New Drug Approvals

Naltrexone for Extended-Release Injectable Suspension 380mg/vial
Approved: July 6, 2023 - Teva Pharmaceuticals USA, Inc.
Treatment for: Alcohol Dependence; Opioid Dependence

Sugammadex Sodium Intravenous Solution 200 mg (base)/2 mL and 500 mg (base)/5 mL
Approved: June 9, 2023 - Aspiro Pharma Ltd.
Treatment for: Reversal of Neuromuscular Blockade

Tipiracil Hydrochloride and Trifluridine Tablets 6.14 mg (base)/15 mg and 8.19 mg (base)/20 mg
Approved: June 13, 2023 - Natco Pharma Ltd.
Treatment for: Colorectal Cancer/Gastric Cancer

Amlodipine Benzoate Oral Suspension 1 mg (base)/mL
Approved: June 13, 2023 - Amneal Pharmaceuticals LLC
Treatment for: Hypertension/Coronary Artery Disease

Safinamide Mesylate Tablets 50mg (base) and 100 mg (base)
Approved: June 14, 2023 - Aurobindo Pharma Limited
Treatment for: Parkinson's Disease

Mometasone Furoate Metered Nasal Spray 0.05 mg/spray (OTC)
Approved: June 14, 2023 - Amneal Pharmaceuticals LLC
Treatment for: Allergic Rhinitis

Tiotropium Bromide Inhalation Powder 0.018mg (base) per inhalation
Approved: June 20, 2023 - Lupin Pharmaceuticals, Inc.
Treatment for: COPD

Amphetamine Extended-Release Orally Disintegrating Tablets 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg
Approved: June 22, 2023 - Actavis Pharma, Inc.
Treatment for: ADHD

Alcaftadine Ophthalmic Solution 0.25%
Approved: June 23, 2023 - Eugia Pharma Specialities Limited
Treatment for: Allergic Conjunctivitis

Cyanocobalamin Metered Nasal Spray 0.5mg/spray
Approved: June 30, 2023 - Lupin Pharmaceuticals, Inc.
Treatment for: Vitamin B12 Deficiency

Methsuximide Capsules 300 mg
Approved: May 1, 2023 - Novitium Pharma LLC
Treatment for: Seizures

Obeticholic Acid Tablets 5 mg and 10 mg
Approved: May 30, 2023 - Apotex Corp.; Lupin Pharmaceuticals, Inc.; MSN Laboratories Private Limited
Treatment for: Primary Biliary Cholangitis

Diazepam Rectal Gel 10mg/2mL (5mg/mL) and 20mg/4mL (5mg/mL)
Approved: May 30, 2023 - Novel Laboratories, Inc.
Treatment for: Seizures

Budesonide Rectal Foam 2mg/actuation
Approved: April 12, 2023 - Padagis Israel Pharmaceuticals Ltd.
Treatment for: Ulcerative Colitis

Loteprednol Etabonate Ophthalmic Suspension 0.2%
Approved: April 12, 2023 - Akorn Operating Company LLC
Treatment for: Seasonal Allergic Conjunctivitis

Estradiol Transdermal System 0.014mg/24hr
Approved: April 17, 2023 - Zydus Pharmaceuticals USA, Inc.
Treatment for: Prevention of Postmenopausal Osteoporosis

Thalidomide Capsules 150 mg
Approved: April 27, 2023 - Natco Pharma Limited
Treatment for: Multiple Myeloma and Erythema Nodosum Leprosum

Bismuth Subcitrate Potassium, Metronidazole and Tetracycline Hydrochloride Capsules 140mg / 125mg / 125mg
Approved: March 6, 2023 - Par Pharmaceutical Inc.
Treatment for: Helicobacter Pylori Infection

Betamethasone Dipropionate and Calcipotriene Topical Aerosol Foam 0.064% / 0.005%
Approved: March 21, 2023 - Glenmark Pharmaceuticals Ltd.
Treatment for: Plaque Psoriasis

