Approvals & Updates

November 2021

New Drug Approvals

Scemblix (asciminib)

Indication: Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML)

Mechanism of Action: Kinase inhibitor

Dosage Form(s): Tablets

Comments: Scemblix is FDA-approved for treating adults with Ph+ CML in chronic phase (CP), previously treated with ≥2 tyrosine kinase inhibitors or with the T315I mutation. Dosing depends on the specific indication and is outlined below.

- Ph+ CML in CP: 80mg by mouth once daily or 40mg twice daily
- Ph+ CML in CP with the T315I mutation: 200mg by mouth twice daily

Consumption of food should be avoided for ≥2 hours before and ≥1 hour after Scemblix. Scemblix carries labeled warnings for myelosuppression, pancreatic toxicity, hypertension, hypersensitivity, cardiovascular toxicity, and embryo-fetal toxicity. Complete blood counts (CBC), serum lipase and amylase, blood pressure, signs of hypersensitivity and/or myelosuppression, and cardiovascular signs and symptoms in patients with a history of cardiovascular risk factors should be monitored throughout therapy. Scemblix has the potential to interact with strong CYP3A4 inhibitors, itraconazole oral solution containing hydroxy-propyl- -cyclodextrin, certain CYP3A4 substrates, CYP2C9 substrates, and certain P-glycoprotein substrates. As such, certain actions, such as close monitoring of side effects, avoidance of co-administration, and/or dose reductions, may be required. The most common adverse reactions (≥20%) and laboratory abnormalities (≥20%) reported with Scemblix were upper respiratory tract infections, musculoskeletal pain, fatigue, nausea, rash, and diarrhea and decreased platelet count, increased triglycerides, decreased neutrophil count, decreased hemoglobin, increased creatine kinase, increased alanine aminotransferase, increased lipase, and increased amylase.

Tavneos (avacopan)

Indication: Anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis

Mechanism of Action: Complement 5a receptor (C5aR) antagonist

Dosage Form(s): Capsules

Comments: Tavneos is FDA-approved as adjunctive treatment in combination with standard therapy (i.e., glucocorticoids) for severe active ANCA-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in adults. Tavneos should be taken as 30mg by mouth twice daily with food; however, prior to initiation, liver function tests and hepatitis B (HBV) serology should be evaluated. Tavneos carries labeled warnings for hepatotoxicity, serious hypersensitivity reactions, HBV reactivation, and serious infections. Liver function tests, HBV serology, and signs of hepatic adverse effects and infection should all be monitored while on Tavneos. Tavneos has the potential to interact with CYP3A4 inducers, inhibitors, and substrates, so coadministration should be avoided, Tavneos doses may need to be reduced, and/or side effects should be closely monitored. The most common adverse reactions (≥5%) reported with Tavneos were nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, increased blood creatinine, and paresthesia.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Fentanyl citrate (Sublimaze) injection
- Furosemide injection
- Potassium chloride concentrate injection

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

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

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Seglentis (celecoxib and tramadol hydrochloride)	Acute pain	NSAID and opioid agonist	Tablets	New combination
Tyrvaya (Varenicline)	Dry eye disease	Cholinergic agonist	Nasal spray	New dosage form
Xipere (triamcinolone acetonide)	Macular edema associated with uveitis	Corticosteroid	Supra-choroidal injection	New dosage form

Creighton University Center for Drug Information & Evidence-Based Practice
Drug Information Consultation Service

Monday through Friday
7:30am-3:30pm Central
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