

## 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.

### **Soanz (torsemide) Tablets**

**Company:** Sarfez Pharmaceuticals

**Date of Approval:** June 14, 2021

**Treatment for:** Edema

Soanz (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<sup>2</sup>) or obese (BMI  $\geq 30$  kg/m<sup>2</sup>).

### **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<sup>G12C</sup> 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  $\mu$ -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.

**Rybrevent (amivantamab-vmjw) Injection**

**Company:** Janssen Pharmaceuticals, Inc.

**Date of Approval:** May 21, 2021

**Treatment for:** Non-Small Cell Lung Cancer

Rybrevent (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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