Tenofovir Alafenamide Fumarate Tablets 25 mg (base)
Approved: March 30, 2023 - Lupin Pharmaceuticals, Inc.
Treatment for: Hepatitis B

Doxepin Hydrochloride Topical Cream 5%
Approved: February 17, 2023 - Teva Pharmaceuticals USA, Inc.
Treatment for: Pruritus

Tiopronin Delayed Release Tablets 100 mg and 300 mg
Approved: February 24, 2023 - Par Pharmaceutical, Inc.
Treatment for: Cystinuria

Acetaminophen and Ibuprofen Tablets 250 mg / 125 mg
Approved: February 28, 2023 - L. Perrigo Company
Treatment for: Pain / Fever

References: www.drugs.com/generic-approvals

References: www.drugs.com/news

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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.

Leqvio (inclisiran) Injection
New Indication Approved: July 7, 2023
Date of Original Approval: December 22, 2021
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 (LDL-C).
US FDA Approves Expanded Indication for Novartis Leqvio (inclisiran) to Include Treatment of Adults with High LDL-C and Who Are At Increased Risk of Heart Disease

Leqembi (lecanemab-irmb) Injection
Labeling Revision Approved: July 6, 2023
Date of Original Approval: January 6, 2023
Leqembi (lecanemab) is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease.
FDA Grants Traditional Approval for Leqembi (lecanemab-irmb) for the Treatment of Alzheimer's Disease

Liletta (levonorgestrel) Intrauterine Device
New Indication Approved: June 29, 2023
Date of Original Approval: February 26, 2015
Liletta (levonorgestrel) is a progestin-containing intrauterine system indicated for the prevention of pregnancy for up to 8 years, and the treatment of heavy menstrual bleeding for up to 5 years in patients who choose intrauterine contraception as their method of contraception.
FDA Approves Medicines360's Supplemental New Drug Application for Liletta (levonorgestrel-releasing intrauterine system) 52 mg as Treatment of Heavy Menstrual Bleeding

Talzenna (talazoparib) Capsules
New Indication Approved: June 20, 2023
Date of Original Approval: October 16, 2018
Talzenna (talazoparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor used for the treatment of BRCA-mutated HER2-negative breast cancer and HRR gene-mutated metastatic castration-resistant prostate cancer.
Pfizer's Talzenna (talazoparib) in Combination with Xtandi (enzalutamide) Receives U.S. FDA Approval for HRR Gene-Mutated Metastatic Castration-Resistant Prostate Cancer

Blincyto (blinatumomab) Injection
Labeling Revision Approved: June 20, 2023
Date of Original Approval: December 3, 2014
Blincyto (blinatumomab) is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL).
FDA Grants Full Approval for Blincyto (blinatumomab) to Treat Minimal Residual Disease-Positive B-Cell Precursor Acute Lymphoblastic Leukemia

Jardiance (empagliflozin) Tablets
Patient Population Altered: June 20, 2023
Date of Original Approval: August 1, 2014
Jardiance (empagliflozin) is a sodium glucose co-transporter-2 (SGLT2) inhibitor used for the treatment of type 2 diabetes; and to reduce the risk of cardiovascular death in patients with heart failure, and type 2 diabetes patients with established cardiovascular disease.
FDA Approves Jardiance (empagliflozin) for the Treatment of Type 2 Diabetes in Children 10 Years and Older

Synjardy (empagliflozin and metformin) Tablets
Patient Population Altered: June 20, 2023
Date of Original Approval: August 26, 2015
Synjardy (empagliflozin and metformin hydrochloride) is a sodium glucose co-transporter-2 (SGLT2) inhibitor and biguanide combination for the treatment of type 2 diabetes.
FDA Approves New Class of Medicines to Treat Pediatric Type 2 Diabetes

