Approvals & Updates

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PharMerica®

New Drug Approvals

Elrexfio (elranatamab-bcmm)

Indication: Relapsed or refractory multiple myeloma

Mechanism of action: Bispecific B-cell maturation antigen (BCMA)- directed CD3 T-cell engager

Dosage form(s): Subcutaneous Injection

Comments: Elrexfio is under accelerated FDA approval for the treatment of relapsed or refractory multiple myeloma in adults who have received at least four prior lines of therapy. The previous therapy needed to include a proteasome inhibitor, immunomodulatory agent, and an anti-CD38 monoclonal antibody. Current dosing guidelines include a step-up dosing schedule followed by weekly and biweekly dosing. Step-up dosing begins with 12 mg, 32 mg, and 76 mg administered on days 1, 4, and 8 respectively. Beginning one week after the first treatment dose (Day 8) and continuing through week 24; a dose of 76 mg per week is recommended. Biweekly dosing, only recommended for responders, begins at week 25 with subsequent treatment doses of 76 mg every 2 weeks. Hospitalization is recommended for 48 hours and 24 hours after the first and second step-up dose respectively. Pre-treatment medications to be administered prior to step-up dose 1 and 2 include acetaminophen 650 mg orally, dexamethasone 20 mg orally or intravenously, and diphenhydramine 25 mg orally. Equivalent pre-treatment medications can be utilized. Additional requirements include a minimum of 2 days between step up dose 1 and 2, a minimum of 3 days between step up dose 2 and the first treatment dose, and a minimum of 6 days should be maintained between treatment subsequent treatment doses. Elrexfio has a black box warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome and is only available through the Risk Evaluation and Mitigation Strategy (REMS) program. There are no listed contraindications. Warnings and precautions associated with Elrexfio include infections, neutropenia, hepatotoxicity, and embryo-fetal toxicity. Patients should be monitored for signs and symptoms of infection and elevated liver enzymes. The most common adverse reactions (≥ 20%) are CRS, fatigue, injection site reactions, diarrhea, upper respiratory tract infection, musculoskeletal pain, pneumonia, decreased appetite, rash, cough, nausea and fever.

Izervay (avacincaptad pegol intravitreal solution)

Indication: Geographic atrophy (GA)

Mechanism of action: Complement inhibitor

Dosage form(s): Solution for intravitreal injection

Comments: Izervay is FDA-approved for GA secondary to age-related macular degeneration (AMD) and is available as a 20 mg/mL single dose vial. Recommended dosing and administration for Izervay is 2 mg (0.1 mL of 20 mg/mL solution) via intravitreal injection by a qualified physician to the affected eye(s) once monthly for 12 months. Izervay is contraindicated in ocular or periocular infections and active intraocular inflammation. Warnings and precautions associated with Izervay include endophthalmitis and retinal detachments, neovascular AMD, and increase in intraocular pressure (IOP). The most common adverse effects included conjunctival hemorrhage (13%), increase IOP (9%), blurred vision (8%), and neovascular AMD (7%).

Sohonos (palovarotene)

Indication: Reduce volume of new heterotopic ossification

Mechanism of action: Retinoid

Dosage form(s): Oral capsules

Comments: Sohonos is FDA-approved to reduce the volume of new heterotopic ossification in adults, pediatric females ≥ 8 years, and pediatric males ≥ 10 years with fibrodysplasia ossificans progressiva (FOP). The recommended dose for patients ≥ 14 years is 5 mg once daily. If patients experience a flare, dosing can be increased to 20 mg once daily for 4 weeks, followed by 10 mg once daily for 8 weeks. Dosing for pediatric females (8-13 years) and males (10-13 years) is weight-adjusted for both daily and flare dosing with a recommended daily dose range of 2.5 to 5 mg. Sohonos should be taken with food at approximately the same time each day. When used in pediatric populations, baseline assessments of growth and skeletal maturity before initiation is recommended. Clinical and radiographic monitoring every 6 to 12 months should be continued until final adult height or skeletal maturity has been reached. Sohonos has a black box warning for embryo-fetal toxicity and premature epiphyseal closure in growing pediatric populations. Sohonos is contraindicated in pregnancy and should only be administered if conditions for pregnancy prevention are met. Additionally, Sohonos is contraindicated in patients with previous hypersensitivity to retinoids or to any other component present. Warnings and precautions associated with Sohonos include premature epiphyseal closure, mucocutaneous adverse reactions, metabolic bone disorders, psychiatric disorders, night blindness. Common adverse reactions (≥10%) include dry skin, lip dryness, arthralgia, pruritis, pain in extremity, rash, alopecia, erythema, headache, back pain, skin exfoliation, nausea, musculoskeletal pain, myalgia, dry eye, hypersensitivity, peripheral edema, and fatigue. Drug-drug interactions may occur with vitamin A, tetracyclines, and CYP3A4 inhibitors or inducers.

