Approvals & Updates

December 2022

PharMerica®

New Drug Approvals

Tzield (teplizumab-mzwv)

Indication: To delay the onset of type 1 diabetes

Mechanism of Action: CD3-directed antibody

Dosage Form(s): Intravenous injection

Comments: Tzield is FDA-approved for delaying the onset of stage 3 type 1 diabetes (T1D) in patients ≥ 8 years and older who currently have stage 2 T1D. Prior to the administration of Tzield, stage 2 T1D must be confirmed by documenting ≥2 positive pancreatic islet autoantibodies in those who have dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) or alternative method. Additionally, a complete blood count and liver enzyme test must be obtained and the use of Tzield is not recommended in patients with certain laboratory abnormalities. Before each dose of Tzield and for at least the first 5 days of the 14-day treatment course the patient should be premedicated with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, antihistamine, and/or an antiemetic. Tzield must be diluted using a 0.9% sodium chloride solution. Tzield is administered as an intravenous infusion over 30 minutes once daily for 14 days. The dosing regimen of Tzield is as follows: Day 1: 65 mcg/m^2, Day 2: 125 mcg/m^2, Day 3: 250 mcg/m^2, Day 4: 500 mcg/m^2, Days 5 to 14: 1,030 mcg/m^2. Tzield carries labeled warnings and precautions for cytokine release syndrome (CRS), serious infections, lymphopenia, hypersensitivity reactions, vaccinations. The most common adverse reactions (≥10%) reported with Tzield are lymphopenia, rash, leukopenia, and headache.

Creighton University Center for Drug Information & Evidence-Based Practice

Drug Information Consultation Service

Monday through Friday

7:30am-3:30pm Central

1-800-561-3728

Voicemail service is available after-hours

Submit your drug information questions

HERE

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Dulaglutide (Trulicity) injection
- Oxybutynin chloride syrup
- Tirzepatide injection

For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

New Drug Approvals (continued)

Elahere (mirvetuximab soravtansine-gynx)

Indication: To treat platinum-resistant ovarian cancer

Mechanism of Action: Folate receptor alpha (FR)-directed antibody and microtubule inhibitor conjugate

Dosage Form(s): Intravenous injection

Comments: Elahere is FDA-approved for treating platinum-resistant, FR -positive, epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who have received one to three prior systemic treatment regimens. Patients are selected for therapy based on FDA-approved tests that measure FR tumor expression. Patients should be premedicated with a corticosteroid, antihistamine, antipyretic, and antiemetic prior to each infusion of Elahere to reduce the incidence and severity of infusion related reactions (IRRs), nausea, and vomiting. Elahere is diluted in 5% dextrose and then administered as an intravenous infusion. Normal saline should never be used as a diluent due to incompatibility with Elahere. Elahere 6mg/kg is dosed according to adjusted ideal body weight and administered as an intravenous infusion every 3 weeks until disease progression or unacceptable toxicity occurs. Elahere carries a boxed warning for severe ocular toxicities (i.e., visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis). An ophthalmic exam that includes a visual acuity and slit lamp exam should be conducted prior to initiation and during every other cycle for the first 8 cycles as clinically indicated. The administration of ophthalmic topical steroids and prophylactic artificial tears is also recommended. Elahere must be discontinued if GRADE 4 ocular toxicity occurs. Elahere carries labeled warnings and precautions for pneumonitis, peripheral neuropathy, and embryo-fetal toxicity. Monitor for adverse reactions with the co-administration of strong CYP3A4 inhibitors. Avoid the use of Elahere with moderate or severe hepatic impairment. The most common adverse reactions (≥20%) reported with Elahere are vision impairment, fatigue, nausea, keratopathy, abdominal pain, peripheral neuropathy, diarrhea, constipation, dry eye, increase in the following: aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, decrease in the following: albumin, magnesium, leukocytes, neutrophils, and hemoglobin.

FDA Safety Alerts

FDA investigating risk of severe hypocalcemia in dialysis patients on the osteoporosis drug Prolia (denosumab)

The FDA recently published a drug safety communication that they are evaluating the risk of severe hypocalcemia, hospitalization, and death in patients with advanced kidney disease and on dialysis who are taking Prolia (denosumab). Prolia is FDA-approved for treating adults with osteoporosis and at high risk for bone fractures. The FDA's recommendation to healthcare professionals are to: 1) consider the increased risk of hypocalcemia in dialysis patients, 2) frequently monitor calcium levels and provide adequate calcium and vitamin D supplementation, 3) advise patients to seek help immediately if symptoms of hypocalcemia occurs. The investigation into this potential safety use with Prolia is currently ongoing and the FDA will provide update communication when there is more information to share.