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 ≥27 kg/m²) or obese (BMI ≥30 kg/m²).

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-menarcheal 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).

**Zynrelf (bupivacaine and meloxicam) Injection**  
**Company:** Heron Therapeutics, Inc.  
**Date of Approval:** May 12, 2021  
**Treatment for:** Postoperative Pain

Zynrelf (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.

Information collected and compiled by:  
Md. Akbar Hossain  
Department of Pharmacy  
ASA University of Science and Technology Bangladesh  
Dhaka, Bangladesh