Talvey (talquetamab-tgvs)

Indication: Relapsed or refractory multiple myeloma

Mechanism of action: Bispecific GPRC5D-directed CD3 T-cell engager

Dosage form(s): Subcutaneous injection

Comments: Talvey is under accelerated FDA approval for adult patients with relapsed or refractory multiple myeloma who have received at least four lines of prior therapy. Weekly and biweekly dosing schedules are available. Weekly dosing begins with an initial step-up approach during the first week with a recommended dose of 0.01 mg/kg and 0.06 mg/kg, on days 1 and 4 respectively. On day 7, the first treatment dose of 0.4 mg/kg is given followed by continued once weekly 0.4 mg/kg doses. One requirement for the weekly dosing schedule is maintaining a minimum of 6 days between weekly doses. Biweekly dosing begins with a step-up approach with doses of 0.01 mg/kg, 0.06 mg/kg and 0.4 mg/kg on days 1,4, and 7 respectively. On day 10, the first treatment dose of 0.8 mg/kg is given followed by 0.8 mg/kg every two weeks. Requirements for biweekly dosing include maintaining a minimum of 12 days between doses and administering the first treatment dose between 2 to 7 days after step-up dose 3. With either dosing schedule; any dose may be administered between 2 to 4 days after the previous dose and up to 7 days after to allow for adverse effects to resolve. All doses are calculated using actual body weight. Additionally, it is recommended patients be hospitalized for 48 hours and receive pretreatment medications (i.e., oral or intravenous (IV) dexamethasone 16 mg or equivalent, oral or IV diphenhydramine 50 mg or equivalent, and oral or IV acetaminophen 650 mg to 1,000 mg or equivalent) 1 to 3 hours prior to reduce the risk of cytokine release syndrome (CRS) with all step-up dosing. Talvey has a black box warning for CRS and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome. Warnings and precautions associated with Talvey include oral toxicity and weight loss, infections, cytopenia, skin toxicity, hepatotoxicity, and embryo-fetal toxicity. Monitoring patients for signs and symptoms of toxicity is recommended and Talvey should be withheld or discontinued based on severity. The most common adverse events (≥ 20%) are pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache. Grade 3 or 4 laboratory abnormalities commonly observed (≥30%) include decreased lymphocyte and neutrophil count, decreased white blood cell count, and decreased hemoglobin.

Veopoz (pozelimab-bbfg)

Indication: CD55-deficient protein-losing enteropathy (PLE)

Mechanism of action: Complement inhibitor

Dosage form(s): Subcutaneous injection

Comments: Veopoz is FDA approved for the treatment of CD55-deficient PLE in pediatric and adult patients ≥ 1 year of age. Recommended dosing includes a single loading dose of 30 mg/kg by intravenous infusion on day 1 followed by 10 mg/kg via subcutaneous injection once weekly beginning on day 8. If response is clinically ineffective after 3 doses, maintenance dosing can be increased to 12 mg/kg once weekly with a max dose of 800 mg weekly. Veopoz carries a black box warning for serious meningococcal infections and patients should be monitored for early signs and symptoms as infections can rapidly become life-threatening or fatal. Updated or completion of meningococcal vaccination at least 2 weeks prior to medication initiation is recommended. Veopoz is contraindicated in patients with unresolved Neisseria meningitidis. Additional warnings and precautions associated with Veopoz include other bacterial infections, systemic hypersensitivity reactions, and immune complex formation. The most common adverse effects in two or more patients include upper respiratory tract infection, fracture, urticaria, and alopecia.

Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Akeega (niraparib and abiraterone acetate)	Deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC)	Poly (ADP-ribose) polymerase (PARP) inhibitor and CYP17 inhibitor	Oral tablet	New combination
Eylea HD (aflibercept)	Neovascular (wet) age-related macular degeneration; diabetic macular edema; diabetic retinopathy	Vascular endothelial growth factor (VEGF)	Injection for intravitreal use	New higher dose
Focinvez (fosaprepitant)	Prevention of acute and delayed nausea and vomiting associated with high and moderate emetogenic cancer chemotherapy	Substance P/neurokinin-1 (NK1) receptor antagonist	Injection of intravenous use	New dosage form
Hepzato (melphalan and diluents for reconstitution and dilution)	Uveal melanoma with unresectable hepatic metastases	Alkylating drug	Injection for intra-arterial infusion	New combination

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