Approvals & Updates

January 2021

New Drug Approvals

Gemtesa (vibegron)

Indication: Overactive bladder syndrome

Mechanism of Action: Beta-3 adrenergic agonist

Dosage Form(s): Oral tablets

Comments: Gemtesa is FDA-approved for treating adults with overactive bladder consisting of urge urinary incontinence, urgency, and urinary frequency symptoms. Gemtesa should be administered as one 75 mg tablet by mouth daily with or without food. Because Gemtesa carries a labeled warning for urinary retention, it should be monitored for, especially in individuals with bladder outlet obstruction or those taking muscarinic antagonists for overactive bladder. In patients taking digoxin, prior to starting and during Gemtesa therapy, serum digoxin concentrations should be measured, monitored, and used to adjust digoxin doses to the desired clinical effect. The most common adverse reactions (≥2%) reported with Gemtesa were headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

Klisyri (tirbanibulin)

Indication: Actinic keratosis

Mechanism of Action: Microtubule inhibitor

Dosage Form(s): Ointment

Comments: Klisyri is FDA-approved for treating actinic keratosis of the face or scalp. Klisyri should be administered topically to the face or scalp once daily for 5 days. Patients should wash their hands immediately following administration, and the treated area should not be touched or washed for about 8 hours after applying. Klisyri carries labeled warnings for eye irritation upon ocular exposure and local skin reactions. No laboratory monitoring is required, and no studies evaluating Klisyri's drug interaction potential have been performed. The most common adverse reactions (≥2%) reported with Klisyri were local skin reactions, application site pruritus, and application site pain.

New Drug Approvals, Continued

Margenza (margetuximab-cmkb)

Indication: HER2-positive breast cancer

Mechanism of Action: HER2/neu receptor antagonist

Dosage Form(s): Intravenous injection

Comments: Margenza is FDA-approved, in combination with chemotherapy, for treating metastatic HER2-positive breast cancer in adults who have received ≥2 prior anti-HER2 regimens, at least one having been for metastatic disease. Margenza should be infused intravenously at 15mg/kg over 120 minutes initially, followed by over at least 30 minutes every 3 weeks for all subsequent doses. When Margenza and chemotherapy are required on the same day, Margenza should be administered immediately following chemotherapy. Margenza has a Boxed Warning for left ventricular dysfunction and embryo-fetal toxicity. Therefore, cardiac function should be monitored prior to initiating and during Margenza therapy, and the need for effective contraception should be advised. Margenza carries a labeled warning for infusion-related reactions, so signs and symptoms should be monitored for. Anthracycline-based therapy should be avoided for up to 4 months following completion of Margenza therapy due to the increased risk of cardiac dysfunction. If concomitant administration is necessary, cardiac function needs to be closely monitored. The most common adverse reactions (>10%) reported with Margenza were fatigue/asthenia, nausea, diarrhea, vomiting, constipation, headache, pyrexia, alopecia, abdominal pain, peripheral neuropathy, arthralgia/myalgia, cough, decreased appetite, dyspnea, infusion-related reactions, palmar-plantar erythrodysesthesia, and extremity pain.

Orgovyx (relugolix)

Indication: Prostate cancer

Mechanism of Action: Gonadotropin-releasing hormone receptor antagonist

Dosage Form(s): Tablets

Comments: Orgovyx is FDA-approved for treating advanced prostate cancer in adults. Orgovyx should be administered as 360mg by mouth on Day 1, followed by 120mg daily thereafter. It may be administered with or without food but should be taken at around the same time each day. Orgovyx carries labeled warnings for QT/QTc interval prolongation and embryo-fetal toxicity. Serum prostate specific antigen (PSA) levels should be monitored periodically to ensure Orgovyx's efficacy. Concomitant administration of Orgovyx with P-glycoprotein inhibitors or combined P-glycoprotein and strong CYP3A inducers should be avoided. However, if concomitant administration with P-glycoprotein inhibitors is necessary, Orgovyx should be administered first and separately administered by at least 6 hours. If concomitant administration with combined P-glycoprotein and strong CYP3A inducers is necessary, Orgovyx should be increased to 240mg once daily. The most common adverse reactions (≥10%) and laboratory abnormalities (≥15%) reported with Orgovyx were hot flush, increased glucose, increased triglycerides, musculoskeletal pain, decreased hemoglobin, increased alanine aminotransferase (ALT), fatigue, increased aspartate aminotransferase (AST), constipation, and diarrhea.

New Drug Approvals, Continued

Orladeyo (berotralstat)

Indication: Hereditary angioedema

Mechanism of Action: Plasma kallikrein inhibitor

Dosage Form(s): Capsules

Comments: Orladeyo is FDA-approved to prevent hereditary angioedema attacks in adults and children ≥12 years. Orladeyo should be taken as 150mg by mouth daily with food. Orladeyo carries a labeled warning for increased QT prolongation. While no laboratory monitoring is required, Orladeyo has the potential to interact with P-glycoprotein or BCRP inhibitors, P-glycoprotein inducers, and CYP2D6, CYP3A4, or P-glycoprotein substrates. Therefore, the Orladeyo dose should be reduced to 110mg if administered concomitantly with P-glycoprotein or BCRP inhibitors, concomitant administration with P-glycoprotein inducers should be avoided, and narrow therapeutic index drugs primarily metabolized by CYP2D6, CYP3A4, or that are P-glycoprotein substrates should be closely monitored or dose adjusted. The most common adverse reactions (≥10%) reported with Orladeyo were abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Ceftolozane and tazobactam (Zerbaxa) injection
- Famotidine injection
- Misoprostol tablets
- Valproate sodium injection, USP

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

Recently Approved Drug Combinations, Dosage Forms, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Riabni (Rituximab-arrx)	Non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis, microscopic polyangiitis	CD20-directed antibody	Intravenous injection	Biosimilar to Rituxan

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Drug Information Consultation Service

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