Bylvay (odevixibat) Capsules
New Indication Approved: June 13, 2023
Date of Original Approval: July 20, 2021
Bylvay (odevixibat) is an ileal bile acid transport (IBAT) inhibitor for the treatment of progressive familial intrahepatic cholestasis and cholestatic pruritus due to Alagille syndrome.
FDA Approves Bylvay for Patients Living with Cholestatic Pruritus Due to Alagille Syndrome

Linzess (linaclotide) Capsules
Patient Population Altered: June 12, 2023
Date of Original Approval: August 30, 2012
Linzess (linaclotide) is a guanylate cyclase-C agonist used for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in adults, and functional

constipation (FC) in pediatric patients 6 to 17 years of age.
Ironwood Pharmaceuticals Announces FDA Approval of New Indication for Linzess (linaclotide) for the Treatment of Functional Constipation in Pediatric Patients Ages 6-17 Years-Old

Prevymis (letermovir) Tablets and Injection
New Indication Approved: June 5, 2023
Date of Original Approval: November 8, 2017
Prevymis (letermovir) is a CMV DNA terminase complex inhibitor used for the prophylaxis of cytomegalovirus (CMV) infection.
U.S. FDA Approves New Indication for Merck's Prevymis (letermovir) for Prevention of Cytomegalovirus (CMV) Disease in High-Risk Adult Kidney Transplant Recipients

Lynparza (olaparib) Tablets
New Indication Approved: May 31, 2023
Date of Original Approval: December 19, 2014
Lynparza (olaparib) is a poly ADP ribose polymerase (PARP) inhibitor for the treatment of ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer.
FDA Approves Lynparza (olaparib) Plus Abiraterone and Prednisone or Prednisolone for Treatment of Adult Patients With BRCA-Mutated Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Injectafer (ferric carboxymaltose) Injection
New Indication Approved: May 31, 2023
Date of Original Approval: July 25, 2013
Injectafer (ferric carboxymaltose) is an iron replacement product for the treatment of iron deficiency anemia.
Injectafer Approved in the U.S. for the Treatment of Iron Deficiency in Adult Patients with Heart Failure

Ayvakit (avapritinib) Tablets
New Indication Approved: May 19, 2023
Date of Original Approval: January 9, 2020
Ayvakit (avapritinib) is a tyrosine kinase inhibitor for use in the treatment of gastrointestinal stromal tumors, advanced systemic mastocytosis, and indolent systemic mastocytosis.
FDA Approves Ayvakit (avapritinib) as the First and Only Treatment for Indolent Systemic Mastocytosis

Rinvoq (upadacitinib) Extended-Release Tablets
New Indication Approved: May 18, 2023
Date of Original Approval: August 16, 2019
Rinvoq (upadacitinib) is a Janus kinase (JAK) inhibitor for the treatment of rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, and non-radiographic axial spondyloarthritis.
U.S. FDA Approves Rinvoq (upadacitinib) as a Once-Daily Pill for Moderately to Severely Active Crohn's Disease in Adults

Cyltezo (adalimumab-adbm) Injection
New Dosage Form Approved: May 18, 2023
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 rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, and hidradenitis suppurativa.
US FDA Approves the Cyltezo Pen, a New Autoinjector Option, Ahead of July 1 Commercial Launch

Caldolor (ibuprofen) Intravenous Injection
Patient Population Altered: May 11, 2023
Date of Original Approval: June 11, 2009
Caldolor (ibuprofen) is an intravenous formulation of the approved nonsteroidal anti-inflammatory drug ibuprofen for use in the treatment of pain and fever.
Caldolor Now FDA Approved for Treatment of Fever & Pain in Infants

Rexulti (brexpiprazole) Tablets
New Indication Approved: May 10, 2023
Date of Original Approval: July 10, 2015
Rexulti (brexpiprazole) is an atypical antipsychotic for use in the treatment of major depressive disorder (MDD), schizophrenia, and agitation associated with dementia due to Alzheimer's disease.
Otsuka and Lundbeck Announce U.S. FDA Approval of Supplemental New Drug Application (sNDA) for Rexulti (brexpiprazole) for the Treatment of Agitation Associated with Dementia Due to Alzheimer's Disease

