

## New Drug Approvals

### 1. Ayvakit (avapritinib)

**Company:** Blueprint Medicines Corporation

**Date of Approval:** January 9, 2020

**Treatment for:** Gastrointestinal Stromal Tumor

Ayvakit (avapritinib) is a potent and highly selective KIT and PDGFR $\alpha$  inhibitor for the treatment of PDGFR $\alpha$  Exon 18 mutant gastrointestinal stromal tumors (GIST) and fourth-line GIST.

### 2. Caplyta (lumateperone) Capsules

**Company:** Intra-Cellular Therapies, Inc.

**Date of Approval:** December 23, 2019

**Treatment for:** Schizophrenia

Caplyta (lumateperone) is first-in-class antipsychotic for the treatment of schizophrenia.

### 3. Ubrelvy (ubrogepant) Tablets

**Company:** Allergan plc

**Date of Approval:** December 23, 2019

**Treatment for:** Migraine

Ubrelvy (ubrogepant) is a potent, orally-administered CGRP receptor antagonist for the acute treatment of migraine.

### 4. Enhertu (fam-trastuzumab deruxtecan-nxki) Injection

**Company:** AstraZeneca and Daiichi Sankyo Company, Limited

**Date of Approval:** December 20, 2019

**Treatment for:** Breast Cancer

Enhertu (fam-trastuzumab deruxtecan-nxki) is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

### 5. Dayvigo (lemborexant) Tablets

**Company:** Eisai Inc.

**Date of Approval:** December 20, 2019

**Treatment for:** Insomnia

Dayvigo (lemborexant) is dual orexin receptor antagonist (DORA) for the treatment of insomnia.

### 6. Conjupri (levamlodipine maleate) Tablets

**Company:** CSPC Pharmaceutical Group Limited

**Date of Approval:** December 19, 2019

**Treatment for:** Hypertension

Conjupri (levamlodipine maleate) is a calcium channel blocker indicated for the treatment of hypertension.

### 7. Ervebo (ebola zaire vaccine, live) Injection - formerly V920

**Company:** Merck

**Date of Approval:** December 19, 2019

**Treatment for:** Prevention of Ebola Zaire Disease

Ervebo (ebola zaire vaccine, live) is a vaccine indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older.

### 8. Arazlo (tazarotene) Lotion

**Company:** Bausch Health Companies Inc.

**Date of Approval:** December 18, 2019

**Treatment for:** Acne

Arazlo (tazarotene) is a lotion formulation of the approved retinoid tazarotene for the topical treatment of acne vulgaris in patients 9 years of age and older.

### 9. Padcev (enfortumab vedotin-efyv) for Injection

**Company:** Astellas and Seattle Genetics

**Date of Approval:** December 18, 2019

**Treatment for:** Urothelial Carcinoma

Padcev (enfortumab vedotin-efyv) is a Nectin-4 targeted antibody-drug conjugate (ADC) for the treatment of patients with locally advanced or metastatic urothelial cancer.

### 10. Nouress (cysteine hydrochloride) Injection

**Company:** Avadel Pharmaceuticals plc

**Date of Approval:** December 13, 2019

Nouress (cysteine hydrochloride) is a sulfur-containing amino acid indicated for use as an additive to amino acids solutions to meet nutritional requirements of neonates requiring total parenteral nutrition.

**11. Vyondys 53 (golodirsen) Injection****Company:** Sarepta Therapeutics**Date of Approval:** December 12, 2019**Treatment for:** Duchenne Muscular Dystrophy

Vyondys 53 (golodirsen) is a phosphordiamidate morpholino oligimer for the treatment of Duchenne muscular dystrophy (DMD) in patients with a confirmed mutation amenable to exon 53 skipping.

**12. EluRyng (ethinyl estradiol and etonogestrel) Vaginal Ring****Company:** Amneal Pharmaceuticals LLC**Date of Approval:** December 11, 2019**Treatment for:** Contraception

EluRyng (ethinyl estradiol/etonogestrel vaginal ring) is an estrogen/progestin combination hormonal contraceptive (CHC) indicated for use by women to prevent pregnancy.

**13. Avsola (infliximab-axxq) Injection****Company:** Amgen Inc.**Date of Approval:** December 6, 2019**Treatment for:** Crohn's disease, Maintenance, Ulcerative Colitis, Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Plaque Psoriasis

Avsola (infliximab-axxq) is a tumor necrosis factor (TNF) blocker biosimilar to Remicade indicated for the treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis.

**14. RediTrex (methotrexate) Injection****Company:** Cumberland Pharmaceuticals Inc.**Date of Approval:** November 27, 2019**Treatment for:** Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriasis

RediTrex (methotrexate) is a folate analog metabolic inhibitor indicated for the management of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), and psoriasis.

**15. Oxbryta (voxelotor) Tablets****Company:** Global Blood Therapeutics, Inc.**Date of Approval:** November 25, 2019**Treatment for:** Sickle Cell Anemia

Oxbryta (voxelotor) is an oral, HbS (sickle hemoglobin) polymerization inhibitor for the treatment of patients with sickle cell disease (SCD).

**16. Exservan (riluzole) Oral Film****Company:** Aquestive Therapeutics, Inc.**Date of Approval:** November 22, 2019**Treatment for:** Amyotrophic Lateral Sclerosis

Exservan (riluzole) an oral film formulation of the approved glutamate Inhibitor riluzole for the treatment of patients with amyotrophic lateral sclerosis (ALS) patients who have difficulty swallowing.

**17. Xcopri (cenobamate) Tablets****Company:** SK Life Science, Inc.**Date of Approval:** November 21, 2019**Treatment for:** Seizures

Xcopri (cenobamate) is an antiepileptic drug for the treatment of partial-onset seizures in adult patients.

**18. Givlaari (givosiran) Injection****Company:** Alnylam Pharmaceuticals, Inc.**Date of Approval:** November 20, 2019**Treatment for:** Acute Hepatic Porphyria

Givlaari (givosiran) is an aminolevulinate synthase 1-directed small interfering RNA (siRNA) indicated for the treatment of adults with acute hepatic porphyria (AHP).

**19. Adakveo (crizanlizumab-tmca) Injection****Company:** Novartis Pharmaceuticals Corporation**Date of Approval:** November 15, 2019**Treatment for:** Prevention of Vaso-Occlusive Crises (VOCs) in Sickle Cell Disease

Adakveo (crizanlizumab-tmca) is a P-selectin inhibitor for the prevention of vaso-occlusive crises (VOCs) in patients with sickle cell disease (SCD).

**20. Abrilada (adalimumab-afzb) Injection****Company:** Pfizer Inc.**Date of Approval:** November 15, 2019**Treatment for:** Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's disease, maintenance, Ulcerative Colitis, Plaque Psoriasis

Abrilada (adalimumab-afzb) is a tumor necrosis factor (TNF) blocker biosimilar to Humira indicated for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn's disease

(CD), ulcerative colitis (UC), and plaque psoriasis (Ps).

*References: [www.drugs.com](http://www.drugs.com)*

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