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.

Information collected and compiled by:
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References: *www.drugs.com/newdrugs*

New Indications & Dosage Forms for Existing Drugs

Tremfya (guselkumab) Injection
New Indication Approved: July 13, 2020
Date of Original Approval: July 13, 2017
Tremfya (guselkumab) is an interleukin-23 blocker indicated for the treatment of moderate-to-severe plaque psoriasis and psoriatic arthritis in adults.

Botox (onabotulinumtoxinA) Injection
New Indication Approved: July 8, 2020
Date of Original Approval: December 9, 1991
Botox (onabotulinumtoxinA) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the treatment of **overactive bladder**, **urinary incontinence**, **chronic migraine, spasticity, cervical dystonia, hyperhidrosis, blepharospasm**, **strabismus**.

Dysport (abobotulinumtoxinA) Injection
New Indication Approved: July 8, 2020
Date of Original Approval: April 29, 2009
Dysport (abobotulinumtoxinA) is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of cervical dystonia in adults, the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age also in the treatment of spasticity in patients 2 years of age and older.

Bavencio (avelumab) Injection
New Indication Approved: June 30, 2020
Date of Original Approval: March 23, 2017
Bavencio (avelumab) is a programmed death ligand-1 (PD-L1) blocking antibody indicated for the treatment of patients with metastatic Merkel cell carcinoma (MCC); patients with advanced or metastatic urothelial carcinoma; and in combination with axitinib for patients with advanced renal cell carcinoma.

Keytruda (pembrolizumab) for Injection
New Indication Approved: June 29, 2020
Date of Original Approval: September 4, 2014
Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, and cutaneous squamous cell carcinoma.

Xpovio (selinexor) Tablets
New Indication Approved: June 22, 2020
Date of Original Approval: July 3, 2019
Xpovio (selinexor) is a first in class Selective Inhibitor of Nuclear Export (SINE) XPO1 antagonist for the treatment of patients adult patients with multiple myeloma (RRMM) and relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

Crysvita (burosumab-twza) Injection
New Indication Approved: June 18, 2020
Date of Original Approval: April 17, 2018
Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody for the treatment of x-linked hypophosphatemia (XLH) and FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO).

Tazverik (tazemetostat) Tablets
New Indication Approved: June 18, 2020
Date of Original Approval: January 23, 2020
Tazverik (tazemetostat) is a methyltransferase inhibitor for the treatment of **epithelioid sarcoma** and **follicular lymphoma**

Dupixent (dupilumab) Injection
New Dosage Form Approved: June 18, 2020
Date of Original Approval: March 28, 2017
Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for the treatment of **atopic**

dermatitis, moderate-to-severe **asthma and** controlled **chronic rhinosinusitis with nasal polyposis**.

Cosentyx (secukinumab) Injection

New Indication Approved: June 16, 2020

Date of Original Approval: January 21, 2015

Cosentyx (secukinumab) is a selective interleukin-17A (IL-17A) inhibitor for the treatment of plaque psoriasis, ankylosing spondylitis, psoriatic arthritis, and non-radiographic axial spondyloarthritis.

Keytruda (pembrolizumab) for Injection

New Indication Approved: June 16, 2020

Date of Original Approval: September 4, 2014

Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, and cutaneous squamous cell carcinoma.

Ilaris (canakinumab) Injection

New Indication Approved: June 16, 2020

Date of Original Approval: June 17, 2009

Ilaris (canakinumab) is a human anti-interleukin-1β monoclonal antibody for the treatment of Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes, Tumor Necrosis Factor Receptor Associated Periodic Syndrome, Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency, Familial Mediterranean Fever), and active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA).

Tivicay (dolutegravir) Tablets

New Dosage Form Approved: June 12, 2020

Date of Original Approval: August 12, 2013

Tivicay (dolutegravir) is a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated for use in combination with other antiretroviral (ARV) agents for the treatment of HIV-1.

Opdivo (nivolumab) Injection

New Indication Approved: June 10, 2020

Date of Original Approval: December 22, 2014

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of advanced melanoma, advanced non-small cell lung cancer, advanced small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma.

