Approvals & Updates

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PharMerica®

New Drug Approvals

Abecma (idecabtagene vicleucel)

Indication: Multiple myeloma

Mechanism of Action: B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy

Dosage Form(s): Suspension for intravenous (IV) infusion

Comments: Abecma is FDA-approved for treating adults with relapsed or refractory multiple myeloma following ≥4 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Prior to starting Abecma, patients need to be pretreated with a lymphodepleting chemotherapy regimen of cyclophosphamide 300mg/m^2 IV and fludarabine 30mg/m^2 IV for 3 days and premedicated with acetaminophen (650mg orally) and diphenhydramine (12.5mg IV or 25 to 50mg orally), or another H1-antihistamine, 30 to 60 minutes before starting Abecma. Two days after completion of lymphodepleting chemotherapy and following confirmation of the patient's identity and availability of tocilizumab, Abecma 300 to 460 x 10^6 chimeric antigen receptor (CAR)-positive T cells can be administered IV at a certified healthcare facility. Prophylactic doses of dexamethasone or other systemic corticosteroids should not be administered while on Abecma therapy. Abecma carries a Boxed Warning for cytokine release syndrome (CRS), neurological toxicities, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), and prolonged cytopenia. As such, it is only available through a Risk Evaluation and Mitigation Strategy (REMS) program and should not be given to patients with active infection or inflammatory disorders. Abecma carries labeled warnings for hypersensitivity reactions, infections, prolonged cytopenias, hypogammaglobulinemia, secondary malignancies, and effects on ability to drive and use machines. Patients should be monitored for ≥7 days after infusion for signs and symptoms of CRS and neurologic toxicities, instructed to remain within proximity of the certified healthcare facility for ≥4 weeks after infusion, and advised to abstain from driving or hazardous activities for 8 weeks. Moreover, hypersensitivity reactions, signs and symptoms of infection, complete blood counts (CBC), immunoglobulin levels, and secondary malignancies should be monitored. Abecma has no known drug interactions, but administration may result in false-positive commercial HIV nucleic acid tests. The most common non-laboratory (≥20%) and laboratory (≥50%) adverse reactions reported with Abecma were CRS, infections, fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite and neutropenia, leukopenia, lymphopenia, thrombocytopenia, and anemia.

Fotivda (tivozanib)

Indication: Renal cell carcinoma (RCC)

Mechanism of Action: Tyrosine kinase inhibitor

Dosage Form(s): Capsules

Comments: Fotivda is FDA-approved for treating adults with relapsed or refractory advanced RCC after ≥2 prior systemic therapies. Fotivda should be taken as 1.34mg by mouth once daily for 21 days on treatment followed by 7 days off treatment for a 28-day cycle until progression of disease or unacceptable toxicity. Fotivda carries labeled warnings for hypertension and hypertensive crisis, cardiac failure, cardiac ischemia and arterial thromboembolic events, venous thromboembolic events, hemorrhagic events, proteinuria, thyroid dysfunction, risk of impaired wound healing, reversible posterior leukoencephalopathy syndrome (RPLS), embryo-fetal toxicity, and allergic reactions to tartrazine. Blood pressure, thyroid function tests, and signs and symptoms of proteinuria and cardiac failure should be monitored throughout therapy. Additionally, patients at risk for or who have a history of cardiac ischemia and arterial thromboembolic events, venous thromboembolic events, or bleeding should be closely monitored throughout therapy. Concomitant administration of Fotivda with strong CYP3A inducers should be avoided. The most common adverse reactions (≥20%) and Grade 3 or 4 laboratory abnormalities (≥5%) reported with Fotivda were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis and decreased sodium, increased lipase, and decreased phosphate.