Farxiga (dapagliflozin) Tablets
New Indication Approved: May 8, 2023
Date of Original Approval: January 8, 2014
Farxiga (dapagliflozin) is a sodium-glucose cotransporter 2 (SGLT2) inhibitor for use in the treatment of type 2 diabetes mellitus, heart failure, and chronic kidney disease.
Farxiga Extended in the US to Reduce Risk of Cardiovascular Death and Hospitalisation for Heart Failure to a Broader Range of Patients

Sogroya (somapacitan-beco) Injection
Patient Population Altered: April 28, 2023
Date of Original Approval: August 28, 2020
Sogroya (somapacitan-beco) is a human growth hormone analog indicated for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

FDA Approves Once-Weekly Sogroya for the Treatment of Children Living with Growth Hormone Deficiency

Prevnar 20 (pneumococcal 20-valent conjugate vaccine) Injection
Patient Population Altered: April 27, 2023
Date of Original Approval: June 8, 2021
Prevnar 20 (pneumococcal 20-valent conjugate vaccine) is a vaccine used for the prevention of invasive pneumococcal disease and otitis media.
U.S. FDA Approves Prevnar 20, Pfizer's 20-Valent Pneumococcal Conjugate Vaccine for Infants and Children

Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) Tablets and Oral Granules
Patient Population Altered: April 26, 2023
Date of Original Approval: October 21, 2019
Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) is a triple combination regimen for the treatment of cystic fibrosis (CF) in patients ages 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data.
Vertex Announces U.S. FDA Approval for Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) in Children With Cystic Fibrosis Ages 2 Through 5 With Certain Mutations

Hizentra (immune globulin subcutaneous (human)) Liquid
New Formulation Approved: April 18, 2023
Date of Original Approval: March 4, 2010
Hizentra (immune globulin subcutaneous (human)) is an immune globulin indicated for the treatment of primary immunodeficiency, and for the maintenance treatment of chronic inflammatory demyelinating polyneuropathy.
CSL Behring Receives FDA Approval for Hizentra (Immune Globulin Subcutaneous [Human] 20% Liquid) 50mL Prefilled Syringe

Qulipta (atogepant) Tablets
New Indication Approved: April 17, 2023
Date of Original Approval: September 28, 2021
Qulipta (atogepant) is an oral, calcitonin gene-related peptide (CGRP) receptor antagonist approved to prevent episodic and chronic migraine.
U.S. FDA Approves Qulipta (atogepant) for Adults With Chronic Migraine

Tepezza (teprotumumab-trbw) Injection
Labeling Revision Approved: April 13, 2023
Date of Original Approval: January 21, 2020
Tepezza (teprotumumab-trbw) is a fully human monoclonal antibody (mAb) and a targeted inhibitor of the insulin-like growth factor 1 receptor (IGF-1R) for the treatment of active thyroid eye disease (TED).
Horizon Therapeutics plc Announces FDA Approval of an Update to the Indication Language for Tepezza (teprotumumab-trbw) to Specify its Use in Thyroid Eye Disease (TED) Patients Regardless of Disease Activity or Duration

Hyqvia (immune globulin and hyaluronidase) Solution for Subcutaneous Administration
Patient Population Altered: April 7, 2023
Date of Original Approval: September 12, 2014
Hyqvia (immune globulin and hyaluronidase) is an immune globulin with a recombinant human hyaluronidase indicated for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older.
Takeda Receives FDA Approval to Expand the Use of Hyqvia to Treat Primary Immunodeficiency in Children

Keytruda (pembrolizumab) for Injection
New Indication Approved: April 3, 2023
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.
FDA Approves Merck's Keytruda (pembrolizumab) in Combination With Padcev (enfortumab vedotin-ejfv) for First-Line Treatment of Certain Patients With Locally Advanced or Metastatic Urothelial Cancer

Narcan (naloxone) Nasal Spray
Labeling Revision Approved: March 29, 2023
Date of Original Approval: November 18, 2015
Narcan Nasal Spray (naloxone) is an intranasal opioid antagonist formulation indicated for the emergency treatment of known or suspected opioid overdose.

