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Clinical Update

FDA Approves First Cell-Based Gene Therapy for Adults with Specific Type of Lymphoma

On July 24, 2020, The U.S. Food and Drug Administration (FDA) announced the approval of Tecartus™ (brexucabtagene autoleucel) intravenous infusion to treat adult patients with mantle cell lymphoma (MCL) who have not achieved adequate response to other treatments. MCL is an aggressive, rare form of cancer that originates in the "mantle" (outer ring) of the lymphocytes, white blood cells that are also one of the body's main types of immune cells for fighting infection. Currently, a variety of treatments are used to help manage the condition, including stem cell transplants, chemotherapy regimens (e.g., cyclophosphamide, doxorubicin, vincristine, prednisone) and blood transfusions. Treatment with Tecartus™ is individualized to each patient through collection and modification of their own immune cells to include a new gene that promotes the targeting and killing of the cancerous cells. Once modification is complete, these cells are infused back into the patient. Clinical trials evaluating the medication showed 62% of patients on Tecartus™ achieved complete remission. Tecartus™ was approved through the Accelerated Approval pathway, and given Breakthrough Therapy, Orphan Drug, and Priority Review designations.

Safety First

FDA Recommends Discussion of Naloxone with Patients at Risk of Opioid Overdose

On July 23, 2020, the FDA published a drug safety communication regarding usage of naloxone. Naloxone is an opioid reversal medication used to reduce the risk of death from opioid overdose in certain patient populations. The FDA recommends that health care professionals discuss the availability of naloxone with all patients being prescribed opioid pain relievers or opioid use disorder (OUD) treatment, and strongly consider prescribing it to patients who are at an increased risk of opioid overdose. Discussion and prescription of naloxone provides added safety measure for these patients, as well as their close contacts, including children and family members, who are at risk for accidental ingestion of opioid products. In addition to making this recommendation to prescribers, the FDA is also requiring drug manufacturers for all opioid pain reliever, and OUD medications, to add recommendations about naloxone to their prescribing information, and update the patient medication guides. The FDA aims to promote safe use of opioid medications and reduce risk of overdose, and recommends that patients talk to their health care professionals about obtaining naloxone according to their state's requirements or guidelines.

From the Industry

Phase III Trial Shows Triple-Therapy Combination Decreases Exacerbations in COPD

On July 20, 2020, the New England Journal of Medicine (NEJM) published results of a large Phase III clinical trial comparing exacerbation rates in Chronic Obstructive Pulmonary Disease (COPD) patients. More specifically, the trial compared COPD patients receiving triple fixed-dose inhaled corticosteroid (ICS), long-acting muscarinic agonist (LAMA), and long-acting beta agonist (LABA), to patients receiving one of two dual-therapy combinations over a 52-week period. The study included 8,509 patients who were randomized on a 1:1:1:1 basis to receive twice daily doses of different medication regimens. The first two groups received a triple therapy regimen consisting of either a low or high dose ICS, LAMA and LABA. The remaining regimens were dual therapy with a LAMA and LABA or high dose ICS and LABA. Triple therapy significantly improved severe exacerbation rates by 13 to 25% depending on the dosage of each medication, when compared to dual therapy, while adverse reactions were similar among all groups. These results provide health care professionals with additional information to consider when weighing the risks and benefits of triple therapy in COPD patients.

FDA Approvals

Recent FDA Approvals

New Formulation: Wynzora® (calcipotriene and betamethasone dipropionate)
Topical cream indicated for the treatment of plaque psoriasis in adult patients. [7/20/2020 – MC2]

Novel Drug Approval: Xeglyze™ (abametapir)
Topical lotion used for the treatment of head lice in patients age 6 months and older. [7/24/2020– Dr. Reddy's Laboratories]

Novel Drug Approval: Monjuvi® (tafasitamab-cxix)
Intravenous injection used in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). [7//2020 – Orphan Drug- MorphoSys US Inc.]

New Generics

New Generics Entering the Marketplace*

*As of this issue, there are no new generics entering the marketplace. However, there are several projected launches we are monitoring, including:

Valchlor® (mechlorethamine)
Indication: Skin Cancer
Dosage Form/Strength: 0.016% gel
Projected Launch: 3Q 2020

Tirosint® (levothyroxine)
Indication: Hypothyroidism
Dosage Form/Strength: 13, 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, and 200 mcg capsules
Projected Launch: 3Q 2020

Entereg® (alvimopan)
Indication: GI Surgery Recovery
Dosage Form/Strength: 12 mg capsules
Projected Launch: 2Q 2020

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