



US Postmarketing Requirements

Status as of 08-Jul-2024

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	31-Mar-2024	Submitted		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	30-Jun-2024	Submitted		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-May-2024	31-Dec-2026	Ongoing	FDA granted deferral extension on March 31, 2023	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
ERVEBO	Ebola Zaire Vaccine (rVSV delta G-ZEBOV-GP, live)	BLA 125690 US	30-Jun-2021	30-Jun-2022	Fulfilled	FDA acknowledged fulfillment on July 27, 2023	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
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.
KEYTRUDA	pembrolizumab	BLA 125514 US	31-Oct-2019	31-Oct-2023	Fulfilled	FDA acknowledged fulfillment on January 25, 2024	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	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 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

Status as of 08-Jul-2024

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	Fulfilled	FDA acknowledged fulfillment on December 15, 2023	PMR 4429-1	Submit results for Clinical Trial EV-302. Conduct clinical trial EV-302, "Enfortumab Vedotin and Pembrolizumab vs. Chemotherapy Alone in Untreated Locally Advanced or Metastatic Urothelial Cancer" and submit the final OS, PFS, ORR and DoR results, intended to verify and describe the clinical benefit of enfortumab vedotin in combination with pembrolizumab in patients with untreated locally advanced or metastatic urothelial cancer.
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

Status as of 08-Jul-2024

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	Fulfilled	FDA acknowledged this commitment fulfilled on October 12, 2023	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-May-2024	31-Dec-2026	Ongoing	FDA granted deferral extension on March 31, 2023	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
PREVYMIS	letermovir	NDA 209939 tablet US	30-Apr-2024	Not Applicable	Submitted		PMR 4457-1	Conduct phenotypic analysis of letermovir against human CMV (HCMV) mutants carrying the following pUL56 and pUL89 substitutions: -pUL56: S229Y, M329I -pUL89: D344Y Include previously identified substitutions with a range of susceptibilities from low fold change (e.g., pUL56: L257I or S229F) to high fold change (e.g., pUL56: C325Y) as references. NDA 209939 and NDA 209940 Final Report Submission
PREVYMIS	letermovir	NDA 209939 tablet US	31-Aug-2024	Not Applicable	Ongoing		PMR 4457-2	Conduct a study to genotype the HCMV gene encoding pUL104 for the subjects with sufficient residual plasma samples who experienced HCMV disease or who discontinued early with HCMV DNAemia in P002 "A Phase 3, Randomized, Double-Blind, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of MK-8228 (Letermovir) Versus Valganciclovir for the Prevention of Human Cytomegalovirus (CMV) Disease in Adult Kidney Transplant Recipients. NDA 209939 and NDA 209940. Final Report Submission



US Postmarketing Requirements

Status as of 08-Jul-2024

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
PREVYMIS	letermovir	NDA 209939 tablet US	31-Oct-2024	Not Applicable	Ongoing		PMR 4465-1	PMR 4465-1 Conduct a study to genotype the HCMV gene encoding the pUL104 for the subjects with sufficient residual plasma samples who experienced HCMV disease or who discontinued early with HCMV DNAemia in Study P040. NDA 209939 and NDA 209940 Final Report Submission
PREVYMIS	letermovir	NDA 209940 injection US	30-Apr-2024	Not Applicable	Submitted		PMR 4457-1	Conduct phenotypic analysis of letermovir against human CMV (HCMV) mutants carrying the following pUL56 and pUL89 substitutions: -pUL56: S229Y, M329I -pUL89: D344Y Include previously identified substitutions with a range of susceptibilities from low fold change (e.g., pUL56: L257I or S229F) to high fold change (e.g., pUL56: C325Y) as references. NDA 209939 and NDA 209940 Final Report Submission
PREVYMIS	letermovir	NDA 209940 injection US	31-Aug-2024	Not Applicable	Ongoing		PMR 4457-2	Conduct a study to genotype the HCMV gene encoding pUL104 for the subjects with sufficient residual plasma samples who experienced HCMV disease or who discontinued early with HCMV DNAemia in P002 "A Phase 3, Randomized, Double-Blind, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of MK-8228 (Letermovir) Versus Valganciclovir for the Prevention of Human Cytomegalovirus (CMV) Disease in Adult Kidney Transplant Recipients. NDA 209939 and NDA 209940. Final Report Submission
PREVYMIS	letermovir	NDA 209940 injection US	31-Oct-2024	Not Applicable	Ongoing		PMR 4465-1	PMR 4465-1 Conduct a study to genotype the HCMV gene encoding the pUL104 for the subjects with sufficient residual plasma samples who experienced HCMV disease or who discontinued early with HCMV DNAemia in Study P040. NDA 209939 and NDA 209940 Final Report Submission
RECARBRIO	relebactam (+) imipenem (+) cilastatin sodium	NDA 212819 US	31-Aug-2024	28-Feb-2025	Ongoing	FDA granted deferral extension on February 28, 2024.	PMR 3865-1	Conduct a randomized, open-label, active controlled trial to evaluate the safety and tolerability of imipenem, cilastatin and rebactam 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 rebactam has developed in organisms specific to the indications in the label. Final Report Submission
SEGLUOMET	ertugliflozin (+) metformin hydrochloride	NDA 209806 US	30-Sep-2026	Not Applicable	Ongoing		PMR 3763-1	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.



US Postmarketing Requirements

Status as of 08-Jul-2024

Registered Trade Name	Generic Name	NDA/BLA #	Original Due Date	FDA Approved Deferred Due Date	Status	Explanation of Status	PMR #	PMR Description
SIVEXTRO®	tedizolid phosphate	NDA 205435 US	31-Jul-2019	30-Jun-2024	Submitted		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	Submitted		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-2024	Submitted		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	Submitted		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.
STEGLATRO	ertugliflozin	NDA 209803 US	30-Sep-2026	Not Applicable	Ongoing		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.
VERQUVO	vericiguat	NDA 214377 US	31-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
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



US Postmarketing Requirements

Status as of 08-Jul-2024

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 4132-2	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
WINREVAIR™	sotatercept	BLA 761363 US	31-Oct-2035	Not Applicable	Ongoing		PMR 4590-1	Conduct a worldwide descriptive study that collects prospective and retrospective data in women exposed to Winerevair (sotatercept-csrk) during pregnancy and/or 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. Final Report Submission.
ZERBAXA™	ceftolozane sulfate (+) tazobactam sodium	NDA 206829 US	30-Nov-2023	30-Jun-2026	Ongoing	FDA Granted Deferral Extension on September 01, 2023	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.