMR 3188-3	Characterize the safety of long-term use in patients with classical Hodgkin lymphoma treated with pembrolizumab 200 mg every 3 weeks. Submit a final report and datasets with safety and efficacy outcomes of trial KN087 with at least 3 years of follow-up data. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	28-Feb-2022	Not Applicable	Fulfilled		PMR 3850-1	PMR 3850-1 Submit the final analysis of overall response rate, duration of response, and safety from Cohort B of the KEYNOTE-555 trial titled, “A Phase 1 Randomized Clinical Study of Pembrolizumab (MK-3475) to Evaluate the Relative Bioavailability of Subcutaneous Injection Versus Intravenous Infusion in Participants With Advanced Melanoma” to verify and describe the anticipated effects of the alternative dosing regimen for pembrolizumab 400 mg every six weeks, that may inform product labeling across indications. All responding patients should be followed for at least 12 months from the onset of response. Provide pharmacokinetic data at first cycle and at steady state from Cohort B and the datasets in the final report. Final Report Submission (Cohort B): 02/2022

US Postmarketing Requirements

Public

Status as of 09-Jan-2023

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Mar-2023	Not Applicable	Submitted		PMR 3213-1	Submit the final report, including datasets, from trials conducted to verify and describe the clinical benefit of pembrolizumab 200 mg intravenously every three weeks in patients with microsatellite instability high or mismatch repair deficient tumors including at least 124 patients with colorectal cancer enrolled in the company-initiated trials; at least 300 patients with non colorectal cancer, including a sufficient number of patients with prostate cancer, thyroid cancer, small cell lung cancer; and ovarian cancer; and 25 children. In order to characterize response rate and duration, patients will be followed for at least 12 months from the onset of response. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Mar-2023	Not Applicable	Submitted		PMR 3213-2	Conduct a trial that will characterize the safety of pembrolizumab administered intravenously at 2 mg/kg up to a maximum of 200 mg intravenously every three weeks or to determine a reasonably safe dosage regimen in an adequate number of children with primary central nervous system malignancies that are mismatch repair deficient or microsatellite instability high. Submit a final report and datasets for pediatric patients with primary CNS malignancies. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	30-Sep-2024	Not Applicable	Ongoing		PMR 3938-1	Submit the final results and datasets characterizing the risk of immune-mediated or potentially immune-mediated toxicities, serious adverse events, and long-term safety for pediatric patients with lymphoma enrolled in KEYNOTE-051 who receive pembrolizumab. All patients with Hodgkin lymphoma should be followed for safety for a minimum of 6 months on pembrolizumab. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	30-Sep-2024	Not Applicable	Ongoing		PMR 3938-2	Submit the final results and datasets for response rate and duration of response as assessed by an independent review committee in all pediatric patients who received pembrolizumab for Hodgkin lymphoma in KEYNOTE-051, to further characterize the clinical benefit of pembrolizumab. All patients who achieve an objective response should be followed for duration of response for a minimum of 6 months. The results from this trial may inform product labeling. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	30-Sep-2024	Not Applicable	Ongoing		PMR 4033-1	Submit the final progression-free survival and final overall survival analyses and datasets for the ongoing clinical trial KEYNOTE-811, “A Phase III, Randomized, Double-blind Trial Comparing Trastuzumab Plus Chemotherapy and Pembrolizumab With Trastuzumab Plus Chemotherapy and Placebo as First-line Treatment in Participants With HER2 Positive Advanced Gastric or Gastroesophageal Junction Adenocarcinoma” to verify and describe the clinical benefit of pembrolizumab with trastuzumab plus chemotherapy for patients with HER2-positive advanced or metastatic gastric or gastroesophageal adenocarcinoma. Final Report Submission

