Approvals & Updates

April 2022

New Drug Approvals

Opdualag (nivolumab and relatlimab-rmbw)

Indication: Melanoma

Mechanism of Action: Programmed death receptor-1 (PD-1) blocking antibody and lymphocyte activation gene-3 (LAG-3) blocking antibody

Dosage Form(s): Intravenous (IV) injection

Comments: Opdualag is FDA-approved for treating unresectable or metastatic melanoma in adults and children (≥12 years old weighing ≥40kg). Opdualag should be given IV over 30 minutes as 480mg nivolumab and 160mg relatlimab every 4 weeks until disease progression or intolerable toxicity occurs. Opdualag carries labeled warnings for immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation, and embryo-fetal toxicity. Immune-mediated adverse reactions and infusion-related reactions should both be monitored. Additionally, liver enzymes, creatinine, thyroid function, and blood glucose should be monitored at baseline and throughout therapy. No drug interactions with Opdualag were discussed. The most common adverse reactions (≥20%) reported with Opdualag were musculoskeletal pain, fatigue, rash, pruritus, and diarrhea.

Pluvicto (lutetium Lu 177 vipivotide tetraxetan)

Indication: Prostate cancer

Mechanism of Action: Radiopharmaceutical

Dosage Form(s): IV injection

Comments: Pluvicto is FDA-approved for treating prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) in adults who have used androgen receptor pathway inhibition and taxane-based chemotherapy. Patients eligible for Pluvicto should be selected based on using Locametz or another approved PSMA-11 imaging agent based on PSMA expression in tumors. Pluvicto should be given IV as 7.4GBq (200mCi) every 6 weeks for a maximum of 6 doses or until disease progression or intolerable toxicity occurs. Pluvicto carries labeled warnings for risk from radiation exposure, myelosuppression, renal toxicity, embryo-fetal toxicity, and infertility. Patients with mild to moderate renal dysfunction should have renal function frequently monitored. No drug interactions with Pluvicto were discussed. The most common adverse reactions (≥20%) reported with Pluvicto were fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation.

New Drug Approvals, Continued

Ztalmy (ganaxolone)

Indication: Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

Mechanism of Action: Gamma-aminobutyric acid (GABA) A receptor positive modulator

Dosage Form(s): Oral suspension

Comments: Ztalmy is FDA-approved for treating patients ≥2 years old with seizures associated with CDKL5 deficiency disorder. Ztalmy should be given three times daily with food. Dosing and titration schedule depend on body weight, and titration should also be based on tolerability and increased no more frequently than every 7 days. Weight-based dosing and titration is outlined below.

- Patients ≤28kg
  - 6mg/kg three times daily for Days 1-7
  - 11mg/kg three times daily for Days 8-14
  - 16mg/kg three times daily for Days 15-21
  - 21mg/kg three times daily for Days 22-ongoing
- Patients >28kg
  - 150mg three times daily (3mL/dose) for Days 1-7
  - 300mg three times daily (6mL/dose) for Days 8-14
  - 450mg three times daily (9mL/dose) for Days 15-21
  - 600mg three times daily (12mL/dose) for Days 22-ongoing

Ztalmy carries labeled warnings for somnolence and sedation, suicidal behavior and ideation, and withdrawal of antiepileptic drugs. Somnolence and sedation and suicidal behavior/thoughts should be monitored. Co-administration of Ztalmy with strong or moderate CYP3A4 inducers should be avoided; however, if not possible, an increased dose of Ztalmy may be considered (but should not exceed maximum recommended doses). The Ztalmy dose may also need to be increased in patients beginning or increasing doses of enzyme-inducing antiepileptic drugs (i.e., carbamazepine, phenytoin, phenobarbital). Finally, co-administration of Ztalmy with CNS depressants may increase the risk for somnolence and sedation. The most common adverse reactions (≥5% and ≥2x placebo) reported with Ztalmy were somnolence, pyrexia, salivary hypersecretion, and seasonal allergy.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Acetazolamide injection
- Metronidazole injection
- Sodium chloride 14.6% injection

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

Safety Updates

FDA recommends thyroid monitoring in babies and young children who receive injections of iodine-containing contrast media for medical imaging

The FDA recently published a safety communication recommending newborns and children (up to 3 years old) have their thyroid monitored within 3 weeks of receiving contrast media injections containing iodine ("contrast dye") for medical imaging procedures. While rare, underactive thyroid or a temporary reduction in thyroid levels has been observed, so they should be identified and treated early to prevent the risk for future complications. Newborns and children up to 3 years old with heart conditions may have an increased risk for thyroid problems. The FDA has approved a new warning that is to be added to the prescribing information for the iodinated contrast media injection class, recommending monitoring and describing the risk for thyroid problems. Providers are advised to appropriately monitor newborns and children up to 3 years old for the possibility of thyroid problems after exposure to iodinated contrast media.

Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Adlarity (donepezil)	Alzheimer's disease	Acetylcholinesterase inhibitor	Transdermal system	New dosage form
Hyftor (sirolimus)	Facial angiofibroma associated with tuberous sclerosis	Mammalian target of rapamycin (mTOR) inhibitor	Topical gel	New dosage form
Nasonex 24HR Allergy (mometasone furoate monohydrate)	Allergic rhinitis	Corticosteroid	Nasal spray	Over-the-counter (OTC) formulation
Xelstrym (dextroamphetamine)	Attention deficit hyperactivity disorder (ADHD)	Central nervous system (CNS) stimulant	Transdermal system	New dosage form

Creighton University Center for Drug Information & Evidence-Based Practice

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