Approvals & Updates

April 2023

New Drug Approvals

Daybue (trofinetide)

Indication: Rett syndrome

Mechanism of Action: Unknown

Dosage Form(s): Oral solution

Comments: Daybue is FDA-approved for treating patients ≥2 years old with Rett syndrome. Daybue is administered twice daily and dosed according to the patient's weight (See package insert for more details). Daybue can also be given with or without food and either orally or via gastrostomy tube (G-tube), or gastrojejunal tube (GJ-tube). Daybue has labeled warnings and precautions for diarrhea and weight loss. Health care providers should advise patients to stop taking laxatives before starting Daybue and to start antidiarrheal treatment and increase fluid intake should diarrhea occur. Monitor for adverse reactions in patients who are taking concurrent orally CYP3A4 sensitive substrates and avoid the concomitant use with OAT1B1 and OATP1B3 substrates as this may lead to serious toxicities. The most common adverse reactions (≥10%) reported with Daybue are diarrhea and vomiting.

Joenja (leniolisib)

Indication: Activated phosphoinositide 3-kinase delta syndrome

Mechanism of Action: Kinase inhibitor

Dosage Form(s): Oral tablets

Comments: Joenja is FDA-approved for treating patients ≥12 years old with activated phosphoinositide 3-kinase delta syndrome (APDS). Joenja has labeled warnings and precautions for embryo-fetal toxicity and decreased efficacy for live, attenuated vaccinations. Prior to initiating treatment, pregnancy status of females of reproductive potential should be verified. Joenja 70mg is administered orally twice daily and approximately 12 hours apart, without consideration of food. Joenja is associated with several drug-drug-interactions. Avoid the concomitant use of Joenja with strong CYP3A4 inhibitors, strong/moderate CYP3A4 inducers, CYP1A2 metabolized drugs with a narrow therapeutic index, BCRP, OATP1B1m and OATP1B3 substrates. The most common adverse reactions (≥10%) reported with Joenja are headache, sinusitis, and atopic dermatitis.

Creighton University Center for Drug Information & Evidence-Based Practice

Drug Information Consultation Service

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Rezzayo (rezafungin)

Indication: Candidemia and invasive candidiasis

Mechanism of Action: Echinocandin antifungal

Dosage Form(s): Intravenous injection

Comments: Rezzayo is FDA-approved for treating adults with limited or no alternative options for the treatment of candidemia and invasive candidiasis; however, the approval of this indication is based on limited clinical data. Rezzayo has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to a Candida infection. Rezzayo 400mg is first administered as loading dose, which is thenfollowed by 200mg once weekly intravenous infusion thereafter. Rezzayo is contraindicated in patients with known hypersensitivity to any of its components or other echinocandins. Rezzayo has labeled warnings and precautions for infusion-related reactions, photosensitivity, and hepatic adverse reactions. The most common adverse reactions (≥5%) reported with Rezzayo are hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia.

Zavzpret (zavegepant)

Indication: Acute treatment of migraine with or without aura in adults

Mechanism of Action: Calcitonin gene-related peptide receptor antagonist

Dosage Form(s): Nasal spray

Comments: Zavzpret is FDA-approved for treating adults with migraines. Zavzpret 10mg (one spray) is recommended to be administered in one nostril as needed. The maximum dose of Zavzpret is 10mg or the equivalent of one spray daily. The safety of using Zavzpret has not been established beyond the treatment of ≥8 migraines in a 30-day-period. Zavzpret is contraindicated in patients with hypersensitivity to its components. Zavzpret has labeled warnings and precautions for hypersensitivity reactions including facial swelling and urticaria. There are several drug-drug interactions associated with Zavzpret. It is recommended to avoid the concomitant use of Zavzpret with inhibitors and inducers of OATP1B3 or NTCP transporters. Additionally, avoid the concomitant use of intranasal decongestants; if use is unavoidable however, intranasal decongestants must be administered more than one hour after the administration of Zavzpret. Avoid the use of Zavzpret in special populations such as patients with severe hepatic impairment and CLCr < 30mL/min. The most common adverse reactions (≥2%) reported with Zavzpret are taste disorders, nausea, nasal discomfort, and vomiting.

Zynyz (retifanlimab-dlwr)

Indication: Metastatic or recurrent local advanced Merkel cell carcinoma

Mechanism of Action: Programmed death receptor-1 (PD-1)-blocking antibody

Dosage Form(s): Intravenous injection

Comments: Zynyz is FDA-approved for treating adults with metastatic or recurrent locally advanced Merkel cell carcinoma. Zynyz 500mg is administered every 4 weeks as a 30-minute intravenous infusion. Zynyz has labeled warnings and precautions for immune-mediated adverse reactions that may be severe or fatal and can occur in anywhere in the body, infusion-related reactions, complications of allogeneic HSCT, and embryo-fetal toxicity. Monitoring for immune-mediated adverse reactions by evaluating liver enzymes, creatinine, and thyroid function at baseline and during treatment is recommended. Also, depending on the severity of the reaction, corticosteroids may need to be administered and Zynyz may need to be withheld or permanently discontinued. The most common adverse reactions (≥10%) reported with Zynyz are fatigue, musculoskeletal pain, pruritus, diarrhea, rash, pyrexia, and nausea.

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

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Combogesic (acetaminophen/ ibuprofen)	Short term management of mild-to-moderate acute pain	Analgesic and nonsteroidal anti-inflammatory drug (NSAID)	Oral tablet	New combination