US Postmarketing Requirements

Public

Status as of 09-Jan-2023

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Dec-2024	Not Applicable	Ongoing		PMR 3188-2	Characterize complications after allogeneic hematopoietic stem cell transplantation (HSCT) following pembrolizumab in at least 90 patients with hematologic malignancies, of which at least 30% had received pembrolizumab alone or in combination as the regimen immediately prior to the allogeneic HSCT conditioning regimen. Evaluate toxicities at least through transplant Day 180. Include details of prior pembrolizumab treatment and the transplant regimen. Characterize toxicities including hyperacute graft-versus-host disease (GVHD), severe (grade 3-4) acute GVHD, febrile syndromes treated with steroids, immune mediated adverse events, pulmonary complications, hepatic veno-occlusive disease and/or sinusoidal obstruction syndrome, critical illness, and transplantrelated mortality. Toxicities may be characterized prospectively, or through a combination of prospective and retrospective data analysis. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	30-Sep-2025	Not Applicable	Ongoing		PMR 3853-1 for S-60 and S-61	PMR 3853-1 Submit the final analysis of overall response rate, duration of response, and safety from a trial evaluating pembrolizumab 400 mg every six weeks in participants with classical Hodgkin lymphoma and primary mediastinal B-cell lymphoma to verify and describe the anticipated effects of the alternative dosing regimen of pembrolizumab 400 mg administered every six weeks, that may inform product labeling across indications. All responding patients should be followed for at least 12 months from the onset of response. Provide pharmacokinetic data at first cycle and at steady state and the datasets in the final report. Final Report Submission: 09/2025
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Dec-2025	Not Applicable	Ongoing		PMR 3871-1	Submit the final report and datasets from clinical trials evaluating overall response rate and duration of response, to verify and describe the clinical benefit of pembrolizumab in adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] solid tumors (as determined by an FDA approved test) that have progressed following prior treatment and who have no satisfactory alternative treatment options. A sufficient number of patients and representation of tumor types (other than lung cancers, MSIH or dMMR cancers, or melanoma; and including CNS tumors that were determined to be TMB-H based on testing of tissue obtained prior to initiation of temozolomide chemotherapy), and with cancers having a TMB of 10 to <13 mut/Mb, will be evaluated to characterize response and duration of response. A minimum of 20 pediatric patients will be studied. Overall response rate and duration of response will be assessed by independent central review for patients with cancers having a TMB of ≥10 mut/Mb, ≥10 mut/Mb to <13 mut/Mb, and ≥13 mut/Mb. All responding patients will be followed for at least 12 months from the onset of response. Final Report Submission

US Postmarketing Requirements

Public

Status as of 09-Jan-2023

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
KEYTRUDA	pembrolizumab	BLA 125514 US	30-Apr-2027	Not Applicable	Ongoing		PMR 3188-4	Characterize the long-term safety of pembrolizumab 2 mg/kg every 3 weeks, in pre-pubertal pediatric patients and those who have not completed pubertal development. Submit a report and datasets that include long-term follow-up of patients enrolled on KN051, a Phase I/II Study of Pembrolizumab (MK-3475) in children with advanced melanoma or a PD-L1 positive advanced, relapsed or refractory solid tumor or lymphoma. Enroll at least 20 patients, including at least 5 patients who are pre-pubertal and 10 who have not yet completed pubertal development. For any pre-pubertal patients and those who have not completed pubertal development, perform the following actions: include in the safety evaluation, immune-mediated, endocrine, and reproductive toxicities for subjects with at least 5 years of follow-up or until pubertal development is complete, whichever is longer. Final Report Submission
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Dec-2032	Not Applicable	Ongoing		PMR 3546-1	Conduct and submit the results of a multicenter clinical trial to confirm the clinical benefit of pembrolizumab in patients with locally advanced or metastatic Merkel cell carcinoma (MCC) who have not received prior systemic therapies for metastatic MCC. The trial will enroll at least 50 patients to be followed for a minimum of 12 months to establish the objective response rate and characterize the durability of response. Overall survival, which is a secondary endpoint, will be followed to maturity until at least 70% of patients have died, or for an additional two years beyond the primary data analysis cut-off, to characterize effects on survival. Final Report Submission
PIFELTRO	doravirine	NDA 210806 US	31-Jan-2022	Not Applicable	Fulfilled	FDA acknowledged fulfillment on 27-Jan-2022	PMR 3415-1	Conduct a study to evaluate the pharmacokinetics, safety and antiviral activity (efficacy) of doravirine in HIV-1 infected pediatric subjects less than 18 years of age and weighing at least 35 kg. The safety and ntiviral activity of doravirine in pediatric subjects must be evaluated for a minimum of 24 weeks. Final Report Submission
PIFELTRO	doravirine	NDA 210806 US	31-May-2024	Not Applicable	Ongoing		PMR 3415-2	Conduct a study to evaluate the pharmacokinetics, safety and antiviral activity (efficacy) of doravirine in HIV-1 infected pediatric subjects at least 2 years of age and weighing less than 35 kg. The study participants must be followed for a minimum of 24 weeks to assess the safety and antiviral activity of doravirine. Final Report Submission
PIFELTRO	doravirine	NDA 210806 US	28-Feb-2029	Not Applicable	Ongoing		PMR 3415-3	Conduct a study to evaluate the pharmacokinetics, safety and antiviral activity (efficacy) of doravirine in HIV-1 infected pediatric subjects 4 weeks of age to 23 months of age. The study participants must be followed for a minimum of 24 weeks to assess the safety and antiviral activity of doravirine. Final Report Submission
RECARBRIO	relebactam (+) imipenem (+) cilastatin sodium	NDA 212819 US	30-Apr-2022	Not Applicable	Fulfilled	FDA acknowledged fulfillment on 18-Oct-2021	PMR 3641-1	Conduct an open label, single-dose study to evaluate the pharmacokinetics, safety and tolerability of imipenem, cilastatin and relebactam in children from birth to less than 18 years of age with proven or suspected Gram-negative infections. The timetable you submitted on July 12, 2019 states that you will conduct this study according to the following schedule: Final Report Submission

