# US Postmarketing Requirements

Status as of 13-Jan-2026

| Registered Trade Name | Generic Name | NDA/BLA # | Original Due Date | FDA Approved Deferred Due Date | Status | Explanation of Status | PMR # | PMR Description |
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| BELSOMRA | suvorexant | NDA 204569 US | 31-Jul-2023 | 31-Mar-2024 | Fulfilled | FDA acknowledged fulfillment on March 10, 2025 | 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. |
| CAPVAXIVE | Pneumococcal 21-valent Conjugate Vaccine | BLA 125814 US | 31-Dec-2026 | Not Applicable | Ongoing | | PMR 125814/0-2: PREA Pediatric Study | Deferred pediatric study under PREA to evaluate the safety and immunogenicity of CAPVAXIVE in pediatric patients ages 2 to <18 years. Final Report Submission |
| CAPVAXIVE | Pneumococcal 21-valent Conjugate Vaccine | BLA 125814 US | 31-Dec-2029 | Not Applicable | Ongoing | | PMR 125814/0-1: Hybrid TND Study | To conduct an observational hybrid study using both primary and secondary data collection with a test-negative case-control design with the objective of assessing the effectiveness of CAPVAXIVE in preventing hospitalized, confirmed community acquired pneumonia (CAP, invasive and non-invasive) caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 65 years of age. The clinical protocol (V116-011-00) is entitled “A Test-Negative Case-Control Study to Evaluate the Effectiveness of V116 Against Pneumococcal Pneumonia in Older Adults. 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 |
| ENFLONSIA | clesrovimab | BLA 761432 US | 31-Aug-2026 | Not Applicable | Ongoing | | PMR 4841-1 PREA Study | Conduct a study in children up to 24 months of age with underlying conditions who are at increased risk for respiratory syncytial virus (RSV) disease. Final Report Submission |
| ENFLONSIA | clesrovimab | BLA 761432 US | 31-Jul-2029 | Not Applicable | Ongoing | | PMR 4841-3 | Conduct a study to assess F protein substitutions in cell culture neutralization assays, in the background subtype in which they were identified based on non-clinical, surveillance, and clinical studies of clesrovimab. The list of substitutions is provided below:<br><br>RSV A: N380S, N426H, N428D, R429H, S436F, V447M, Y457H, K465R, S466N, K470R<br><br>Also: test S443T if RSV B S443L shows reduced susceptibility to clesrovimab, and test K445R if RSV B K445N shows reduced susceptibility.<br><br>RSV B: I402V, K433R, F435S, V442M, S443L, K445N, G446V, V452E<br><br>Also: test V447I if RSV A V447M shows reduced susceptibility to clesrovimab.<br><br>Final Report Submission |
| ENFLONSIA | clesrovimab | BLA 761432 US | 31-Jul-2034 | Not Applicable | Ongoing | | PMR 4841-2 Public Sequence Database Analysis | Conduct a surveillance study of current and emerging respiratory syncytial virus (RSV) variants from global locations, with F protein sequencing and identification of clesrovimab binding site substitutions and their frequency. These surveillance activities should include active collection and characterization of RSV samples from global regions (i.e., North America [US/Canada], Europe, rest of the world) and will target at least 100 samples from each region when fully operational, as well as periodic analysis of sequences from public databases (i.e., GISAID, NCBI, GenBank). The surveillance study should also determine the cell culture neutralization activity of clesrovimab against those RSV clesrovimab binding epitope variants carrying substitutions (VAF >10%) and with unknown impact on clesrovimab susceptibility that are capable of growing in cell culture. Phenotypic characterization will include RSV variants whose prevalence is ≥5% within an RSV season (or over two consecutive years in public databases) and/or ≥3-fold increase above 1% from the previous season across all sequenced samples and from all sites within a global region. RSV variants of interest for phenotypic testing will include those carrying substitutions of unknown impact on clesrovimab susceptibility, detected in Site IV, adjacent to the clesrovimab binding epitope (within ≤5 Å distance), or outside Site IV at highly conserved positions (≥99% in GenBank). Final Report Submission |

