Approvals & Updates

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PharMerica

New Drug Approvals

Daxxify (daxibotulinumtoixnA-lanm)

Indication: Temporary improvement in the appearance of moderate-to-severe galbellar lines associated with corrugator and/or procerus muscle activity

Mechanism of Action: Acetylcholine release inhibitor and neuromuscular blocking agent

Dosage Form(s): Intramuscular injection

Comments: Daxxify is FDA-approved for treating adult patients with moderate to severe galbellar lines associated with corrugator and/or procerus muscle activity. The total recommended dose of Daxxify is 40 units per treatment session divided into 5 equal intramuscular injections of 8 units each (two injections in each corrugator muscle and one injection in the procerus muscle). Daxxify has a black boxed warning for the distant spread of toxin effect. Daxxify is contraindicated in the presence of infection at the injection site. Daxxify is not interchangeable with other preparations of other botulinum toxin products. Daxxify has labeled warnings and precautions for the spread of toxin effects, patients with pre-existing cardiovascular disease, concomitant neuromuscular disorder, compromised respiratory function or dysphagia, and with the unapproved use of Daxxify. Agents that interfere with neuromuscular transmission (i.e., aminoglycoside antibiotics, anticholinergics) may potentiate the effect of Daxxify so the co-administration of these drugs should be done with caution and close observation. The most common adverse reactions (≥1%) reported with Daxxify are headache (6%), eyelid ptosis (2%), and facial paresis (1%).

Lytgobi (futibatinib)

Indication: To treat intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements

Mechanism of Action: Kinase inhibitor

Dosage Form(s): Oral tablet

Comments: Lytgobi is FDA-approved for treating adults with previously treated unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring FGFR2 gene fusions or other rearrangements. Prior to the initiation of Lytgobi the presence of an FGFR2 gene fusion or other rearrangement should be confirmed. Lytgobi is administered as 20 mg dose (five 4 mg tablets) orally once daily until disease progression or inacceptable toxicity occurs. Lytgobi tablets are swallowed whole, with or without food. Lytgobi has labeled warnings for ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity. Avoid the co-administration of Lytgobi with dual P-gp and strong CYP3A inhibitors and inducers. Due to the potential for serious adverse reactions in breastfed children, avoid the use of Lytgobi in breastfeeding women during treatment and for 1 week after the last dose. The most common laboratory abnormalities (≥20%) reported with Lytgobi are increased phosphate, creatinine, glucose, calcium, alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, activated partial thromboplastin time, creatine kinase, bilirubin, prothrombin international normalized ratio and decreased hemoglobin, sodium, phosphate, lymphocytes, platelets, leukocytes, albumin, neutrophils, glucose, and potassium. The most common adverse reactions (≥20%) reported with Lytgobi are nail toxicity, musculoskeletal pain, constipation, diarrhea, fatigue, dry mouth, alopecia, stomatitis, abdominal pain, dry skin, arthralgia, dysgeusia, dry eye, nausea, decreased appetite, urinary tract infection, palmar-plantar erythrodysesthesia syndrome, and vomiting.

Omlonti (omidenepag isopropyl ophthalmic solution)

Indication: Reduces elevated intraocular pressure (IOP) with open-angle glaucoma or ocular hypertension

Mechanism of Action: Selective prostaglandin E2 (EP2) receptor agonist

Dosage Form(s): Ophthalmic solution

Comments: Omlonti is FDA-approved for the reduction of IOP in patients with opening-angle glaucoma or ocular hypertension. Omlonti is administered as one drop in the affected eye(s) once daily in the evening. The label warnings and precautions include pigmentation changes, eyelash changes, ocular inflammation, and macular edema. The most common adverse reactions (≥1%) reported with Omlonti are conjunctival hyperemia, photophobia, blurred vision, dry eye, instillation site pain, eye pain, ocular hyperemia, punctate keratitis, headache, eye irritation, visual impairment.

Relyvrio (sodium phenylbutyrate and taurursodiol)

Indication: Amyotrophic lateral sclerosis (ALS)

Mechanism of Action: Histone deacetylase inhibitor and hydrophilic bile acid

Dosage Form(s): oral suspension

Comments: Relyvrio is FDA-approved in treating adults with ALS. Relyvrio is administered as 1 packet (3 g sodium phenylbutyrate and 1 g taurursodiol) orally or via feeding tube. The initial dosage is 1 packet daily for the first 3 weeks and then a maintenance dosage of 1 packet twice daily thereafter. Prior to administration, the contents of one packet are emptied into a cup with 8 ounces of room temperature water and stirred vigorously. Relyvrio should be taken within 1 hour of preparation. Relyvrio is administered before a snack or meal. There is no available data on the use of Relyvrio in pregnant women, but the use of Relyvrio is animal studies have resulted in increased fetal harm. Relyvrio has labeled warnings and precautions for risk in patients with enterohepatic circulation, pancreatic or intestinal disorders, and use in patients sensitive to high sodium intake. Consider consultation with a specialist for patients with disorders interfering with bile acid circulation. For patients sensitive to salt intake, consider the amount of sodium in each dose of Relyvrio and monitor appropriately due to the high sodium content of Relyvrio. The most common adverse reactions (≥15% and ≥5% greater than placebo) are diarrhea, abdominal pain, nausea, and upper respiratory tract infection.