U.S. FDA Approves Over-the-Counter Designation for Emergent BioSolutions' Narcan Nasal Spray, a Historic Milestone for the Opioid Overdose Emergency Treatment

Keytruda (pembrolizumab) for Injection
Labeling Revision Approved: March 28, 2023
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.
FDA Converts to Full Approval Indication for Keytruda (pembrolizumab) for Certain Adult and Pediatric Patients With Advanced Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors

Evkeeza (evinacumab-dgnb) Injection
Patient Population Altered: March 21, 2023
Date of Original Approval: February 11, 2021
Evkeeza (evinacumab-dgnb) is an angiopoietin-like 3 (ANGPTL3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH).
FDA Approves First-in-class Evkeeza (evinacumab-dgnb) for Young Children with Ultra-Rare Form of High Cholesterol

Hyrimoz (adalimumab-adaz) Injection
New Formulation Approved: March 20, 2023
Date of Original Approval: October 30, 2018
Hyrimoz (adalimumab-adaz) is an anti-TNF-α monoclonal antibody biosimilar to Humira, approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, and hidradenitis suppurativa.
Sandoz Receives US FDA Approval for Biosimilar Hyrimoz (adalimumab-adaz) High-Concentration Formulation

Tafinlar (dabrafenib) Capsules and Tablets for Oral Suspension
New Indication Approved: March 16, 2023
Date of Original Approval: May 29, 2013
Tafinlar (dabrafenib) is a kinase inhibitor for the treatment of melanoma, non-small cell lung cancer, thyroid cancer, solid tumors, and low-grade glioma with BRAF V600 mutations.
Novartis Tafinlar + Mekinist Approved by FDA for Pediatric Patients with BRAF V600E Low-Grade Glioma

Illuccix (gallium Ga 68 gozetotide) Injection Kit
Patient Population Altered: March 15, 2023
Date of Original Approval: December 17, 2021
Illuccix (gallium Ga 68 gozetotide) is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer.
FDA Approves Expanded Indication for Telix's Illuccix to Include Patient Selection for PSMA-Directed Radioligand Therapy

Verzenio (abemaciclib) Tablets
New Indication Approved: March 3, 2023
Date of Original Approval: September 28, 2017
Verzenio (abemaciclib) is a selective ATP-competitive 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.
FDA Broadens Indication for Verzenio (abemaciclib) in HR+, HER2-, Node-Positive, High Risk Early Breast Cancer

Kevzara (sarilumab) Injection
New Indication Approved: February 28, 2023
Date of Original Approval: May 22, 2017
Kevzara (sarilumab) is an interleukin-6 (IL-6) receptor antagonist for the treatment of rheumatoid arthritis and polymyalgia rheumatica.
Kevzara (sarilumab) Approved by FDA as First and Only Biologic Indicated for Patients with Polymyalgia Rheumatica

Austedo XR (deutetrabenazine) Extended-Release Tablets
New Formulation Approved: February 17, 2023
Date of Original Approval: February 17, 2023
Austedo XR (deutetrabenazine) is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated in adults for the treatment of tardive dyskinesia, and chorea associated with Huntington's disease.

