New Drug Approvals

Rylaze (Asparaginase Erwinia chrysanthemi **(recombinant) Injection**
Company: Jazz Pharmaceuticals plc
Date of Approval: June 30, 2021
Treatment for: Acute Lymphoblastic Leukemia
Rylaze (Asparaginase Erwinia chrysanthemi (recombinant) is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL).

Verkazia (cyclosporine) Ophthalmic Emulsion
Company: Santen Inc.
Date of Approval: June 23, 2021
Treatment for: Vernal Keratoconjunctivitis
Verkazia (cyclosporine) is a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

Astepro Allergy (azelastine) Nasal Spray
Company: Bayer HealthCare Pharmaceuticals Inc.
Date of Approval: June 17, 2021
Treatment for: Allergic Rhinitis
Astepro Allergy (azelastine) is a nasal antihistamine for the treatment of seasonal allergic rhinitis.

Rezipres (ephedrine hydrochloride) Injection
Company: Eton Pharmaceuticals, Inc.
Date of Approval: June 14, 2021
Treatment for: Hypotension
Rezipres (ephedrine hydrochloride) is an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

Soaanz (torsemide) Tablets
Company: Sarfez Pharmaceuticals
Date of Approval: June 14, 2021
Treatment for: Edema
Soaanz (torsemide) is a loop diuretic indicated for the treatment of edema associated with heart failure or renal disease in adults.

Prevnar 20 (pneumococcal 20-valent conjugate vaccine) Injection
Company: Pfizer Inc.
Date of Approval: June 8, 2021
Treatment for: Pneumococcal Disease Prophylaxis
Prevnar 20 (pneumococcal 20-valent conjugate vaccine) is a vaccine indicated for active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older.

Aduhelm (aducanumab-avwa) Injection
Company: Biogen
Date of Approval: June 7, 2021
Treatment for: Alzheimer's Disease
Aduhelm (aducanumab-avwa) is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease.This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aduhelm. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Wegovy (semaglutide) Injection
Company: Novo Nordisk
Date of Approval: June 4, 2021
Treatment for: Obesity
Wegovy (semaglutide) is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise for chronic weight management in adult patients who are overweight (BMI $\geq$27 kg/m^2) or obese (BMI $\geq$30 kg/m^2).

Ryplazim (plasminogen, human-tvmh) Injection
Company: Liminal BioSciences Inc.
Date of Approval: June 4, 2021
Treatment for: Plasminogen Deficiency Type 1
Ryplazim (plasminogen, human-tvmh) is a plasma-derived plasminogen replacement therapy for the

treatment of patients with plasminogen deficiency type 1 (hypoplasminogenia).

Tembexa (brincidofovir) Tablets and Oral Suspension
Company: Chimerix, Inc.
Date of Approval: June 4, 2021
Treatment for: Smallpox
Tembexa (brincidofovir) is a nucleotide analog broad-spectrum antiviral indicated for use as a medical countermeasure for smallpox.

Brexafemme (ibrexafungerp) Tablets
Company: Scynexis, Inc.
Date of Approval: June 1, 2021
Treatment for: Vaginal Candidiasis
Brexafemme (ibrexafungerp) is a first-in-class, triterpenoid antifungal agent for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).

Lumakras (sotorasib) Tablets
Company: Amgen Inc.
Date of Approval: May 28, 2021
Treatment for: Non-Small Cell Lung Cancer
Lumakras (sotorasib) is a $KRAS^{G12C}$ inhibitor for the treatment of patients with *KRAS G12C*-mutated locally advanced or metastatic non- small cell lung cancer (NSCLC), following at least one prior systemic therapy.

Truseltiq (infigratinib) Capsules
Company: Bridge BioPharma, Inc.
Date of Approval: May 28, 2021
Treatment for: Cholangiocarcinoma
Truseltiq (infigratinib) is an FGFR tyrosine kinase inhibitor indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

Lybalvi (olanzapine and samidorphan) Tablets
Company: Alkermes, Inc.
Date of Approval: May 28, 2021
Treatment for: Schizophrenia, Bipolar Disorder
Lybalvi (olanzapine and samidorphan) is a combination of an established antipsychotic agent (olanzapine) and a novel μ-opioid receptor antagonist (samidorphan) for the treatment of schizophrenia and bipolar I disorder.

Myfembree (relugolix, estradiol and norethindrone acetate) Tablets
Company: Myovant Sciences
Date of Approval: May 26, 2021
Treatment for: Uterine Fibroids
Myfembree (relugolix, estradiol and norethindrone acetate) is an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, estrogen, and progestin combination indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Camcevi (leuprolidemesylate) Injection
Company: Foresee Pharmaceuticals
Date of Approval: May 26, 2021
Treatment for: Prostate Cancer
Camcevi (leuprolidemesylate) is a ready-to-use, 6-month depot formulation of the approved gonadotropin releasing hormone (GnRH) agonist leuprolide indicated for the treatment of adult patients with advanced prostate cancer.

