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.

Xaciato (clindamycin phosphate) Vaginal Gelformerly DARE-BV1

Date of Approval: December 7, 2021

Company: Daré Bioscience, Inc.

Treatment for: Bacterial Vaginosis

Xaciato (clindamycin phosphate) is a topical lincosamide antibacterial for the vaginallyadministered 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 5α -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).

Livtencity (maribavir) Tablets

Date of Approval: November 23, 2021

Company: Takeda Pharmaceutical Company Limited Treatment for: CMV Infection in Transplant Patients Livtencity (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 3antigen 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

New Indications & Dosage Forms for Existing Drugs

Drugs that have gained FDA approval for the treatment of additional diseases/conditions or new dosage forms/regimens are mentioned below.

Cosentyx (secukinumab) Injection

Patient Population Altered: December 22, 2021 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.

Xarelto (rivaroxaban) Tablets and Oral Suspension

Patient Population Altered: December 20, 2021 Date of Original Approval: July 1, 2011

Xarelto (rivaroxaban) is a factor Xa inhibitor used for the treatment and prevention of blood clots that are related to certain conditions involving the heart and blood vessels.

Otezla (apremilast) Tablets

New Indication Approved: December 20, 2021 Date of Original Approval: March 21, 2014

Otezla (apremilast) is a phosphodiesterase 4 (PDE4) inhibitor indicated for the treatment of psoriatic arthritis, plaque psoriasis, and oral ulcers associated with Behçet's disease.

Oxbryta (voxelotor) Tablets

Patient Population Altered: December 17, 2021 Date of Original Approval: November 25, 2019 Oxbryta (voxelotor) is an oral, HbS (sickle hemoglobin) polymerization inhibitor for the treatment of patients with sickle cell disease (SCD).

Caplyta (lumateperone) Capsules

New Indication Approved: December 17, 2021 Date of Original Approval: December 20, 2019 Caplyta (lumateperone) is an atypical antipsychotic for the treatment of schizophrenia and bipolar depression.

Orencia (abatacept) Injection

New Indication Approved: December 15, 2021 Date of Original Approval: December 23, 2005 Orencia (abatacept) is a selective T cell costimulation modulator indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, and the prophylaxis of acute graft versus host disease (aGVHD).

Xeljanz (tofacitinib) Tablets and Oral Solution

New Indication Approved: December 14, 2021 Date of Original Approval: November 6, 2012

Xeljanz (tofacitinib) is an oral Janus kinase (JAK) inhibitor used for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, and polyarticular course juvenile idiopathic arthritis.

Rinvoq (upadacitinib) Extended-Release Tablets

New Indication Approved: December 14, 2021 Date of Original Approval: August 16, 2019 Rinvoq (upadacitinib) is a Janus kinase (JAK) inhibitor for the treatment of rheumatoid arthritis and psoriatic arthritis.

Zynrelef (bupivacaine and meloxicam) Injection

New Indication Approved: December 8, 2021 Date of Original Approval: May 12, 2021

Zynrelef (bupivacaine and meloxicam) is an extended-release, fixed-dose combination of the local anesthetic bupivacaine and the nonsteroidal antiinflammatory drug (NSAID) meloxicam indicated for the management of postoperative pain.

Keytruda (pembrolizumab) for Injection

New Indication Approved: November 17, 2021 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, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.

Dyanavel XR (amphetamine) Extended-Release Oral Suspension and Extended-Release Tablets

New Dosage Form Approved: November 4, 2021 Date of Original Approval: October 19, 2015

Dyanavel XR (amphetamine) is an extended-release central nervous system (CNS) stimulant for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Dupixent (dupilumab) Injection

Patient Population Altered: October 20, 2021 Date of Original Approval: March 28, 2017

Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist used for the treatment of atopic dermatitis, asthma, and chronic rhinosinusitis with nasal polyposis (CRSwNP).

Cyltezo (adalimumab-adbm) Injection

Labeling Revision Approved: October 15, 2021 Date of Original Approval: August 25, 2017

Cyltezo (adalimumab-adbm) is an anti-TNF- α monoclonal antibody biosimilar to Humira, approved for the treatment of various inflammatory diseases including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.

Tecentriq (atezolizumab) Injection

New Indication Approved: October 15, 2021 Date of Original Approval: May 18, 2016

Tecentriq (atezolizumab) is a programmed deathligand 1 (PD-L1) blocking antibody indicated for use in the treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), small cell lung cancer (SCLC), hepatocellular carcinoma and melanoma.

Verzenio (abemaciclib) Tablets

New Indication Approved: October 13, 2021

Date of Original Approval: September 28, 2017

Verzenio (abemaciclib) is a selective ATPcompetitive inhibitor of cyclin dependent kinases (CDK) 4 and 6 used for the treatment of patients with hormone receptor-positive, human epidermal growth factor receptor 2 negative (HR+ HER2-) metastatic breast cancer.

Keytruda (pembrolizumab) for Injection

New Indication Approved: October 13, 2021 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, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer. microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burdenhigh (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.