Rolvedon (eflapegrastim-xnst)

Indication: Decreases infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia

Mechanism of Action: Leukocyte growth factor

Dosage Form(s): Subcutaneous injection

Comments: Rolvedon is FDA-approved to decrease the incidence of infection in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. Rolvedon 13.2 mg is administered subcutaneously once per chemotherapy cycle. Rolvedon should not be administered within the period from 14 days before to 24 hours after administration of cytotoxic chemotherapy. Rolvedon is contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors (e.g., pegfilgrastim or filgrastim). Rolvedon has labeled warnings for fatal splenic rupture, Acute respiratory distress syndrome (ARDS), serious allergic reactions, Sickle Cell Crisis in Patients with Sickle Cell Disorders, glomerulonephritis, leukocytosis, thrombocytopenia, Myelodysplastic Syndrome (MDS), and Acute Myeloid Leukemia (AML). The most common adverse reactions (≥20%) reported with Rolvedon are fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain.

Sotyktu (deucravacitinib)

Indication: Moderate-to-severe plaque psoriasis

Mechanism of Action: Tyrosine kinase 2 (TYK2) inhibitor

Dosage Form(s): Oral tablet

Comments: Sotyktu is FDA-approved for treating adults with moderate-to-severe plaque who are candidates for systemic therapy or phototherapy. Sotyktu is not recommended for use in combination with other potent immunosuppressants. Patients should be evaluated for active and latent (TB) infection and immunizations should be updated according to current immunization guidelines prior to the administration of Sotyktu. If positive, treatment for TB should be started prior to Sotyktu use. The recommended dose of Sotyktu is 6 mg administered orally once daily with or without food. Sotyktu is not recommended in patients with severe hepatic impairment (Child-Pugh C). Sotyktu has labeled warnings for hypersensitivity, increased risk of infections, tuberculosis, malignancy, rhabdomyolysis and elevated CPK, laboratory abnormalities, live vaccines, and potential risks related to JAK inhibition. The most common adverse reactions (≥ 1%) reported with Sotyktu are upper respiratory infections, increased blood creatine phosphokinase, herpes simplex, mouth ulcers, folliculitis, and acne.

Spevigo (spesolimab-sbzo)

Indication: Generalized pustular psoriasis flares

Mechanism of Action: Interleukin-36 receptor antagonist

Dosage Form(s): Intravenous injection

Comments: Spevigo is FDA-approved for treating adults with generalized pustular psoriasis flares. Spevigo must be diluted before use and is administered as a single 900 mg dose via intravenous infusion over 90 minutes. An additional 900 mg may be administered one week after the initial dose if flare symptoms persist. Spevigo carries label warnings for infections, risk of tuberculosis (TB), hypersensitivity and infusion-related reactions, and vaccinations. Spevigo may increase the risk of infections and should not be initiated during any clinically important active infections. Patients should be evaluated for TB infection prior to the initiation of Spevigo. Do not administer Spevigo to patients with active TB infection. Avoid the concurrent administration of live vaccines with Spevigo. The most common adverse reactions (≥5%) reported with Spevigo are nausea, vomiting, asthenia, fatigue, headache, pruritis and prurigo, infusion site hematoma and bruising, and urinary tract infections.

Terlivaz (terlipressin)

Indication: Improves kidney function in hepatorenal syndrome with rapid reduction in kidney function

Mechanism of Action: Vasopressin receptor agonist

Dosage Form(s): Intravenous injection

Comments: Terlivaz is FDA-approved for treating adults with hepatorenal syndrome with rapid reduction in kidney function. Prior to the initial dose of Terlivaz, patients should be assessed for acute-on-chronic liver failure (ACLF) Grade 3 and baseline oxygenation saturation (e.g., SpO_2). Terlivaz 0.85 mg (1 vial) is administered intravenously (IV) every 6 hours on days 1 to 3. On day 4, serum creatinine (SCr) versus baseline is assessed. If SCr has decreased by ≥ 30% from baseline, continue the IV administration of Terlivaz 0.85 mg (1 vial) every 6 hours. If SCr has decreased by ≤ 30% from baseline, the dose may be increased to Terlivaz 1.7 mg (2 vials) IV every 6 hours. Discontinue Terlivaz if SCr is above baseline value. Continue Terlivaz for 24 hours after two consecutive SCr ≤1.5 mg/dL values are obtained at least 2 hours apart or for a maximum of 14 days. Terlivaz is contraindicated in patients experiencing hypoxia or worsening respiratory symptoms and in patients with ongoing coronary, peripheral, or mesenteric ischemia. Terlivaz has a black box warning for serious or fatal respiratory failure. Terlivaz carries labeled warnings and precautions for ineligibility for liver transplant, ischemic events, and embryo-fetal toxicity. The most common adverse reactions (≥10%) reported with Terlivaz are abdominal pain, nausea, respiratory failure, diarrhea, and dyspnea.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Fludarabine phosphate injection
- Iodixanol (Visipaque) injection
- Iohexol (Omnipaque) 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/Strengths, Indications, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Iheezo (chloroprocaine hydrochloride ophthalmic)	Ocular surface anesthesia	Ester anesthetic	Topical ophthalmic gel	New dosage form
Stimufend (pegfilgrastim fpgk)	Prevention of chemotherapy-induced neutropenia	Leucocyte growth factor	Subcutaneous injection	Biosimilar to Neulasta
Vegzelma (bevacizumab-adcd)	Metastatic colorectal cancer	Vascular endothelial growth factor inhibitor (VEGF)	Intravenous injection	Biosimilar to Avastin