Approvals & Updates

July 2023

New Drug Approvals

Columvi (glofitamab-gxbm)

Indication: Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma

Mechanism of action: Bispecific CD20-directed CD3 T-cell engager

Dosage form(s): Injection, for intravenous infusion

Comments: Columvi is FDA-approved for treating adults with relapsed or refractory diffuse large B-Cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy. Pre-medications (i.e., dexamethasone, acetaminophen, diphenhydramine) are recommended. The recommended doses of Columvi are based on the cycle and day of treatment; each cycle consists of 21 days. Administration includes pretreatment with a single 1,000 mg dose of Obinutuzumab intravenously on day 1 of cycle 1, followed by Columvi 2.5 mg on day 8 and Columvi 10 mg on day 15. For the remaining cycles 2-12, Columvi 30 mg is administered on day 1. Additional dosing information includes hospitalization for the first Columvi step-up dose (2.5 mg on Cycle 1 day 8), ensure adequate hydration prior to administration, have a healthcare professional with immediate access to medical support present, and administer only as an intravenous infusion through a dedicated infusion line that includes a 0.2 micron in-line filter. Columvi has a boxed warning for cytokine release syndrome (CRS) and should be withheld until CRS resolves or permanently discontinued depending on severity. Warnings and precautions associated with Columvi include neurologic toxicity, serious infections, tumor flare, and embryo-fetal toxicity. The most common adverse reactions (≥ 20%) include cytokine release syndrome, musculoskeletal pain, rash, and fatigue. The most common (≥ 20%) Grade 3 to 4 laboratory abnormalities include a decrease in lymphocyte count, neutrophil count, phosphate, and fibrinogen. Uric acid was increased.

Litfulo (ritlecitinib)

Indication: Severe alopecia areata

Mechanism of action: Kinase inhibitor

Dosage form(s): Oral capsules

Comments: Litfulo is FDA-approved for the treatment of severe alopecia areata in adults and adolescents 12 years and older. Recommended dosage is 50 mg by mouth daily. Litfulo has a boxed warning for increased risk of serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis. Treatment should be interrupted if serious infection occurs and testing for latent TB before and during therapy is recommended. Litfulo is not recommended in combination with other JAK inhibitors, immunomodulators, cyclosporine, other potent immunosuppressants, or severe hepatic impairment and is contraindicated in patients with known hypersensitivity to ritlectimib or any of its excipients. Warnings and precautions associated with Litfulo include hypersensitivity, laboratory abnormalities and the use of live vaccines during or shortly prior to treatment. Most common adverse reactions reported (≥ 1%) include headache, diarrhea, acne, rash, urticaria, folliculitis, pyrexia, atopic dermatitis, dizziness, blood creatine phosphokinase increased, herpes zoster, red blood cell count decreased, and stomatitis.

Ngenla (somatrogon-ghla)

Indication: Growth failure in pediatric patients aged 3 years and older

Mechanism of action: Human growth hormone analog

Dosage form(s): Subcutaneous injection

Comments: Ngenla is FDA-approved for the treatment of growth failure due to inadequate secretion of endogenous growth hormone in patients aged 3 years and older. Ngenla is administered subcutaneously once weekly on the same day each week. The recommended dose is 0.66 mg/kg based on actual body weight. Ngenla administration and treatment should be supervised by a healthcare provider and individualized for each patient. Ngenla is contraindicated in patients with acute critical illness, hypersensitivity to somatrogon-ghla or excipients, closed epiphyses, active malignancy, active proliferative or severe non-proliferative diabetic retinopathy, and Prader-Willi syndrome who are severely obese or have severe respiratory impairment. Warnings and precautions associated with Ngenla include severe hypersensitivity, increased risk of neoplasms, glucose intolerance and diabetes mellitus, intracranial hypertension, fluid retention, hypoadrenalism, hypothyroidism, slipped capital femoral epiphysis, progression of preexisting scoliosis, pancreatitis, and lipoatrophy. The most common adverse reactions reported (≥5%) include injection site reactions, nasopharyngitis, headache, pyrexia, anemia, cough, vomiting, hypothyroidism, abdominal pain, rash, and oropharyngeal pain. Ngenla has reported drug interactions with replacement glucocorticoid treatment, pharmacologic glucocorticoid therapy and supraphysiologic glucocorticoid treatment, cytochrome P450-metabolized drugs, oral estrogens, and insulin or other antihyperglycemic agents.

Rystiggo (rozanolixizumab-noli)

Indication: Generalized myasthenia gravis in adults positive for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK), antibody.

Mechanism of action: Neonatal Fc receptor blocker

Dosage form(s): Subcutaneous injection

Comments: Rystiggo is FDA-approved to treat adults with myasthenia gravis who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase antibody positive. Recommended dosage is based on body weight (i.e., less than 50 kg receive 420 mg, 50 kg to less than 100 kg receive 560 mg, and 100 kg or more receive 840 mg) administered as a subcutaneous infusion once weekly for 6 weeks. Warnings and precautions associated with Rystiggo include infections, aseptic meningitis, and hypersensitivity reactions. Delayed administration is recommended in patients with an active infection and if serious infections occur, withholding treatment should be considered. The most common adverse reactions reported (≥10%) include headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea.

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

Indication: Generalized myasthenia gravis in adults positive for anti-acetylcholine receptor (AChR) antibody

Mechanism of action: Combination neonatal Fc receptor blocker and endoglycosidase

Dosage form(s): Subcutaneous injection

Comments: Vyvgart Hytrulo is FDA-approved to treat generalized myasthenia gravis (gMG) in adult patients who are positive for anti-acetylcholine receptor antibodies. Current recommended dose is 1,008 mg/ 11,200 units (1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase) administered by a health care professional via subcutaneous injections with a winged infusion set in cycles of once weekly injections for 4 weeks. Subsequent treatment cycles are administered according to clinical evaluation.. Warnings and precautions associated with Vyvgart Hyrtulo include infections and hypersensitivity reactions. Vygart Hyrtulo administration should be delayed if an active infection is present and if serious infections occur, holding the medication should be considered. The most common adverse reactions reported (≥10%) include respiratory tract infections, headache, and urinary tract infections. Additionally, injection site reactions were experienced.

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

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Cyclophosphamide	Malignant diseases	Alkylating agent	Injection	New formulation
Lodoco (Colchicine)	Reduce risk of myocardial infarction, stroke, coronary revascularization, and cardio-vascular death in adults with ASCVD	Anti-inflammatory	Oral tablet	New indication
Suflave (Polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, sodium chloride)	Colon cleanse	Osmotic laxative	Oral solution	New combination