US Postmarketing Requirements

Public

Status as of 09-Jan-2023

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
RECARBRIO	relebactam (+) imipenem (+) cilastatin sodium	NDA 212819 US	31-Aug-2024	Not Applicable	Ongoing		PMR 3865-1	Conduct a randomized, open-label, active controlled trial to evaluate the safety and tolerability of imipenem, cilastatin and relebactam in children from birth to less than 18 years of age with complicated urinary tract infections, complicated intra-abdominal infections and hospital-acquired bacterial pneumonia or ventilator-associated bacterial pneumonia. Final Report Submission
RECARBRIO	relebactam (+) imipenem (+) cilastatin sodium	NDA 212819 US	31-Dec-2024	Not Applicable	Ongoing		PMR 3865-2	Conduct a United States surveillance study for 5 years from the date of marketing to determine if resistance to imipenem, cilastatin and relebactam has developed in organisms specific to the indications in the label. Final Report Submission
SEGLUROMET	ertugliflozin (+) metformin hydrochloride	NDA 209806 US	30-Sep-2026	Not Applicable	Submitted		PMR 3311-1	Conduct a 24-week, randomized, double-blind, placebo-controlled, parallel group study of the safety, efficacy, and pharmacokinetics (PK) of ertugliflozin as add-on to metformin background therapy for the treatment of type 2 diabetes mellitus in pediatric patients ages 10 to 17 years (inclusive), followed by a 30-week doubleblind, controlled extension. Patients will be randomized to receive one of two doses of ertugliflozin or placebo once daily. The ertugliflozin doses will be determined using a population PK model derived from the Phase 3 program (in adult subjects) for ertugliflozin. As part of the pediatric study, sparse blood samples for population PK and exposures-response analysis will be collected. An interim analysis of the PK data will be performed during this study to confirm acceptable exposure to ertugliflozin with the selected doses. Final Report Submission. This study is being conducted for NDA 209803 and NDA 209806.
SIVEXTRO®	tedizolid phosphate	NDA 205435 US	31-Jul-2019	30-Jun-2023	Ongoing	FDA granted deferral extension November 04, 2022, Study Completion June 2023	PMR 2159-5	Conduct a Phase 1 Single-Dose Safety and Pharmacokinetic Study of Oral and Intravenous SIVEXTRO in Inpatients Under 2 Years Old. Final Report Submission. This study is being conducted for NDA 205435 and NDA 205436.
SIVEXTRO®	tedizolid phosphate	NDA 205435 US	31-Aug-2021	31-Dec-2024	Ongoing	FDA granted deferral extension November 04, 2022, Study Completion June 2024, Deferral extension December 2024	PMR 2159-7	Conduct a Randomized, Single Blind, Multicenter Safety and Efficacy Study of Intravenous to Oral Sivextro (tedizolid phosphate) and Intravenous to Oral Comparator for the Treatment of Acute Bacterial Skin and Skin Structure Infections in Pediatric Patients Aged Birth to <12 Years. Final Report Submission. This study is being conducted for NDA 205435 and NDA 205436.
SIVEXTRO®	tedizolid phosphate	NDA 205436 US	31-Jul-2019	30-Jun-2023	Ongoing	FDA granted deferral extension November 04, 2022, Study Completion June 2023	PMR 2159-5	Conduct a Phase 1 Single-Dose Safety and Pharmacokinetic Study of Oral and Intravenous SIVEXTRO in Inpatients Under 2 Years Old. Final Report Submission. This study is being conducted for NDA 205435 and NDA 205436.
SIVEXTRO®	tedizolid phosphate	NDA 205436 US	31-Aug-2021	31-Dec-2024	Ongoing	FDA granted deferral extension November 04, 2022, Study Completion June 2024, Deferral extension December 2024	PMR 2159-7	Conduct a Randomized, Single Blind, Multicenter Safety and Efficacy Study of Intravenous to Oral Sivextro (tedizolid phosphate) and Intravenous to Oral Comparator for the Treatment of Acute Bacterial Skin and Skin Structure Infections in Pediatric Patients Aged Birth to <12 Years. Final Report Submission. This study is being conducted for NDA 205435 and NDA 205436.

