



# AU InforMed

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*Guest Editors:*

Courtney McDonald, Hannah Smith, and Susannah Sport, Pharm.D. Candidates 2020

## New Drugs Approved in 2019

Generic Name Trade Name (Manufacturer)	Category	Use	Route	Warnings	Review Classification *
<b>afamelanotide</b> Scenesse® (Clinuvel)	Melanocortin 1 receptor agonist	Increase pain-free light exposure in patients with history of phototoxic reactions due to erythropoietic protoporphyria	Subcutaneous Implant	– Skin monitoring	O, P
<b>air polymer-type A</b> ExEm Foam® (Giskit B.V.)	Ultrasound Contrast Agent	Imaging, Contrast	Foam, Intrauterine	– Risk for fetal harm: Confirm negative pregnancy test within the 24 hours before ExEm® Foam administration and confirm patient is in pre-ovulatory phase of menstrual cycle (cycle days 6 through 11) – Risk for Post-Procedure Gynecologic Infections: Do not use if contraindicated even if patient is receiving antimicrobial therapy.	S
<b>apelisib</b> Piqray® (Novartis)	Kinase Inhibitor	HR positive, HER-2 negative, PIK3CA-mutated, advanced or metastatic breast cancer.	Oral	– Severe hypersensitivity reactions – Severe cutaneous reactions – Hyperglycemia – Pneumonitis – Diarrhea – Embryo-fetal toxicity	P
<b>bremelanotide</b> Vyleesi™ (AMAG)	Melanocortin Receptor Agonist	Hypoactive sexual desire disorder in premenopausal women	Subcutaneous Injection	– Transient increase in blood pressure and decrease in heart rate – Focal hyperpigmentation – Nausea	S
<b>brexanolone</b> Zulresso™ (Sage Therapeutics)	Gamma-Aminobutyric Acid A Receptor Positive Modulator	Postpartum Depression	Intravenous	– Suicidal thoughts and behaviors	B, P
<b>brilliant blue G ophthalmic Solution</b> TissueBlue (Dutch Ophthalmic)	Ophthalmic Agent	Stains the internal limiting membrane	Ophthalmic topical solution	– Excessive staining	O, P

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<b>brolocizumab-dbli</b> Beovu® (Novartis)	Human vascular endothelial growth factor inhibitor	Neovascular age-related macular degeneration	Intravitreal injection	<ul style="list-style-type: none"> <li>– Endophthalmitis and retinal detachments</li> <li>– Increases intraocular pressure</li> <li>– Potential risk for arterial thromboembolic events</li> </ul>	N/A
<b>caplacizumab-yhdp</b> Cabliivi® (Ablynx)	Anti-von Willebrand Factor	Acquired thrombotic thrombocytopenic purpura	Intravenous and Subcutaneous Injection	<ul style="list-style-type: none"> <li>– Bleeding</li> </ul>	O
<b>cefiderocol</b> Fetroja® (Shionogi)	Antibiotic, Cephalosporin	Complicated Urinary Tract Infection (including Pyelonephritis)	Intravenous	<ul style="list-style-type: none"> <li>– Increase in all-cause mortality in patients with a resistance to carbapenems</li> <li>– Gram-negative bacterial infections</li> <li>– Hypersensitivity Reactions</li> </ul>	P
<b>cenobamate</b> Xcopri® (SK Life Science)	Anticonvulsant	Partial-onset seizure	Oral	<ul style="list-style-type: none"> <li>– Drug reaction with eosinophilia and systemic symptoms (DRESS)/Multi-organ hypersensitivity</li> <li>– QT shortening</li> <li>– Suicidal ideation/behavior</li> <li>– Neurological adverse reactions</li> <li>– Withdrawal of antiepileptic drugs</li> </ul>	S
<b>crizanlizumab-tmca</b> Adakveo® (Novartis)	Selectin blocker	Reduce the frequency of vaso-occlusive crises in patients with sickle cell	Intravenous	<ul style="list-style-type: none"> <li>– Infusion-related reactions</li> <li>– Interference with automated platelet counts (platelet clumping)</li> </ul>	B, O, P
<b>darolutamide</b> Nubeqa™ (Bayer)	Androgen receptor inhibitor	Non-metastatic castration resistant prostate cancer	Oral	<ul style="list-style-type: none"> <li>– Embryo-fetal toxicity</li> </ul>	Fa, P
<b>elexacaftor + ivacaftor + tezacaftor</b> Trikafta™ (Vertex)	Cystic fibrosis transmembrane conductance regulator corrector	Cystic Fibrosis	Oral	<ul style="list-style-type: none"> <li>– Elevated liver function tests</li> </ul>	B, Fa, O, P
<b>enfortumab vedotin-ejfv</b> Padcev™ (Astellas)	Nectin-4-directed antibody and microtubule inhibitor conjugate	Urothelial cancer, locally, advanced, or metastatic	Intravenous	<ul style="list-style-type: none"> <li>– Hyperglycemia</li> <li>– Peripheral neuropathy</li> <li>– Ocular disorders</li> <li>– Skin reactions</li> <li>– Infusion site extravasation</li> <li>– Embryo-fetal toxicity</li> </ul>	A, B, P
<b>entrectinib</b> Rozlytrek™ (Genetech)	Kinase Inhibitor	Metastatic non-small cell lung cancer with ROS1-positive tumors; adult and pediatric 12 years and older with solid tumors	Oral	<ul style="list-style-type: none"> <li>– Congestive heart failure</li> <li>– CNS effects</li> <li>– Skeletal fractures</li> <li>– Hepatotoxicity</li> <li>– Hyperuricemia</li> <li>– QT interval prolongation</li> <li>– Vision disorders</li> <li>– Embryo-fetal toxicity</li> </ul>	A, B, O, P

