Approvals & Updates

February 2023

New Drug Approvals

Brenzavvy (bexagliflozin)

Indication: Type 2 diabetes mellitus

Mechanism of Action: Sodium-glucose co-transporter 2 (SGLT2) inhibitor

Dosage Form(s): Oral tablets

Comments: Brenzavvy is FDA-approved as an adjunct to diet and exercise for improving glycemic control in adults with type 2 diabetes mellitus. Brenzavvy is 20mg is taken once daily in the morning without regard to food. The tablet should not be crushed or chewed. Renal function should be addressed prior to the initiation of Brenzavvy and as clinically indicated, and any signs of volume depletion should be corrected. Brenzavvy is not recommended in patients with an eGFR ≤30mL/min/1.73m^2. Brenzavvy has a boxed warning for hypersensitivity to any component of the medication and for patients on dialysis. Brenzavvy has labeled warnings and precautions for ketoacidosis, lower limb amputation, volume depletion, urosepsis and pyelonephritis, hypoglycemia, Necrotizing Fasciitis of the Perineum (Fournier's Gangrene), and genital mycotic infection. There is a higher incidence of adverse reactions associated with volume depletion in geriatric patients. A higher incidence of adverse reactions associated with reduced renal function have been reported in those with renal impairment. Brenzavvy is not recommended for patients with severe hepatic impairment. The most common adverse reactions (>5%) reported with Brenzavvy are female genital mycotic infections, urinary tract infection, and increased urination.

Jayprica (pirtobrutinib)

Indication: Relapsed or refractory mantle cell lymphoma (MCL)

Mechanism of Action: Non-covalent (reversible) Bruton's tyrosine kinase (BTK) inhibitor

Dosage Form(s): Oral tablets

Comments: Jayprica is FDA-approved for treating adults with relapsed or refractory MCL after treatment with ≥2 lines of systemic therapy, including a BTK inhibitor. The recommended dosage is Jayprica 200mg swallowed whole, orally once daily, without regard to food. Do not cut, crush, or chew Jayprica tablets. Any toxicity that occurs should be managed by using treatment interruption, dosage reduction, or discontinuation. The dosage should be reduced in patients with severe renal impairment. Jayprica has labeled warnings are precautions for infections, hemorrhage, cytopenias, atrial fibrillation and atrial flutter, second primary malignancies, and embryo-fetal toxicity. Jayprica comes with several drug-drug interactions. Avoid the concomitant use of Jayprica with strong CYP3A4 inhibitors; reduce the dose of Jayprica if concomitant use is unavoidable. Avoid the concomitant use of Jayprica with strong/moderate CYP3A4 inducers; increase the dose if Jayprica if concomitant use if unavoidable. Follow recommendations in approved product labeling for co-administration with CYP2C8, CYP2c19, CYP3A, P-gp, or BCRP inhibitors, as small changes in concentration may increase the risk of adverse effects. The most common laboratory abnormalities (≥10%) reported with Jayprica are decreased neutrophil count, lymphocyte count, and platelet count. The most common adverse reactions (15%) reported with Jayprica are fatigue, musculoskeletal pain, diarrhea, edema, dyspnea, pneumonia, and bruising.

Leqembi (lecanemab-irmb)

Indication: Alzheimer's disease

Mechanism of Action: Amyloid beta-directed antibody

Dosage Form(s): Intravenous injection

Comments: Leqembi is FDA-approved for the treatment of Alzheimer's disease. Leqembi should only be initiated in patients with mild cognitive impairment or mild dementia associated with Alzheimer's disease as this was the population studied in clinical trials. The safety and effectiveness have yet to be established for the early and late stages of the disease. Several diagnostic tests must be obtained prior to initiating Leqembi. The presence of amyloid beta pathology, a recent (within one year) brain MRI to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA), and MRIs prior to the 5th, 7th, and 14th infusions should all be obtained. If radiographically observed ARIA does occur, be prepared to initiate treatment based the type, severity, and presence of symptoms. The recommended dosage of Leqembi is 10mg/kg diluted in 250 mL of 0.9% sodium chloride. Leqembi is administered as an intravenous infusion over approximately one hour, once every two weeks via a terminal low-protein binding 0.2 micron in-line filter. Leqembi has labeled warnings and precautions for ARIA and infusion-related reactions. The most common adverse reactions (≥10%) reported with Leqembi are infusion-related reactions, headache, and ARIA-edema.

Orserdu (elecestrant)

Indication: Estrogen receptor-positive, human epidermal growth factor receptor 2-negative, *ESR1*-mutated, advanced or metastatic breast cancer

Mechanism of Action: Estrogen receptor antagonist

Dosage Form(s): Oral tablets

Comments: Orserdu is FDA-approved for treating postmenopausal women or adult men with ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following ≥1 line of endocrine therapy. Patients are selected for Orserdu treatment based on the presence of *ESR1* mutations. Orserdu 345mg tablet is administered once daily with food. However, due to adverse reactions dose interruption, reduction, or permanent discontinue may occur. Orserdu has labeled warnings and precautions for dyslipidemia and embryo-fetal toxicity. Avoid concomitant use of strong and moderate CYP3A4 inhibitors and inducers with Orserdu. Avoid the use of Orserdu with severe hepatic impairment (Child-Pugh C) and reduce the dosage in patients with moderate hepatic impairment (Child-Pugh B). The most common adverse reactions (≥10%) reported with Orserdu are musculoskeletal pain, nausea, fatigue, vomiting, diarrhea, headache, constipation, abdominal pain, hot flush, dyspepsia, increased cholesterol, AST, ALT, triglycerides, creatinine, and decreased hemoglobin, sodium, appetite.

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

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Airsupra (albuterol sulfate/ budesonide)	Asthma	Beta2-adrenergic agonist and corticosteroid	Oral inhalation	New combination
Rykindo (risperidone extended-release injectable suspension)	Schizophrenia and bipolar I disorder	Atypical antipsychotic	Intramuscular injection	New dosage form