US Postmarketing Requirements

Public

Status as of 09-Jan-2023

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
STEGLATRO	ertugliflozin	NDA 209803 US	30-Sep-2026	Not Applicable	Submitted		PMR 3311-1	Conduct a 24-week, randomized, double-blind, placebo-controlled, parallel group study of the safety, efficacy, and pharmacokinetics (PK) of ertugliflozin as add-on to metformin background therapy for the treatment of type 2 diabetes mellitus in pediatric patients ages 10 to 17 years (inclusive), followed by a 30-week doubleblind, controlled extension. Patients will be randomized to receive one of two doses of ertugliflozin or placebo once daily. The ertugliflozin doses will be determined using a population PK model derived from the Phase 3 program (in adult subjects) for ertugliflozin. As part of the pediatric study, sparse blood samples for population PK and exposures-response analysis will be collected. An interim analysis of the PK data will be performed during this study to confirm acceptable exposure to ertugliflozin with the selected doses. Final Report Submission. This study is being conducted by NDA 209803 and NDA 209806.
VAXNEUVANCE	Pneumococcal 15-valent Conjugate Vaccine	BLA 125741 US	31-Jul-2021	30-Sep-2021	Fulfilled	FDA acknowledged fulfillment on 17-Jun-2022	PMR 3	Deferred pediatric study under PREA (Study V114-027) to evaluate the safety and immunogenicity of four-dose schedules of VAXNEUVANCE and Prevnar 13 with doses administered at 2, 4, 6 and 12 to 15 months of age, as compared to mixed schedules which begin with Prevnar 13 and change to VAXNEUVANCE at doses 2, 3 or 4. Final Report Submission
VAXNEUVANCE	Pneumococcal 15-valent Conjugate Vaccine	BLA 125741 US	31-Dec-2021	Not Applicable	Fulfilled	FDA acknowledged fulfillment on 17-Jun-2022	PMR 2	Deferred pediatric study under PREA (Study V114-024) to evaluate the safety and immunogenicity of VAXNEUVANCE when given as catch-up vaccination in healthy children 7 months through 17 years of age. Final Report Submission
VAXNEUVANCE	Pneumococcal 15-valent Conjugate Vaccine	BLA 125741 US	30-Apr-2022	Not Applicable	Fulfilled	FDA acknowledged fulfillment on 17-Jun-2022	PMR 1	Deferred pediatric study under PREA (Study V114-029) to evaluate the safety and immunogenicity of VAXNEUVANCE in healthy infants 6 through 12 weeks of age as a 4-dose schedule (2, 4, 6, and 12 to15 months of age). Final Report Submission
VAXNEUVANCE	Pneumococcal 15-valent Conjugate Vaccine	BLA 125741 US	31-Dec-2022	Not Applicable	Fulfilled	FDA acknowledged fulfillment on 17-Jun-2022	PMR 4	Deferred pediatric study under PREA (Study V114-030) to evaluate the safety and immunogenicity of VAXNEUVANCE in HIV-infected children 6 through 17 years of age. Final Report Submission
VERQUVO	vericiguat	NDA 214377 US	30-Oct-2027	Not Applicable	Ongoing		PMR 4001-2	A double-blind, randomized, placebo-controlled, clinical trial to evaluate PK, the efficacy and safety of vericiguat in pediatric patients >28 days to <18 years with heart failure due to left ventricular systolic dysfunction consistent with dilated cardiomyopathy. Final Report Submission
VERQUVO	vericiguat	NDA 214377 US	31-Mar-2034	Not Applicable	Ongoing		PMR 4001-3	A worldwide descriptive study that collects prospective and retrospective data in women exposed to vericiguat during pregnancy to assess risk to the 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 study will collect information for a minimum of 10 years. Results will be analyzed and reported descriptively. Data collected retrospectively will be analyzed separately and reported with the interim and final study reports. Final Report Submission