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| ENFLONSIA | clesrovimab | BLA 761432 US | 31-Jul-2034 | Not Applicable | Ongoing | | PMR 4841-2 Strain Surveillance Study | Conduct a surveillance study of current and emerging respiratory syncytial virus (RSV) variants from global locations, with F protein sequencing and identification of clesrovimab binding site substitutions and their frequency. These surveillance activities should include active collection and characterization of RSV samples from global regions (i.e., North America [US/Canada], Europe, rest of the world) and will target at least 100 samples from each region when fully operational, as well as periodic analysis of sequences from public databases (i.e., GISAID, NCBI, GenBank). The surveillance study should also determine the cell culture neutralization activity of clesrovimab against those RSV clesrovimab binding epitope variants carrying substitutions (VAF >10%) and with unknown impact on clesrovimab susceptibility that are capable of growing in cell culture. Phenotypic characterization will include RSV variants whose prevalence is ≥5% within an RSV season (or over two consecutive years in public databases) and/or ≥3-fold increase above 1% from the previous season across all sequenced samples and from all sites within a global region. RSV variants of interest for phenotypic testing will include those carrying substitutions of unknown impact on clesrovimab susceptibility, detected in Site IV, adjacent to the clesrovimab binding epitope (within ≤5 Å distance), or outside Site IV at highly conserved positions (≥99% in GenBank). Final Report Submission |
| GARDASIL®9 | Human Papillomavirus 9-valent Vaccine, Recombinant | BLA 125508 US | 30-Sep-2026 | 30-Sep-2028 | Ongoing | FDA acknowledged revised due date to September 30, 2028 | PMR 1/PMR 125508/868-1 | 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 | 30-Sep-2024 | Not Applicable | Fulfilled | FDA acknowledged fulfilled March 19, 2025 | 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 |
| KEYTRUDA | pembrolizumab | BLA 125514 US | 30-Sep-2024 | Not Applicable | Submitted | | 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.<br>Final Report Submission |
| KEYTRUDA | pembrolizumab | BLA 125514 US | 31-Dec-2024 | Not Applicable | Fulfilled | FDA Acknowledged fulfilled December 17, 2025 | 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 fulfilled July 24, 2025 | 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. |

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| KEYTRUDA | pembrolizumab | BLA 125514 US | 31-Dec-2025 | Not Applicable | Submitted | | 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<br>or dMMR cancers, or melanoma; and including CNS tumors that were<br>determined to be TMB-H based on testing of tissue obtained prior to<br>initiation of temozolomide chemotherapy), and with cancers having a TMB of 10 to <13<br>mut/Mb, will be evaluated to characterize response and duration of response. A minimum of 20<br>pediatric patients will be studied.<br>Overall response rate and duration of response will be assessed by<br>independent central review for patients with cancers having a TMB of ≥10<br>mut/Mb, ≥10 mut/Mb to <13 mut/Mb, and ≥13 mut/Mb. All responding<br>patients will be followed for at least 12 months from the onset of response. Final Report Submission |
| 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 QLEX™ | pembrolizumab (+) berahyaluronidase alfa | BLA 761467 US | 31-Dec-2025 | Not Applicable | Submitted | | PMR 4904-1 | 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, MSI- H 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 |
| 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 | Fulfilled | FDA acknowledged fulfillment on January 30, 2025 | PMR 4457-1 | Conduct phenotypic analysis of letermovir against human CMV (HCMV) mutants carrying the following pUL56 and pUL89 substitutions:<br>-pUL56: S229Y, M329I<br>-pUL89: D344Y<br>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-Oct-2024 | Not Applicable | Fulfilled | FDA acknowledged fulfillment on May 15, 2025 | 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 209939 tablet US | 30-Apr-2026 | Not Applicable | Submitted | | PMR 4692-1 | Conduct phenotypic analysis of letermovir against human cytomegalovirus (HCMV) mutants carrying substitutions (1) pUL51 P91H and (2) pUL56 S229Y + pUL56 M329I with and without pUL89 D344Y. The analysis should include previously identified substitutions with a range of susceptibilities from low fold change (e.g. pUL56 L257I) to high fold change (e.g. pUL56 C325Y) as references. Final Report Submission. NDAs 209939,209940,219104 |