Dextenza (dexamethasone) Ophthalmic Insert

New Indication Approved: October 7, 2021 Date of Original Approval: November 30, 2018

Dextenza (dexamethasone ophthalmic insert) is a corticosteroid intracanalicular insert for the treatment of post-surgical ocular inflammation and pain, and ocular itching associated with allergic conjunctivitis.

Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide) Tablets

Patient Population Altered: October 7, 2021 Date of Original Approval: February 7, 2018 Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide) is a combination of an integrase strand transfer inhibitor (bictegravir) and two HIV-1 nucleoside analog reverse transcriptase inhibitors (emtricitabine and tenofovir alafenamide) used for the treatment of HIV-1 infection.

Tecartus (brexucabtagene autoleucel) Suspension for Intravenous Infusion

New Indication Approved: October 1, 2021 Date of Original Approval: July 24, 2020

Information collected and compiled by Md. Akbar Hossain ASA University (ASAUB) Shyamoli, Mohammadpur Dhaka-1207, Bangladesh Tecartus (brexucabtagene autoleucel) is a CD19directed genetically modified autologous T cell immunotherapy for the treatment of mantle cell lymphoma (MCL) and B-cell precursor acute lymphoblastic leukemia (ALL).

Reference: www.drugs.com

Current Health News

Exercise alters brain chemistry to protect aging synapses

Date: January 7, 2022

Source: University of California - San Francisco

When elderly people stay active, their brains have more of a class of proteins that enhances the connections between neurons to maintain healthy cognition, a new study has found. This protective impact was found even in people whose brains at autopsy were riddled with toxic proteins associated with Alzheimer's and other neurodegenerative diseases.

No more annual flu shot? New target for universal influenza vaccine

Date: December 23, 2021

Source: Scripps Research Institute

Summary: A new antibody discovered in the blood of some people vaccinated against or infected with influenza can recognize a broad variety of flu viruses.

Can a dangerous microbe offer a new way to silence pain?

Date: December 20, 2021

Source: Harvard Medical School

Summary: A new study shows that a toxin from the microbe that causes anthrax can silence multiple types of pain in mice. Researchers found the toxin targets pain-sensing cells to alter signaling and block pain. Building on that finding, researchers engineered an anthrax protein vehicle to deliver different types of treatments into pain receptors and modulate nerve-cell function. The findings can inform the design of therapies that selectively target pain-sensing fibers without the widespread systemic effects of opioids and other pain killers.

Shark antibody-like proteins neutralize COVID-19 virus, help prepare for future coronaviruses

Date: December 17, 2021

Source: University of Wisconsin-Madison

Summary: Small, unique antibody-like proteins known as VNARs -- derived from the immune systems of sharks -- can prevent the virus that causes COVID-19, its variants, and related coronaviruses from infecting human cells, according to a new study.

Cellular receptors identified for eastern equine encephalitis

Date: January 14, 2022

Source: Harvard Medical School

Summary: A new study has identified a set of cellular receptors for at least three related alpha viruses shared across mosquitoes, humans, and animals that host the virus.

Repeated exposure to major disasters has longterm mental health impacts

Date: January 16, 2022

Source: Texas A&M University

Summary: Repeated exposure to major disasters does not make people mentally stronger, a recent study found: individuals who have been repeatedly exposed to major disasters show a reduction in mental health scores.

Being in space destroys more red blood cells

Date: January 14, 2022

Source: The Ottawa Hospital

Summary: A world-first study has revealed how space travel can cause lower red blood cell counts, known as space anemia. Analysis of 14 astronauts showed their bodies destroyed 54 percent more red blood cells in space than they normally would on Earth, according to a new study.

Biologists pinpoint key factor in immune system response to viral infection

Date: January 14, 2022

Source: University of California - San Diego

Summary: Researchers studying how small worms defend themselves against pathogens have discovered a gene that acts as a first-line response against infection. They identified 'ZIP-1' as a centralized hub for immune response, a finding could have implications for understanding human immunity against viruses.

Like our social media feeds, our brains take a little while to update

Date: January 13, 2022

Source: University of California - Berkeley

Summary: Our brains are constantly uploading rich visual stimuli. But instead of seeing the latest image in real time, we actually see earlier versions because our brain's refresh time is about 15 seconds. The findings add to a growing body of research about the mechanism behind the 'continuity field,' a function of perception in which our brain merges what we see to give us a sense of visual stability.

Novel treatment target for heart disease found in the blood vessel wall

Date: January 14, 2022

Source: Medical College of Georgia at Augusta University

Summary: A molecule of RNA called CARMN has been found in abundance in the healthy smooth muscle cells that help give our blood vessels strength and flexibility, and distinctly decreased in vascular diseases like atherosclerosis, a major cause of heart attack and stroke, scientists report.

Reference: sciencedaily.com

Common cold may shield against COVID

Tuesday, January 11, 2022

Vaccination is still the best way to protect someone from COVID-19, but new research suggests that immune system activation of T-cells by common colds may offer some cross-protection. The study might also provide a blueprint for a secondgeneration, universal vaccine that could prevent infection from current and future variants, the research team said.