US Postmarketing Requirements

Public

Status as of 09-Jan-2023

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
WELIREG	belzutifan	NDA 215383 US	30-Apr-2026	Not Applicable	Ongoing		PMR 4132-1	Conduct a carcinogenicity study in mice to evaluate the potential for carcinogenicity. Submit a carcinogenicity protocol for a Special Protocol Assessment (SPA) prior to initiating the study; Final Report Submission
WELIREG	belzutifan	NDA 215383 US	30-Apr-2026	Not Applicable	Ongoing		PMR 4132-2	Conduct a carcinogenicity study in rats to evaluate the potential for carcinogenicity. Submit a carcinogenicity protocol for a Special Protocol Assessment (SPA) prior to initiating the study; Final Report Submission
WELIREG	belzutifan	NDA 215383 US	31-Dec-2026	Not Applicable	Ongoing		PMR 4132-3	Conduct an analysis from Study MK-6482-004 to further characterize and determine the incidence and severity of anemia, hypoxia, second primary malignancies and other serious adverse events in patients receiving belzutifan. Include incidence rates, time to onset, outcomes, red cell transfusion and the use of erythropoiesis stimulating agents for anemia and steps taken to mitigate these risks in the reports. Provide interim reports annually for 3 years; Final Report Submission
ZERBAXA™	ceftolozane sulfate (+) tazobactam sodium	NDA 206829 US	31-Dec-2020	30-Jun-2021	Fulfilled	FDA acknowledged fulfillment on 21-Apr-2022	PMR 2809-1	Conduct a randomized, double-blind, multicenter, comparative study to establish the safety and tolerability profile of ceftolozane/tazobactam compared to that of meropenem in hospitalized children from birth to <18 years with cUTI. The dose for this study will be determined upon review of the data to be submitted by December 2016 from a single-dose, multicenter, non-comparative study assessing the pharmacokinetics (PK) of ceftolozane/tazobactam in pediatric patients ages 0 to <18 years that was initiated in June 2014. Final Report Submission
ZERBAXA™	ceftolozane sulfate (+) tazobactam sodium	NDA 206829 US	31-Dec-2020	30-Jun-2021	Fulfilled	FDA acknowledged fulfillment on 21-Apr-2022	PMR 2809-2	A randomized, double-blind, multicenter, comparative study to establish the safety and tolerability profile of ceftolozane/tazobactam compared to that of meropenem in hospitalized children from birth to <18 years with cIAI. The dose from this study will be determined upon review of the data to be submitted by December 2016 from the a single-dose, multicenter, non-comparative study to assessing the PK pharmacokinetics (PK) of ceftolozane/tazobactam in pediatric patients ages 0 to <18 years that was initiated in June 2014. Final Report Submission
ZERBAXA™	ceftolozane sulfate (+) tazobactam sodium	NDA 206829 US	30-Nov-2023	Not Applicable	Ongoing		PMR 3637-1	Conduct a safety and pharmacokinetic study in HABP/VABP in children from birth to less than 18 years of age. Final Report Submission.
ZINPLAVA	bezlotoxumab	BLA 761046 US	30-Nov-2022	Not Applicable	Submitted		PMR 3118-1	Conduct a randomized, double-blind, placebo-controlled trial of safety, efficacy, and pharmacokinetics of Zinplava (bezlotoxumab) in pediatric patients from 1 to less than 18 years of age receiving antibacterial therapy for C. difficile infection. Final Report Submission