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| PREVYMIS | letermovir | NDA 209940 injection US | 30-Apr-2024 | Not Applicable | Fulfilled | FDA acknowledged fulfillment on January 30, 2025 | PMR 4457-1 | Conduct phenotypic analysis of letermovir against human CMV (HCMV) mutants carrying the following pUL56 and pUL89 substitutions:<br>-pUL56: S229Y, M329I<br>-pUL89: D344Y<br>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-Oct-2024 | Not Applicable | Fulfilled | FDA acknowledged fulfillment on May 15, 2025 | 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-2026 | Not Applicable | Submitted | | PMR 4692-1 | Conduct phenotypic analysis of letermovir against human cytomegalovirus (HCMV) mutants carrying substitutions (1) pUL51 P91H and (2) pUL56 S229Y + pUL56 M329I with and without pUL89 D344Y. The analysis should include previously identified substitutions with a range of susceptibilities from low fold change (e.g. pUL56 L257I) to high fold change (e.g. pUL56 C325Y) as references. Final Report Submission. NDAs 209939,209940,219104 |
| PREVYMIS | letermovir | NDA 219104 Oral Granules | 30-Apr-2026 | Not Applicable | Submitted | | PMR 4692-1 | Conduct phenotypic analysis of letermovir against human cytomegalovirus (HCMV) mutants carrying substitutions (1) pUL51 P91H and (2) pUL56 S229Y + pUL56 M329I with and without pUL89 D344Y. The analysis should include previously identified substitutions with a range of susceptibilities from low fold change (e.g. pUL56 L257I) to high fold change (e.g. pUL56 C325Y) as references. Final Report Submission. NDAs 209939,209940,219104 |
| RECARBRIO | relebactam (+) imipenem (+) cilastatin sodium | NDA 212819 US | 31-Aug-2024 | 28-Feb-2025 | Fulfilled | FDA acknowledged fulfillment December 9, 2025 | 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 | Fulfilled | FDA acknowledged fulfillment on September 3, 2025 | 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 | 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 209806 (and PMR 3311-1: NDA 209803). |
| SIVEXTRO® | tedizolid phosphate | NDA 205435 US | 31-Jul-2019 | 30-Jun-2024 | Fulfilled | FDA acknowledged fulfillment on April 4, 2025 | 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 | Fulfilled | FDA acknowledged fulfilled on April 4, 2025 | 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 205435 US | 31-Aug-2025 | Not Applicable | Submitted | | PMR 4827-1 | Complete development of the powder for oral suspension (PFOS) formulation including product stability studies – long-term and accelerated storage, stress studies, and applicable in-use stability and compatibility. NDA 205435 and 205436 |
| SIVEXTRO® | tedizolid phosphate | NDA 205436 US | 31-Jul-2019 | 30-Jun-2024 | Fulfilled | FDA acknowledged fulfillment on April 4, 2025 | 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 | Fulfilled | FDA acknowledged fulfilled on April 4, 2025 | 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-Aug-2025 | Not Applicable | Submitted | | PMR 4827-1 | Complete development of the powder for oral suspension (PFOS) formulation including product stability studies – long-term and accelerated storage, stress studies, and applicable in-use stability and compatibility. NDA 205435 and 205436 |

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| 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 PMR 3763-1: NDA 209806.) |
| 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 | Fulfilled | FDA acknowledged fulfillment on September 15, 2025 | 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 |
| WELIREG | belzutifan | NDA 215383 US | 31-Jul-2034 | Not Applicable | Ongoing | | PMR 4842-1 | Conduct a comprehensive, integrated safety analysis after 5 years of follow-up from clinical trials in a sufficient number of pediatric patients to adequately characterize and evaluate, in pediatric patients, the known serious risks of anemia and hypoxia following exposure to belzutifan. Include an assessment of clinical responses. 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 | Submitted | 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. |

Merck Sharp Dohme LLC, Rahway, NJ, USA