CDC updates mask guidelines - cloth masks least effective

January 16, 2022 -- The U.S. Centers for Disease Control and Prevention has updated its guidance on face masks, saying loosely woven cloth masks offer the least protection against COVID-19 and N95 and KN95 masks offer the most. The CDC update doesn't come out and say Americans should avoid cloth masks but clarifies that some kinds of masks work better than others.

Reference: cnn.com/health

To stop blood cancer, target the bone

Date: January 19, 2022

Source: Columbia University Irving Medical Center

Summary: New research suggests that targeting neighboring bone cells may be a better strategy than targeting malignant stem cells to treat acute myeloid leukemia.

Artificial pancreas proves 'life-changing' for very young children with type 1 diabetes and their families

Date: January 20, 2022

Source: University of Cambridge

Summary: An artificial pancreas is helping protect very young children with type 1 diabetes at a particularly vulnerable time of their lives. A study published today found that it is both safe to use and more effective at managing their blood sugar levels than current technology.

You can feel this acid when you work out. Now it may increase knowledge of cancer medicine

Date: January 20, 2022

Source: University of Copenhagen - The Faculty of Health and Medical Sciences

Summary: New research shows that specific enzymes can remove lactic acid marks. This finding may increase our understanding of cancer medicine and how physical exercise, among other things, can affect human epigenetics.

Supplement appears to boost muscle, mitochondria health

Date: January 20, 2022

Source: University of Washington School of Medicine/UW Medicine

Summary: An oral supplement intended to stimulate a natural body process appears to promote muscle endurance and mitochondrial health in humans. New research suggests that the supplement, urolithin A, may help improve or prolong muscle activity in people who are aging or who have diseases that make exercise difficult.

COVID-19 vaccines do not cause infertility, study finds

Date: January 20, 2022

Source: Boston University School of Medicine

Summary: New findings indicate that COVID-19 vaccination does not impair fertility, but males who become infected by the coronavirus may experience short-term reduced fertility.

An all-in-one approach to diabetes treatment

Date: January 20, 2022

Source: Massachusetts Institute of Technology

Summary: A team of researchers has come up with a new approach to streamline the process that people with diabetes use to estimate the carbohydrate content of a meal, draw blood to measure current blood glucose levels, and calculate and deliver the correct insulin dose.

Mapping dementia-linked protein interactions yields potential new treatment targets

Date: January 20, 2022

Source: Weill Cornell Medicine

Summary: By mapping all the protein interactions of a dementia-linked protein in the brain called Tau, a team of investigators has created a road map for identifying potential new treatment targets for Alzheimer's disease and related dementia.

Newly discovered DNA repair mechanisms point to potential therapy targets for cancer and neurodegenerative diseases

Date: January 20, 2022

Source: Massachusetts General Hospital

Summary: Faulty DNA damage repair can lead to many types of cancer, neurodegenerative diseases, and other serious disorders. Investigators have developed high-throughput microscopy and machine learning systems that can identify and classify DNA repair factors. The investigators have identified nine previously unknown factors involved in the process of cellular DNA repair.

TV watching linked with potentially fatal blood clots

Date: January 19, 2022

Source: European Society of Cardiology

Summary: Take breaks when binge-watching TV to avoid blood clots, say scientists. The warning comes as a study reports that watching TV for four hours a day or more is associated with a 35% higher risk of blood clots compared with fewer than 2.5 hours.

'Decoy' protein works against multiple SARS-CoV-2 variants, researchers report

Date: January 19, 2022

Source: University of Illinois Chicago

Summary: A drug treatment that acts as a decoy against SARS-CoV-2 was highly effective at preventing death and lung damage in humanized animal models of severe COVID-19 disease. The study suggests that the drug has the potential to treat COVID-19 patients, including those who are infected with aggressive SARS-CoV-2 variants.

For Glioma patients, a mutated gene may open the door to new treatment options

Date: January 19, 2022

Source: Michigan Medicine - University of Michigan Summary: A mutated gene affects growth of brain tumor cells in young adults, indicating sensitivity to a new treatment strategy, a team of researchers has discovered. These findings present possibilities for more effective therapies for glioma patients with this gene mutation.

The role of ribosomes in age-related diseases

Date: January 19, 2022

Source: Stanford University

Summary: Research finds that the cellular assembly line that produces proteins can stall with age, triggering a snowball effect that increases the output of misfolded proteins. In humans, clumps of misfolded proteins contribute to age-linked Alzheimer's and Parkinson's diseases.

Magnesium is essential for the immune system, including in the fight against cancer

Date: January 19, 2022

Source: University of Basel

Summary: The level of magnesium in the blood is an important factor in the immune system's ability to tackle pathogens and cancer cells. Researchers have reported that T cells need a sufficient quantity of magnesium in order to operate efficiently. Their findings may have important implications for cancer patients.

Tracking the lifespan and myriad functions of mRNA

Date: January 19, 2022

Source: Yale University

Summary: New studies shed light on how mRNAs are born and how they regulate production of proteins inside of our cells once they reach maturity. The findings have implications not only for achieving effective doses for new vaccines, but for helping determine the biological roots of many cancers and diseases.

Reference: www.sciencedaily.com

Information collected and compiled by

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