Teva Announces FDA Approval of Austedo XR (deutetrabenazine) Extended-Release Tablets, a New Once-Daily Formulation of Austedo

Jemperli (dostarlimab-gxly) Injection
Labeling Revision Approved: February 9, 2023
Date of Original Approval: April 22, 2021
Jemperli (dostarlimab-gxly) is a programmed death receptor-1 (PD-1)–blocking antibody for the treatment of mismatch repair deficient (dMMR) endometrial cancer, and dMMR solid tumors.
US FDA Grants Regular Approval for Jemperli for the Treatment of Patients with Recurrent or Advanced Mismatch Repair-Deficient Endometrial Cancer

Cibinqo (abrocitinib) Tablets
Patient Population Altered: February 9, 2023
Date of Original Approval: January 14, 2022
Cibinqo (abrocitinib) is a Janus kinase (JAK) 1 inhibitor for the treatment of moderate-to-severe atopic dermatitis.
FDA Approves Pfizer's Supplemental New Drug Application for Cibinqo (abrocitinib) to Include Adolescents with Moderate-to-Severe Atopic Dermatitis

Eylea (aflibercept) Injection
New Indication Approved: February 8, 2023
Date of Original Approval: November 18, 2011
Eylea (aflibercept) is a VEGF inhibitor indicated for the treatment of patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and retinopathy of prematurity.
Eylea (aflibercept) Injection Approved as the First Pharmacologic Treatment for Preterm Infants with Retinopathy of Prematurity (ROP) by the FDA

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Trodelvy (sacituzumab govitecan-hziy) Injection
New Indication Approved: February 3, 2023
Date of Original Approval: April 22, 2020
Trodelvy (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate used for the treatment of breast cancer and urothelial cancer.
U.S. FDA Approves Trodelvy in Pre-treated HR+/HER2- Metastatic Breast Cancer

Takhzyro (lanadelumab-flyo) Injection
Patient Population Altered: February 3, 2023
Date of Original Approval: August 23, 2018
Takhzyro (lanadelumab-flyo) is a plasma kallikrein inhibitor (monoclonal antibody) for the prevention of angioedema attacks in patients with hereditary angioedema.
U.S. FDA Approves Takeda's Takhzyro (lanadelumab-flyo) to Prevent Hereditary Angioedema (HAE) Attacks in Children 2 Years of Age and Older

Tezspire (tezepelumab-ekko) Injection
New Dosage Regimen: February 1, 2023
Date of Original Approval: December 17, 2021
Tezspire (tezepelumab-ekko) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
Tezspire Approved for Self-Administration in the U.S. With a New Pre-filled Pen

References: www.drugs.com/new-indications

Current Health News

Frequent Use of Antibiotics Linked With Higher Odds for Crohn's, Colitis
By Steven Reinberg HealthDay Reporter
FRIDAY, Jan. 13, 2023 -- Overuse of antibiotics may trigger inflammatory bowel disease (IBD), new research suggests.
Among folks who were 40 or older, a new study found that antibiotics may increase the risk for bowel diseases, such as Crohn's and ulcerative colitis, for one to two years after use.

Social Isolation Can Raise Odds for Dementia
By Cara Murez HealthDay Reporter
FRIDAY, Jan. 13, 2023 -- Social isolation is a substantial risk factor for dementia in older adults, according to a pair of studies that add evidence to past research on this threat.
But these new studies offer a potential solution: using technology to encourage older adults to text and email to stay in touch.

Artificial Pancreas Device May Help Folks With Type 2 Diabetes
By Denise Mann HealthDay Reporter
FRIDAY, Jan. 13, 2023 -- An artificial pancreas has long been considered the holy grail for people with type 1 diabetes, and new research suggests a more convenient version of this technology may help the millions of people living with type 2 diabetes.
Type 2 is the more common form of diabetes, and is closely linked to obesity.

DNA Fragments in Blood Promise Cheap, Easy Test for Cancer
By Amy Norton HealthDay Reporter
THURSDAY, Jan. 12, 2023 -- Researchers are reporting progress on a blood test that can detect multiple cancers in a relatively simpler, and potentially less pricey, way than other tests under development.

