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Clinical Update

FDA Approves Breyanzi® for Adults with Large B-Cell Lymphoma

On February 5, 2021, the U.S. Food and Drug Administration (FDA) approved Breyanzi® (lisocabtagene maraleucel) for the treatment of adults who have not responded to, or who have relapsed after, at least two other types of systemic treatment for large B-cell lymphoma. Breyanzi®, a chimeric antigen receptor T-cell (CAR-T) therapy, provides an individualized treatment for patients. T-cells, white blood cells that contribute to the body's immune response, are first collected from patients via a blood draw and are then genetically adapted to target and kill lymphoma cells. Modified cells are infused back into the patient to provide a direct attack on lymphoma cells. The approval of Breyanzi® comes after results from a multicenter clinical trial showed a 54% complete remission rate in 250 adults with refractory or relapsed large B-cell lymphoma. Common side effects of Breyanzi® include hypersensitivity reactions, infections, low blood cell counts, and a weakened immune system. More serious side effects include neurologic toxicities [12% occurrence rate in trial] and cytokine release syndrome (CRS) [4% occurrence rate in trial], which often results in a high fever and flu-like symptoms. Because of these risks, Breyanzi® is being approved with a risk evaluation and mitigation strategy (REMS), which requires health care professionals handling Breyanzi® to be trained to recognize signs and symptoms of CRS and neurologic toxicities. Post-marketing studies will be ongoing to evaluate the long-term safety.

Safety First

FDA Halts Trial for Alzheimer's Medication

The FDA recently placed a partial clinical hold on Cortexyme's atuzaginstat, which is being studied to treat Alzheimer's Disease (AD). Atuzaginstat specifically targets enzymes known as gingipains that are secreted by a specific type of bacteria, P. gingivalis, normally found in the oral cavity. P. gingivalis, which has been identified in 90% of AD patients, is thought to enter the blood stream, cross the blood-brain barrier, and contribute to damaging neuronal cells leading to the cognitive dysfunction associated with AD. Atuzaginstat's safety and efficacy is currently being evaluated in the GAIN Trial, where patients were randomly assigned to take either atuzaginstat or placebo for one year. Prior to the partial clinical hold, once participants had completed the GAIN trial, they were given the option to continue in an open-label extension (OLE) in which all participants received treatment with atuzaginstat. The hold was initiated after results showed occurrence of liver damage in patients being treated with atuzaginstat, which have been found to be reversible and hold no long-term effects. Since these findings, recruitment into the GAIN trial has been stopped and all subjects in the OLE have discontinued treatment with atuzaginstat. Results from the ongoing double-blinded trial, expected in late 2021, will provide a critical assessment of the safety and efficacy of atuzaginstat in the treatment of AD and will guide the FDA's decision on a potential continuation of the OLE trial.

From the Industry

Novo Nordisk Looks to Expand Obesity Drug Market

Novo Nordisk has been moving into the anti-obesity market through the expansion of the indications of their GLP-1 agonist (GLP-1a) medications, which have historically been used to treat Type 2 diabetes. GLP-1a's are injectable medications that work to reduce blood sugar levels and promote weight loss in a variety of pathways such as stimulating insulin secretion, decreasing glucose output from the liver, and promoting early satiety at mealtime. Obesity is a significant health concern, as it often has implications on both morbidity and mortality. As a result of the ongoing concerns associated with obesity in both diabetic and non-diabetic patients, the FDA approved an expansion for Novo's Saxenda® (liraglutide) injection to include the treatment of obesity in patients aged 12 years and older with or without diabetes, which represents a step forward for weight-loss promoting drugs. Now, Novo Nordisk is looking to obtain a new FDA approved indication for another GLP-1a, semaglutide, also known as Ozempic®. Data from a phase 3 trial, which compared semaglutide injection to placebo in overweight patients without diabetes, showed that the average participant taking once-weekly semaglutide injection lost over 33 pounds, with one-third of patients losing over 20% of their bodyweight during the 68-week trial. With these promising results, Novo Nordisk hopes to take another step into the obesity-drug market with an FDA approval coming as soon as mid-2021.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Tepmetko® (tepotinib)
Oral tablet approved for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a specific mutation [2/3/21 – Orphan Drug; Priority Review – EMD SERONO INC]

Novel Drug Approval: Ukoniq™ (umbralisib)
Oral tablet approved for the treatment of adult patients with follicular or marginal zone lymphoma who have tried and failed previous therapy [2/5/21 – Orphan Drug; Priority Review – TG THERAPS]

Novel Drug Approval: Cosela™ (trilaciclib)
Intravenous injection approved to reduce the incidence of myelosuppression associated with chemotherapy in adult patients being treated for extensive-stage small-cell lung cancer [2/12/21 – Priority Review – G1 THERAPEUTICS INC]

New Generics

New Generics Entering the Marketplace

Foscavir® (foscarnet sodium)
Indication: Treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS) and acyclovir-resistant herpes simplex virus (HSV) infections in immunocompromised patients.
Dosage Form/Strength: 250 mL infusion bottle containing 6000 mg of foscarnet sodium
Average Wholesale Price (AWP): Generic = $567 | Brand = $570

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