

New Drug Approvals

The following drugs have recently been approved by the FDA. These include newly approved drugs and new indications.

Quviviq (daridorexant) Tablets

Date of Approval: January 7, 2022

Company: Idorsia Ltd.

Treatment for: Insomnia

Quviviq (daridorexant) is a dual orexin receptor antagonist (DORA) for the treatment of insomnia.

Xaciatto (clindamycin phosphate) Vaginal Gel- formerly DARE-BV1

Date of Approval: December 7, 2021

Company: Daré Bioscience, Inc.

Treatment for: Bacterial Vaginosis

Xaciatto (clindamycin phosphate) is a topical lincosamide antibacterial for the vaginally-administered treatment of bacterial vaginosis in female patients of 12 years of age and older.

Entadfi (finasteride and tadalafil) Capsules

Date of Approval: December 9, 2021

Company: Veru Inc.

Treatment for: Benign Prostatic Hyperplasia

Entadfi (finasteride and tadalafil) is a 5 α -reductase inhibitor and phosphodiesterase 5 (PDE5) inhibitor combination indicated for the treatment of urinary tract symptoms caused by benign prostatic hyperplasia (BPH).

Tarpeyo (budesonide) Delayed Release Capsules - formerly Nefecon

Date of Approval: December 15, 2021

Company: Calliditas Therapeutics AB

Treatment for: IgA Nephropathy

Tarpeyo (budesonide) is a targeted release formulation of the approved corticosteroid budesonide indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN).

Dartisla ODT (glycopyrrolate) Orally Disintegrating Tablets

Date of Approval: December 16, 2021

Company: Edenbridge Pharmaceuticals, LLC

Treatment for: Peptic Ulcer

Dartisla ODT (glycopyrrolate) is an anticholinergic indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.

Tezspire (tezepelumab-ekko) Injection

Date of Approval: December 17, 2021

Company: Amgen and AstraZeneca

Treatment for: Asthma

Tezspire (tezepelumab-ekko) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2 λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Vyvgart (efgartigimod alfa-fcab) Injection

Date of Approval: December 17, 2021

Company: Argenx SE

Treatment for: Myasthenia Gravis

Vyvgart (efgartigimod alfa-fcab) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Yusimry (adalimumab-aqvh) Injection

Date of Approval: December 17, 2021

Company: Coherus BioSciences, Inc.

Treatment for: Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis

Yusimry (adalimumab-aqvh) is a tumor necrosis factor (TNF) blocker biosimilar to Humira, approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.

Apretude (cabotegravir) Extended-Release Injectable Suspension

Date of Approval: December 20, 2021

Company: ViiV Healthcare

Treatment for: Pre-Exposure Prophylaxis

Apretude (cabotegravir) is a long-acting injectable integrase strand transfer inhibitor (INSTI) indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.

Leqvio (inclisiran) Injection

Date of Approval: December 22, 2021

Company: Novartis

Treatment for: High Cholesterol, Familial Heterozygous

Leqvio (inclisiran) is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA used to reduce low-density lipoprotein cholesterol.

Adbry (tralokinumab-ldrm) Injection

Date of Approval: December 27, 2021

Company: LEO Pharma Inc.

Treatment for: Atopic Dermatitis

Adbry (tralokinumab-ldrm) is an interleukin-13 antagonist used for the treatment of moderate-to-severe atopic dermatitis.

Recorlev (levoketoconazole) Capsules

Date of Approval: December 30, 2021

Company: Xeris Biopharma Holdings

Treatment for: Cushing's Syndrome

Recorlev (levoketoconazole) is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome.

Eprontia (topiramate) Oral Solution

Date of Approval: November 5, 2021

Company: Azurity Pharmaceuticals, Inc.

Treatment for: Epilepsy, Migraine Prevention

Eprontia (topiramate) is a ready-to-use liquid formulation of the approved anticonvulsant topiramate for use in the treatment of epilepsy and the preventive treatment of migraine.

Besremi (ropeginterferon alfa-2b-njft) Injection

Date of Approval: November 12, 2021

Company: PharmaEssentia Corporation

Treatment for: Polycythemia Vera

Besremi (ropeginterferon-alfa-2b-njft) is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera.

Voxzogo (vosoritide) Lyophilized Powder for Injection

Date of Approval: November 19, 2021

Company: BioMarin Pharmaceutical Inc.

Treatment for: Achondroplasia

Voxzogo (vosoritide) is a C type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia.

Fyarro (sirolimus protein-bound) Lyophilized Powder for Injectable Suspension

Date of Approval: November 22, 2021

Company: Aadi Bioscience, Inc.

Treatment for: Malignant Perivascular Epithelioid Cell Tumor (PEComa)

Fyarro (sirolimus protein-bound particles) is an inhibitor of mechanistic target of rapamycin kinase (mTOR) for the treatment of malignant perivascular epithelioid cell tumor (PEComa).

Livtency (maribavir) Tablets

Date of Approval: November 23, 2021

Company: Takeda Pharmaceutical Company Limited

Treatment for: CMV Infection in Transplant Patients

Livtency (maribavir) is a cytomegalovirus (CMV) pUL97 kinase inhibitor used for the treatment of post-transplant CMV infection/disease.

Cytalux (pafolacianine) Injection

Date of Approval: November 29, 2021

Company: On Target Laboratories, Inc.

Treatment for: Identification of Ovarian Cancer During Surgery

Cytalux (pafolacianine) is a fluorescent imaging agent indicated as an adjunct for the intraoperative identification of malignant lesions in patients with ovarian cancer.

PreHevbrio (hepatitis B vaccine (recombinant) Injection

Date of Approval: November 30, 2021

Company: VBI Vaccines Inc.

Treatment for: Hepatitis B Prevention

PreHevbrio (hepatitis B vaccine (recombinant) is a 3-antigen hepatitis B vaccine indicated for the prevention of hepatitis B virus (HBV) infection in adults.

Lyvispah (baclofen) Oral Granules

Date of Approval: November 22, 2021

Company: Saol Therapeutics, Inc.

Treatment for: Spasticity

Lyvispah (baclofen) is an oral granule formulation of the approved gamma-aminobutyric acid agonist baclofen indicated for the treatment of spasticity.

Reference: www.drugs.com

Information collected and compiled by

Md. Akbar Hossain

ASA University (ASAUB)

Shyamoli, Mohammadpur

Dhaka-1207, Bangladesh