Approvals & Updates

August 2023

New Drug Approvals

Beyfortus (nirsevimab-alip)

Indication: Prevention of respiratory syncytial virus (RSV) lower respiratory tract disease

Mechanism of action: RSV F protein-directed fusion inhibitor

Dosage form(s): Intramuscular injection

Comments: Beyfortus is FDA-approved for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season and in children up to 24 months of age who are vulnerable to severe RSV disease through their second RSV season. Neonates and infants born during or entering their first RSV season should receive 50 mg if body weight is less than 5 kg and those equal to or greater than 5 kg should receive 100 mg. Children who are vulnerable through their second RSV season should receive 200 mg. Additional administration instructions include administration by a healthcare provider, do not mix other vaccines or medications in the same vial, and inspect for particulate matter and discoloration visually. Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis to the active ingredient or the excipients. Warnings and precautions associated with Beyfortus include hypersensitivity reactions. The most common adverse effects were rash (0.9%) and injection site reactions (0.3%).

Vanflyta (quizartinib)

Indication: FLT3 internal tandem duplication (ITD)-positive acute myeloid leukemia (AML)

Mechanism of action: Kinase inhibitor

Dosage form(s): Oral tablet

Comments: Vanflyta is a kinase inhibitor FDA-approved for FLT3 ITD-positive AML in newly diagnosed adults in combination with standard cytarabine and anthracycline induction, cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy. Dosing of Vanflyta is 35.4 mg by mouth once daily in both the induction phase (i.e., 2 cycles in combination with cytarabine and anthracycline) on days 8 to 21 or in consolidation (i.e., 4 cycles in combination with high-dose cytarabine) on days 6 to 19. Maintenance dosing should be initiated following consolidation chemotherapy at 26.5 mg by mouth once daily on days 1 through 14 of the first cycle if QTcF is $\leq$ 450 ms. Dosing is increased to 53 mg once daily on Day 15 of cycle 1 if QTcF is $\leq$ 450 ms for up to 36 cycles; each cycle consists of 28 days. Recovery of absolute neutrophil count $>$ 500/mm^3 and platelet count $>$ 50,000/mm^3 should be established prior to maintenance dosing. Vanflyta has a black box warning for QT prolongation, torsades de pointes, and cardiac arrest. Electrocardiograms are recommended prior to administration and periodically during treatment. Additional administration requirements include taking each dose at the same time each day. Vanflyta is contraindicated in patients with severe hypokalemia, hypomagnesemia, long QT syndrome, or patients with a history of ventricular arrhythmias or torsades de pointes. Vanflyta carries warnings and precautions for QT prolongation, torsades de pointes, cardiac arrest and embryo-fetal toxicity. The most common ($>$ 20%) adverse reactions include laboratory abnormalities, decreased lymphocytes, potassium, albumin, phosphorous, magnesium and calcium, increased alkaline phosphatase and creatine phosphokinase, febrile neutropenia, diarrhea, mucositis, nausea, abdominal pain, sepsis, neutropenia, headache, vomiting, and upper respiratory tract infection. Drug interactions are associated with strong CYP3A inhibitors and strong or moderate CYP3A inducers.

Xdemvy (lotilaner ophthalmic solution)

Indication: Demodex blepharitis

Mechanism of action: Ectoparasiticide

Dosage form(s): Ophthalmic solution

Comments: Xdemvy is an FDA-approved ophthalmic solution containing lotilaner 0.25% to treat demodex blepharitis. Current recommended dose is one drop in each eye twice daily for six weeks. Other administration recommendations include separating multiple ophthalmic medications by at least 5 minutes, removal of contact lenses prior to drops and allowing 15 minutes prior to reinsertion, and to avoid touching the tip of the dispenser to the eye or other structures. There are no contraindications reported with Xdemvy. Warnings and precautions include risk of contamination and use with contact lenses. The most common adverse reaction (10%) was stinging and burning.

Ycanth (cantharidin)

Indication: Molluscum contagiosum

Dosage form(s): Topical solution

Comments: Ycanth is FDA-approved for the treatment of molluscum contagiosum in adults and pediatric patients 2 years of age and over. A single application directly to each lesion every 3 weeks as needed is the recommended dosing. Administration recommendations state to remove with soap and water 24 hours after treatment and to avoid covering lesions with bandages. Additional requirements include training for healthcare providers, using nitrile or vinyl gloves and eye protection prior to preparation and administration, avoiding fire, flame or smoking near lesions during treatment, and using no more than 2 applicators during a single treatment session. Warnings and precautions associated with Ycanth include toxicities associated with inappropriate administration (i.e., life threatening or fatal toxicity if consumed orally and ocular toxicity), local skin reactions (i.e., vesiculation, pain, discoloration, and erythema), and flammability. The most common (≥ 1%) adverse effects are local skin reactions.