Clinical Pharmacy News Letter

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OFATUMUMAB

January 19, 2016, the U.S. Food and Drug Administration approved ofatumumab (Arzerra Injection) for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL). Ofatumumab is a monoclonal antibody which binds specifically the extracellular (large and small) loops of the CD20 molecule (which is expressed on normal B lymphocytes and in B-cell CLL) resulting in potent complement-dependent cell lysis and antibody-dependent cell-mediated toxicity in cells that overexpress CD20.

Do not administer IV push, IV bolus, or as a subcutaneous injection. Premedicate with acetaminophen, an antihistamine, and a corticosteroid 30 to 120 minutes prior to administration.

Some medical conditions may interact with ofatumumab. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you have a history of hepatitis B infection or you are at risk for hepatitis B infection
- if you have chronic obstructive pulmonary disease (COPD), blockage of the stomach or bowel, nervous system problems, or white blood cell problems
- if you have flu-like symptoms or other signs of infection (eg, fever; chills; cough; warm, red, or painful skin), have recently received a vaccine, or are scheduled to receive a vaccine. All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:
  - Diarrhea; headache; muscle spasms; nausea; tiredness or weakness; trouble sleeping.

ERIBULIN: January 28, 2016, the U. S. Food and Drug Administration approved eribulin (HALAVEN injection) for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen. Halaven is indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease**.**

Eribulin inhibits the growth phase of microtubules without affecting the shortening phase and sequesters tubulin into nonproductive aggregates. In addition, eribulin treatment of human breast cancer cells caused changes in morphology and gene expression as well as decreased migration and invasiveness in vitro. The most common serious adverse reactions were neutropenia (4.9%) and pyrexia (4.5%). Febrile neutropenia occurred in 0.9% and fatal neutropenic sepsis in 0.9% of patients treated with eribulin. The most frequent adverse reactions leading to discontinuation were fatigue (0.9%) and thrombocytopenia (0.9%).

To make sure Halaven is safe for you, tell your doctor if you have:

- liver disease;
- kidney disease;
- heart disease;
- peripheral vascular disease such as Raynaud's syndrome;
- personal or family history of long QT syndrome; or
- an electrolyte imbalance (such as low levels of potassium or magnesium in your blood).

Do not use Halaven if you are pregnant. It could harm the unborn baby. Use effective birth control, and tell your doctor if you become pregnant during treatment. It is not known whether eribulin passes into breast milk or if it could harm a nursing baby. You should not breast-feed while you are using Halaven.

BRIVIACT (BRIVARACETAM)

Briviact (brivaracetam) displays a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to the anticonvulsant effect. However, the precise mechanism by which Briviact exerts its anticonvulsant activity is not known. Briviact is specifically indicated as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.

SIDE EFFECTS

- somnolence/sedation
- dizziness
- fatigue
- nausea/vomiting

MECHANISM OF ACTION: Briviact (brivaracetam) displays a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to the anticonvulsant effect. However, the precise mechanism by which Briviact exerts its anticonvulsant activity is not known.

ONZETRA XSAIL (SUMATRIPTAN NASAL POWDER)

Onzetra Xsail is a nasal powder formulation of sumatriptan, a serotonin 5-HT1B/1D receptor agonist. Onzetra Xsail is specifically indicated for the acute treatment of migraine with or without aura in adults. Onzetra Xsail is supplied as a powder for intranasal administration, delivered with the Xsail breath-powered delivery device only. The recommended dose is 22 mg, administered by use of one nosepiece (11 mg) in each nostril. The maximum dose in a 24-hour period should not exceed two doses (44 mg) separated by at least 2 hours.

SIDE EFFECTS: Adverse effects associated with the use of Onzetra Xsail may include, but are not limited to, the following:

- abnormal taste
- nasal discomfort
- rhinorrhea
- rhinitis

MECHANISM OF ACTION: Onzetra Xsail is a nasal powder formulation of sumatriptan, a serotonin 5-HT1B/1D receptor agonist. Sumatriptan binds with high affinity to human cloned 5-HT1B/1D receptors. Sumatriptan presumably exerts its therapeutic effects in the treatment of migraine headache through agonist effects at the 5-HT1B/1D receptors on intracranial blood vessels and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of proinflammatory neuropeptide release.