Ponvory (ponesimod)

Indication: Multiple sclerosis (MS)

Mechanism of Action: Sphingosine 1-phosphate (S1P) receptor modulator

Dosage Form(s): Tablets

Comments: Ponvory is FDA-approved for treating adults with relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Prior to starting Ponvory, the following should be assessed: complete blood count (CBC), cardiac function, liver function, ophthalmic function, and antibodies to varicella zoster virus (VZV). The potential for additive immunosuppressive effects should also be considered prior to starting Ponvory in patients taking or who have a history of taking anti-neoplastic, immunosuppressive, or immune-modulating therapies. Ponvory needs to be titrated over 14 days upon initiation, starting at 2mg by mouth once daily, to reach a maintenance dose of 20mg once daily beginning on day 15. Ponvory carries labeled warnings for infections, bradyarrhythmia and atrioventricular conduction delays, respiratory effects, liver injury, increased blood pressure, cutaneous malignancies, fetal risk, and macular edema. Patients with sinus bradycardia, first- or second-degree AV block, or a history of myocardial infarction or heart failure should be monitored for 4 hours following the first dose of Ponvory. Additionally, throughout therapy, blood pressure, liver function tests, vision changes, suspicious skin lesions, and signs and symptoms of infection should be monitored. Concomitant administration of Ponvory with strong CYP3A4 and UGT1A1 inducers should be avoided, and administration of live attenuated vaccines during therapy and for 1-2 weeks following therapy should be avoided. The most common adverse reactions (≥10%) reported with Ponvory were upper respiratory tract infection, hepatic transaminase elevation, and hypertension.

Zegalogue (dasiglucagon)

Indication: Hypoglycemia

Mechanism of Action: Glucagon receptor agonist

Dosage Form(s): Subcutaneous single-dose autoinjector or prefilled syringe

Comments: Zegalogue is FDA-approved for treating diabetic adults and children ≥6 years old with severe hypoglycemia. Zegalogue should be injected as 0.6mg subcutaneously into the lower abdomen, buttocks, thigh, or outer upper arm as soon as severe hypoglycemia is recognized. Following administration, emergency assistance should be contacted immediately, and if there is no response 15 minutes after the initial dose, an additional dose of Zegalogue may be administered. After response to treatment, patients should be administered oral carbohydrates to restore liver glycogen and prevent hypoglycemia recurrence. Zegalogue carries labeled warnings for substantial increase in blood pressure in patients with pheochromocytoma, hypoglycemia in patients with insulinoma, hypersensitivity and allergic reactions, and lack of efficacy in patients with decreased hepatic glycogen. Blood glucose and signs and symptoms of hypersensitivity and allergic reactions should be monitored. Zegalogue has the potential to interact with beta-blockers, indomethacin, and warfarin, so the risks and benefits of coadministration should be considered. The most common adverse reactions (≥2%) reported with Zegalogue in adults were nausea, vomiting, headache, diarrhea, and injection site pain.

Safety Updates

FDA warns that abuse and misuse of the nasal decongestant propylhexedrine causes serious harm

The FDA recently published a safety communication warning about the serious complications associated with abuse and misuse of over-the-counter (OTC) propylhexedrine. Propylhexedrine is a nasal decongestant available as an inhaler OTC. It has been increasingly abused and misused over the past few years, with complications, such as fast or abnormal heart rhythm, high blood pressure, and paranoia, that may lead to hospitalization, disability, or death. As such, the FDA is asking that manufacturers of OTC propylhexedrine consider making product design changes to prevent tampering and ensure it is used safely. In the meantime, it is important providers are aware of the serious harm associated with the abuse and misuse of OTC propylhexedrine, and if overdose is suspected, symptomatic and supportive care should be provided.

Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine (Lamictal) in patients with heart disease

The FDA recently published a safety communication regarding results from a safety study which showed an increased risk of arrhythmias in patients with heart disease taking lamotrigine. They are requiring and waiting on manufacturers of other medications within the same drug class to evaluate whether or not similar adverse cardiac effects occur. In the meantime, providers are advised to consider the benefits and risk of arrhythmias associated with lamotrigine when deciding whether or not to prescribe or discontinue the medication. The FDA also recommends patients consult with their providers first before discontinuing lamotrigine.