Pylarify (piflufolastat F 18) Injection
Company: Progenics Pharmaceuticals, Inc.
Date of Approval: May 26, 2021
Treatment for: Positron Emission Tomography Imaging
Pylarify (piflufolastat F 18) is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer.

Rybrevant (amivantamab-vmjw) Injection
Company: Janssen Pharmaceuticals, Inc.
Date of Approval: May 21, 2021
Treatment for: Non-Small Cell Lung Cancer
Rybrevant (amivantamab-vmjw) is a bispecific EGF receptor-directed and MET receptor-directed antibody indicated for the treatment of adult patients

with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test.

Empaveli (pegcetacoplan) Injection
Company: Apellis Pharmaceuticals, Inc.
Date of Approval: May 14, 2021
Treatment for: Paroxysmal Nocturnal Hemoglobinuria
Empaveli (pegcetacoplan) is a targeted C3 inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria (PNH).

Zynrelef (bupivacaine and meloxicam) Injection
Company: Heron Therapeutics, Inc.
Date of Approval: May 12, 2021
Treatment for: Postoperative Pain
Zynrelef (bupivacaine and meloxicam) is an extended-release, fixed-dose combination of the local anesthetic bupivacaine and the nonsteroidal anti-inflammatory drug (NSAID) meloxicam indicated for the management of postoperative pain.

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First-Time Generic Approvals

Tofacitinib
Brand name: *Xeljanz, Xeljanz XR*
Dosage forms: oral solution (1 mg/mL); oral tablet (10 mg; 5 mg); oral tablet, extended release (11 mg; 22 mg)
Drug class: Antirheumatics
Tofacitinib is used to treat moderate to severe rheumatoid arthritis or active psoriatic arthritis in adults who have tried methotrexate or other medications without successful treatment of symptoms. Tofacitinib is sometimes given in combination with methotrexate or other arthritis medicines.

Lopinavir and Ritonavir
Brand name: *Kaletra*
Dosage forms: oral liquid (400 mg-100 mg/5 mL); oral tablet (100 mg-25 mg; 200 mg-50 mg)
Drug class: Protease inhibitors
Lopinavir and ritonavir is a combination antiviral medicine used to treat human immunodeficiency virus (HIV), the virus that can cause acquired immunodeficiency syndrome (AIDS). lopinavir and ritonavir is not a cure for HIV or AIDS.

Etravirine
Brand name: *Intelence*
Dosage forms: Oral tablet (100 mg; 200 mg; 25 mg)
Drug class: NNRTIs
Etravirine is an antiviral medicine that is used with other medicines to treat human immunodeficiency virus (HIV). HIV causes the acquired immunodeficiency syndrome (AIDS). Etravirine is not a cure for HIV or AIDS.

Formoterol (inhalation)
Brand name: *Perforomist, Foradil Aerolizer*
Dosage forms: Inhalation Solution (20 mcg/2 mL)
Drug class: Adrenergic bronchodilators
Formoterol inhalation is used to control the symptoms of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Arformoterol Inhalation
Brand name: *Brovana*
Dosage forms: Inhalation Solution (15 mcg/2 mL)
Drug class: Adrenergic bronchodilators
Arformoterol inhalation is used to help control the symptoms of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Enzalutamide
Brand name: *Xtandi*
Dosage forms: Oral Capsule (40 mg); oral tablet (40 mg; 80 mg)
Drug class: Antiandrogens, Hormones / antineoplastics
Enzalutamide is a prescription medicine used to treat prostate cancer in men who have received surgery or hormone therapy to lower testosterone.

Lenalidomide
Brand name: *Revlimid*
Dosage forms: Oral Capsule (10 mg; 15 mg; 2.5 mg; 20 mg; 25 mg; 5 mg)
Drug class: Miscellaneous antineoplastics, Other immunosuppressants
Lenalidomide is used to treat multiple myeloma (bone marrow cancer), either in combination with another medicine or after stem cell transplant.

Deoxycholic Acid
Brand name: *Kybella*
Dosage forms: Subcutaneous Solution (10 mg/mL)
Drug class: Miscellaneous uncategorized agents
Deoxycholic acid is a manmade form of a substance your body makes that helps to absorb fats. Deoxycholic acid works by destroying fat cells where it is injected into the body.

Macitentan
Brand name: *Opsumit*
Dosage forms: Oral Tablet (10 mg)
Drug class: Agents for pulmonary hypertension

Macitentan lowers blood pressure in your lungs, helping your heart pump blood more efficiently. Macitentan is used to treat pulmonary arterial hypertension (PAH). It improves your ability to exercise and prevents your condition from getting worse.