BELL'S PALSY

What is bell's palsy: Bell's palsy is a paralysis or weakness of the muscles on one side of your face. Damage to the facial nerve that controls muscles on one side of the face causes that side of your face to droop. The nerve damagemay also affect your sense of taste and how you make tears and saliva. This condition comes on suddenly, often overnight, and usually gets better on its own within a few weeks. Bell's palsy is not the result of a stroke or a transient ischemic attack (TIA). While stroke and TIA can cause facial paralysis, there is no link between Bell's palsy and either of these conditions. But sudden weakness that occurs on one side of your face should be checked by a doctor right away to rule out these more serious causes. The cause of Bell's palsy is not clear. Most cases are thought to be caused by the herpes virus that causes cold sores. In most cases of Bell's palsy, the nerve that controls muscles on one side of the face is damaged by inflammation. Many health problems can cause weakness or paralysis of the face. If a specific reason cannot be found for the weakness, the condition is called Bell's palsy.

Symptoms of Bell's palsy include:

- Sudden weakness or paralysis on one side of your face that causes it to droop. This is the main symptom. It may make it hard for you to close your eye on that side of your face.
- Drooling.
- Eye problems, such as excessive tearing or a dry eye.
- Loss of ability to taste.
- Pain in or behind your ear.
- Numbness in the affected side of your face.
- Increased sensitivity to sound.

How is bell's palsy diagnosed: Your doctor may diagnose Bell's palsy by asking you questions, such as about how your symptoms developed. He or she will also give you a physical and neurological exam to check facial nerve function. If the cause of your symptoms is not clear, you may need other tests, such as blood tests, an MRI, or a CT scan.

How is it treated: Treatment with corticosteroid medicines (such as prednisone) can make it more likely that you will regain all facial movement. They work best if they are taken soon after symptoms start (within 3 days). Sometimes antiviral medicines (such as acyclovir) may be added to corticosteroid medicines to treat Bell's palsy. But evidence for using antiviral medicines is weak. They may help in some cases, but in general they do not affect recovery.

How can you care for yourself at home?

Facial exercises. As the nerve in your face begins to work again, doing simple exercises-such as tightening and relaxing your facial muscles-may make those muscles stronger and help you recover more quickly. Massaging your forehead, cheeks, and lips with oil or cream may also help.

Eye care. If you can't blink or close your eye fully, your eye may become dry. A dry eye can lead to sores and serious vision problems. To help protect the eye and keep it moist:

- Use your finger to close and open your eyelid often throughout the day.

- Use eyedrops ("artificial tears") or ointment. Those that containmethylcellulose are a good choice and don't require a prescription. You may want to use drops during the day and ointment at night while you sleep. Ask your doctor how often to use the drops.
- Wear an eye patch while you sleep, and wear glasses or goggles the rest of the time.

Mouth care. If you have no feeling and little saliva on one side of your tongue, food may get stuck there, leading to gum disease or tooth decay. Brush and floss your teeth often and well to help prevent these problems. To prevent swallowing problems, eat slowly and chew your food well. Eating soft, smooth foods, such as yogurt, may also help.

IDELVION (coagulation factor IX (recombinant), albumin fusion protein)

Idelvion is a long-acting albumin fusion protein linking recombinant coagulation factor IX with recombinant albumin. Idelvion was specifically approved for use in children and adults with hemophilia B for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; on-demand control and prevention of bleeding episodes; and the perioperative management of bleeding. Idelvion is supplied as a powder for solution for intravenous use after reconstitution only.

Control and prevention of bleeding episodes and perioperative management: •Dosage and duration of treatment with Idelvion depends on the severity of the Factor IX deficiency, the location and extent of bleeding, and the patient's clinical condition, age and recovery of Factor IX. •Determine the initial dose using the following formula: •Required

Side effects: The most common adverse event associated with the use of Indelvion was headache.

Mechanism of action: Idelvion is a recombinant protein that temporarily replaces the missing coagulation Factor IX needed for effective hemostasis. Idelvion is comprised of genetically fused recombinant coagulation Factor IX and recombinant albumin. Fusion with recombinant albumin extends the half-life of Factor IX

ZEPATIER (ELBASVIR AND GRAZOPREVIR)

Zepatier is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor. Zepatier is specifically indicated with or without ribavirin for the treatment of chronic HCV genotypes 1 or 4 infection in adults. Zepatier is supplied as a tablet for oral administration. Recommended dosage: One tablet taken orally once daily with or without food. Please see drug label for dosage regimens and durations for patients with Genotype 1 or 4 HCV with or without cirrhosis.

SIDE EFFECTS: Adverse effects associated with the use of Zepatier may include, but are not limited to, the following:

- Fatigue
- Headache
- Nausea
- Anemia

MECHANISM OF ACTION: Zepatier is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor.

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