Long COVID After Mild Infection? It Fades Within a Year
By Denise Mann HealthDay Reporter
THURSDAY, Jan. 12, 2023 -- A large, new study offers reassuring news for folks dealing with long COVID symptoms such as trouble breathing, mental fog and loss of taste or smell: Most of these issues resolve within a year for those who had a mild COVID infection.

Fast Food May Be Toxic to Your Liver
By Cara Murez HealthDay Reporter
THURSDAY, Jan. 12, 2023 -- Do your liver a favor and steer clear of fast food, new research urges.
People with obesity or diabetes who consumed 20% or more of their daily calories from fast food had severely elevated levels of fat in their liver compared to those who ate less fast food or none.

Uric Acid Linked to Later Risk For Irregular Heart Rhythm
By American Heart Association News
THURSDAY, Jan. 12, 2023 (American Heart Association News) -- High levels of uric acid in midlife may significantly raise the risk for a serious type of irregular heartbeat in the decades that follow, even in people without traditional risk factors, new research shows.

FDA Approves New 2-Drug Combo Medicine, Airsupra, for Asthma
By Cara Murez HealthDay Reporter
THURSDAY, Jan. 12, 2023 -- Adults with asthma now have a new rescue medication to turn to after the U.S. Food and Drug Administration approved Airsupra on Wednesday.
The drug is the first approved to combine albuterol (a beta-2 adrenergic agonist) and budesonide (a corticosteroid).
It's meant for the as-needed treatment or prevention of bronchoconstriction (narrowed airways) and to reduce the risk of asthma attacks in patients with asthma aged 18 and older.

Happy, Loved Teens Become Heart-Healthier as Adults
By Amy Norton HealthDay Reporter
WEDNESDAY, Jan. 11, 2023 -- When teenagers feel good about themselves and their lives, it may also do their hearts good in the long run, a new study suggests.
Researchers found that teenagers who generally felt happy, optimistic and loved went on to show better cardiovascular health in their 20s and 30s, versus kids who lacked that level of mental well-being.

Kids Living Near Airports Face Lead Poisoning Dangers
By Cara Murez HealthDay Reporter
WEDNESDAY, Jan. 11, 2023 -- While U.S. policymakers have attempted to lower lead exposure among children since the 1970s, new research finds that kids living near airports are still being exposed to dangerous levels of the heavy metal.

'Cellular Atlas' Could Be Step Against Endometriosis

By Cara Murez HealthDay Reporter

WEDNESDAY, Jan. 11, 2023 -- Few good treatment options exist for the millions of women dealing with the intense pain caused by endometriosis, but researchers say a new "cellular atlas" could help.

Blood Test Might Warn of Dangerous Complication of Pregnancy

By Dennis Thompson HealthDay Reporter

TUESDAY, Jan. 10, 2023 -- An experimental blood test could one day provide early warning for a life-threatening complication of pregnancy, a new study reports.

Placenta accreta occurs when the placenta — the food and oxygen source for a fetus — grows too deeply into the wall of a woman’s uterus.

Sleep Key to Good Mental Health for Older Women

By Denise Mann HealthDay Reporter

MONDAY, Jan. 9, 2023 -- Older women who don’t stick to a set sleep and wake schedule may be more likely to struggle with feelings of depression and anxiety.

Does Your Home Have Dangerous Levels of Cancer-Causing Radon?

By Cara Murez HealthDay Reporter

FRIDAY, Jan. 6, 2023 -- People should test for the naturally occurring radioactive gas radon in their homes to help prevent ill health, the American Lung Association urges.

Good Parental Leave Gives Big Boost to Moms' Mental Health

By Denise Mann HealthDay Reporter

THURSDAY, Jan. 5, 2023 -- Generous parental leave policies at work can do wonders for a new mom's mental health.

This is among the key messages from a new review of 45 studies examining how parental leave policies affect mom and dad’s mental health and well-being.

References: www.drugs.com/news

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