Tiopronin
Brand name: *Thiola, Thiola EC*
Dosage forms: oral delayed release tablet (100 mg; 300 mg); oral tablet (100 mg)

Drug class: Miscellaneous genitourinary tract agents
Tiopronin is used together with diet, fluids, and other medicines to help prevent kidney stones in adults and children weighing at least 44 pounds (20 kilograms).

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New Indications & Dosage Forms for Existing Drugs

Pradaxa (dabigatranetexilate) Capsules and Oral Pellets

Patient Population Altered: June 21, 2021
Date of Original Approval: October 19, 2010

Pradaxa (dabigatranetexilate) is a direct thrombin inhibitor.

Pradaxa capsules are indicated:

- to reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation
- for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5-10 days
- to reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated
- for the prophylaxis of DVT and PE in adult patients who have undergone hip replacement surgery
- for the treatment of venous thromboembolic events (VTE) in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days
- to reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated.

Pradaxa oral pellets are indicated:

- for the treatment of venous thromboembolic events (VTE) in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days
- to reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated.

Ayvakit (avapritinib) Tablets

New Indication Approved: June 16, 2021
Date of Original Approval: January 9, 2020

Ayvakit (avapritinib) is a kinase inhibitor for the treatment of PDGFRα exon 18 mutant gastrointestinal stromal tumors (GIST), and advanced systemic mastocytosis (AdvSM).

Epclusa (sofosbuvir and velpatasvir) Tablets and Oral Pellets

New Dosage Form Approved: June 10, 2021
Date of Original Approval: June 28, 2016

Epclusa (sofosbuvir and velpatasvir) is a nucleotide analog polymerase inhibitor and pan-genotypic NS5A inhibitor fixed-dose combination for the treatment of chronic genotype 1-6 hepatitis C virus (HCV) infection.

Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) Tablets

Patient Population Altered: June 8, 2021
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 6 years and older who have at least one copy of the *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.

Ultomiris (ravulizumab-cwvz) Injection

Patient Population Altered: June 7, 2021
Date of Original Approval: December 21, 2018

Ultomiris (ravulizumab-cwvz) is a long-acting C5 complement inhibitor for:

- the treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)
- the treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

Cosentyx (secukinumab) Injection

Patient Population Altered: May 28, 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.

Nurtec ODT (rimegepant) Orally Disintegrating Tablets (ODT)

New Indication Approved: May 27, 2021
Date of Original Approval: February 27, 2020

Nurtec ODT (rimegepant) is an orally-dosed calcitonin gene-related peptide (CGRP) receptor antagonist for the acute treatment of migraine with or without aura, and the preventive treatment of episodic migraine, in adults.

Zeposia (ozanimod) Capsules

New Indication Approved: May 27, 2021
Date of Original Approval: March 25, 2020

Zeposia (ozanimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults; and moderately to severely active ulcerative colitis (UC) in adults.

Nuzyra (omadacycline) Tablets and Lyophilized Powder for Injection

New Dosage Regimen: May 27, 2021
Date of Original Approval: October 2, 2018

Nuzyra (omadacycline) is an aminomethylcycline tetracycline antibiotic for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

Opdivo (nivolumab) Injection

New Indication Approved: May 20, 2021
Date of Original Approval: December 22, 2014

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

KedRAB (rabies immunoglobulin human) Injection

Patient Population Altered: May 17, 2021
Date of Original Approval: August 23, 2017

KedRAB [rabies immunoglobulin (human)] is a human plasma derived anti-rabies immunoglobulin indicated for post-exposure prophylaxis (PEP) of rabies infection.

Keytruda (pembrolizumab) for Injection

New Indication Approved: May 5, 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 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.

Ferriprox (deferiprone) Tablets and Oral Solution

New Indication Approved: May 1, 2021
Date of Original Approval: October 14, 2011

Ferriprox (deferiprone) is an iron chelator indicated for the treatment of transfusional iron overload in:

- thalassemia syndromes
- sickle cell disease or other anemias.

Ferriprox Tablets are indicated in adult and pediatric patients ≥8 years of age and Ferriprox Oral Solution is indicated in patients ≥3 years of age.

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Current Health News

Too Little Sunlight, Vitamin D May Raise Colon Cancer Risk

MONDAY, July 5, 2021 -- New research finds that countries with more cloudy days tend to have higher colon cancer rates. Lower levels of vitamin D, the "sunshine vitamin," may be to blame. So, boosting your vitamin D levels through exposure to sunlight could help reduce your risk of colon cancer, according to researchers at the University of California, San Diego.

Hearing Impairment Tied to Poorer Physical Function

FRIDAY, July 2, 2021 -- Hearing impairment is associated with significantly poorer physical function and faster declines in physical function among older people over time compared with those with normal hearing, according to a study published online June 25 in *JAMA Network Open*.

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