New Drug Approvals

Upneeq (oxymetazoline hydrochloride) Ophthalmic Solution

Company: Osmotica Pharmaceuticals plc
Date of Approval: July 8, 2020
Treatment for: Blepharoptosis

Upneeq (oxymetazoline hydrochloride ophthalmic solution, 0.1%) is a novel, once-daily ophthalmic formulation of the direct-acting α-adrenergic receptor agonist oxymetazoline, indicated for the treatment of acquired blepharoptosis (droopy eyelid).

Inqovi (decitabine and cedazuridine) Tablets

Company: Astex Pharmaceuticals, Taiho Oncology, and Otsuka Pharmaceutical
Date of Approval: July 7, 2020
Treatment for: Myelodysplastic Syndrome

Inqovi (decitabine and cedazuridine) is a nucleoside metabolic inhibitor and cytidine deaminase inhibitor combination indicated for the treatment of adults with intermediate and high-risk myelodysplastic syndromes (MDS) including chronic myelomonocytic leukemia (CMML).

Qwo (collagenase clostridium histolyticum-aaes) for Injection

Company: Endo International plc
Date of Approval: July 6, 2020
Treatment for: Cellulite

Qwo (collagenase clostridium histolyticum-aaes) is a combination of bacterial collagenases indicated for the treatment of moderate to severe cellulite in the buttocks of adult women.

Hulio (adalimumab-fkjp) Injection

Company: Mylan Pharmaceuticals Inc.

Date of Approval: July 6, 2020

Treatment for: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease -- Maintenance, Ulcerative Colitis, Plaque Psoriasis Hulio (adalimumab-fkjp) is a tumor necrosis factor (TNF) blocker biosimilar to Humira indicated for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn's disease (CD), ulcerative colitis (UC), and plaque psoriasis (Ps).

Byfavo (remimazolam) Injection

Company: Cosmo Pharmaceuticals NV
Date of Approval: July 2, 2020
Treatment for: Sedation

Byfavo (remimazolam) is an ultra-short-acting, intravenous benzodiazepine sedative/anesthetic for the induction and maintenance of procedural sedation in adults.

Rukobia (fostemsavir) Extended-Release Tablets

Company: ViiV Healthcare
Date of Approval: July 2, 2020
Treatment for: HIV Infection

Rukobia (fostemsavir) is a first-in-class, human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor indicated for use in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection.

Dojolvi (triheptanoin) Oral Liquid

Company: Ultragenyx Pharmaceutical Inc.
Date of Approval: June 30, 2020
Treatment for: Long-Chain Fatty Acid Oxidation Disorders

Dojolvi (triheptanoin) is a medium-chain triglyceride indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) Injection

Company: Genentech, Inc.
Date of Approval: June 29, 2020
Treatment for: Breast Cancer

Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) is a combination of two HER2/neu receptor antagonists and the endoglycosidase hyaluronidase indicated for the treatment of early and metastatic HER2-positive breast cancer, as detected by an FDA-approved companion diagnostic test.

Mycapssa (octreotide) Delayed-Release Capsules

Company: Chiasma, Inc.
Date of Approval: June 26, 2020
Treatment for: Acromegaly

Mycapssa (octreotide) is an oral formulation of the approved somatostatin analog octreotide for the treatment of acromegaly.

Fintepla (fenfluramine) Oral Solution

Company: Zogenix, Inc.
Date of Approval: June 25, 2020
Treatment for: Dravet Syndrome

Fintepla (fenfluramine) is an amphetamine derivative indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.

Gimoti (metoclopramide) Nasal Spray

Company: Evoke Pharma, Inc.
Date of Approval: June 19, 2020
Treatment for: Gastroparesis

Gimoti (metoclopramide) is an intranasal formulation of the approved drug metoclopramide for the relief of symptoms of acute and recurrent diabetic gastroparesis in adults.

Zepzelca (lurbinectedin) Injection

Company: PharmaMar and Jazz Pharmaceuticals plc
Date of Approval: June 15, 2020
Treatment for: Small Cell Lung Cancer

Zepzelca (lurbinectedin) is a selective oncogenic transcription inhibitor indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

Lyumjev (insulin lispro-aabc) Injection

Company: Eli Lilly and Company
Date of Approval: June 15, 2020
Treatment for: Diabetes Type 1, Diabetes Type 2

Lyumjev (insulin lispro-aabc) is a rapid-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.

Semglee (insulin glargine) Injection

Company: Mylan N.V. and Biocon Ltd.
Date of Approval: June 11, 2020
Treatment for: Diabetes Type 1, Diabetes Type 2

Semglee (insulin glargine) is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

Semglee (insulin glargine) Injection

Company: Mylan N.V. and Biocon Ltd.
Date of Approval: June 11, 2020
Treatment for: Diabetes Type 1, Diabetes Type 2

Semglee (insulin glargine) is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

Nyvepria (pegfilgrastim-apgf) Injection

Company: Pfizer Inc.
Date of Approval: June 10, 2020
Treatment for: Neutropenia Associated with Chemotherapy

Nyvepria (pegfilgrastim-apgf) is a PEGylated growth colony-stimulating factor biosimilar to Neulasta (pegfilgrastim) used to reduce the incidence of febrile neutropenia in patients treated with chemotherapy.

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References: *www.drugs.com/newdrugs*