Recarbrio (imipenem, cilastatin, and relebactam) for Injection

New Indication Approved: June 4, 2020

Date of Original Approval: July 16, 2019

Recarbrio (imipenem, cilastatin, and relebactam) is a combination of **imipenem**, a penem antibacterial, **cilastatin**, a renal dehydropeptidase inhibitor, and **relebactam**, a betalactamase inhibitor, indicated for the treatment of complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI), and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in adults.

Information collected and compiled by:

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References: *www.drugs.com/newdrugs*

Alternative Medicine News

Study reveals antiviral effects of curcumin

Date: 17 July 2020

Curcumin, a natural compound found in the spice turmeric, could help eliminate certain viruses, research has found. A study published in the *Journal of General Virology* showed that curcumin can prevent Transmissible gastroenteritis virus (TGEV) - an alpha-group coronavirus that infects pigs - from infecting cells. At higher doses, the compound was also found to kill virus particles.

Study links fermented vegetable consumption to low COVID-19 mortality

Date: 08 July 2020

An intriguing new study by researchers in Europe suggests that coronavirus disease 2019 (COVID-19) mortality rates are likely to be lower in countries where diets are rich in fermented vegetables. Earlier this year, Jean Bousquet (Charité, Universitäts medizin Berlin) and colleagues investigated whether diet may contribute to the significant variation in COVID-19 death rates that have been observed between countries. The study found that in some countries with low mortality rates, the consumption of traditional fermented foods was high.

Brazil's remote tribes in Amazon turn to tree bark and honey to treat coronavirus

Date: 20 May 2020

An Amazon tribe has turned to traditional remedies to tackle coronavirus amid rising concern over the Brazilian government's failure to tackle the pandemic. The Satere-Mawe community told reporters they used their ancestral knowledge of preparations made from tree bark, honey and native plants to treat symptoms of Covid-19. They include carapanauba, saracuramira, caferana and saratudo, which are said to have either anti-malarial or anti-inflammatory properties.

Reference: www.medicalnewstoday.com

Complementary, alternative medicine use increasing for MS

Date: July 8, 2020

HealthDay News – For people with multiple sclerosis (pwMS), there has been an increase in use of complementary and alternative medicine (CAM), according to a study published in the June issue of *Multiple Sclerosis and Related Disorders*. The researchers found that in 2018, to treat their MS, 81% of the respondents used a CAM supplement (vitamins, minerals, or herbs), 39% used mind-body therapies, 41% used a specific diet, and 81% used exercise. There were increases in the use of supplements (65 to 81%), exercise (67 to 81%), and mind-body therapies (14 to 39%).

Pre/Probiotics may be useful for depression, anxiety

Date: July 8, 2020

HealthDay News – Pre/probiotic therapy may be useful for patients with depression and/or anxiety disorders, according to a review published online July 6 in *BMJ Nutrition, Prevention & Health*. The researchers found that comparing taking pre/probiotics versus no treatment/placebo or when compared to baseline measures, all the studies demonstrated significant improvements in one or more of the outcomes. Eleven of the 12 different probiotics investigated were potentially useful agents.

'Dead' probiotic treatment may help reduce irritable bowel symptoms

Date: April 10, 2020

HealthDay News – Probiotic treatment with dead bacteria is better than placebo at alleviating symptoms of irritable bowel syndrome (IBS), according to a study published online April 8 in *The Lancet Gastroenterology & Hepatology*.

Adding curcumin to mesalamine may benefit patients with ulcerative colitis

Date: January 22, 2020

Adjunctive therapy with curcumin was found to provide a greater clinical benefit than placebo in patients with ulcerative colitis (UC) being treated with mesalamine, according to the findings of a recently published systematic review and meta-analysis.

Fish oil supplement intake linked to better testicular function

Date: January 22, 2020

HealthDay News – For young men, fish oil supplement intake is associated with better testicular function, according to a study published online January 17 in *JAMA Network Open*.

Reference: www.empr.com/home/news/alternative-medicine

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