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<b>erdafitinib</b> Balversa™ (Janssen)	Kinase Inhibitor	Locally advanced or metastatic urothelial carcinoma	Oral	<ul style="list-style-type: none"> <li>– Ocular disorders</li> <li>– Hyperphosphatemia</li> <li>– Embryo-fetal toxicity</li> </ul>	A
<b>fam-trastuzumab deruxtecan-nxki</b> Enhertu® (Daiichi Sanko)	HER2 Directed Antibody and Topoisomerase Inhibitor	Unresectable or Metastatic HER-2 Positive Breast Cancer	Intravenous	<ul style="list-style-type: none"> <li>– Neutropenia</li> <li>– Left Ventricular Dysfunction</li> </ul>	A, B, Fa
<b>fedratinib</b> Inrebic® (Celgene Corp.)	Kinase Inhibitor	Intermediate-2 or high risk primary or secondary myelofibrosis	Oral	<ul style="list-style-type: none"> <li>– Congestive Heart Failure</li> <li>– CNS effects</li> <li>– Skeletal fractures</li> <li>– Hepatotoxicity</li> <li>– Hyperuricemia</li> <li>– QT interval prolongation</li> <li>– Vision disorders</li> <li>– Embryo-fetal toxicity</li> </ul>	O, P
<b>ferric maltol</b> Accrufer™ (Shield Therapeutics)	Iron Replacement	Iron Deficiency Anemia	Oral	<ul style="list-style-type: none"> <li>– Irritable bowel disease flare</li> <li>– Iron overload</li> </ul>	S
<b>fluorodopa F 18</b> (The Feinstein Institutes)	Radioactive Diagnostic Agent	Positron emission tomography for Parkinson	Intravenous	<ul style="list-style-type: none"> <li>– Use smallest dose necessary for imaging and ensure safe handling to protect the patient and healthcare worker from radiation exposure</li> </ul>	S
<b>GA-88-DOTATOC</b> (UIHC PET Imaging)	Radioactive Diagnostic Agent	Positron emission tomography for localization of somatostatin receptor positive neuroendocrine tumors	Intravenous	<ul style="list-style-type: none"> <li>– Radiation risk</li> <li>– Risk for image misinterpretation</li> </ul>	O, P
<b>givosiran</b> Givlaari™ (Alnylam)	Aminolevulinatase Synthase 1-Directed Small Interfering RNA	Acute Hepatic Porphyria	Subcutaneous Injection	<ul style="list-style-type: none"> <li>– Anaphylactic reactions</li> <li>– Hepatic toxicity</li> <li>– Renal toxicity</li> <li>– Injection site reactions</li> </ul>	B, O, P
<b>golodisen</b> Vyondys 53™ (Septra Therapeutics)	Antisense oligonucleotide	Duchenne Muscular Dystrophy	Intravenous	<ul style="list-style-type: none"> <li>– Hypersensitivity Reactions</li> <li>– Renal Toxicity</li> </ul>	A, Fa, O, P
<b>imipenem + cilastatin + relebactam</b> Recarbrio™ (Merck)	Antibiotic Combination of a penem antibacterial cilastatin, a renal dehydropeptidase inhibitor, and a beta-lactamase inhibitor.	Complicated urinary tract infections; complicated intra-abdominal infections	Intravenous	<ul style="list-style-type: none"> <li>– Hypersensitivity Reactions</li> <li>– Seizures and CNS adverse reactions</li> <li>– Increased seizure potential due to interaction with valproic acid</li> <li>– <i>C. difficile</i> Associated Diarrhea</li> <li>– Dyskinesia, hallucinations/psychotic behavior, impulse control/compulsive behaviors</li> </ul>	P
<b>istradefylline</b> Nourianz™ (Kyowa Kirin)	Adenosine receptor antagonist	Parkinson's disease in patients experiencing "off" episodes	Oral	<ul style="list-style-type: none"> <li>– Dyskinesia</li> <li>– Hallucinations/psychotic behavior</li> <li>– Impulse control/compulsive behaviors</li> </ul>	S

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<b>lasmiditan</b> Reyvow™ (Eli Lilly)	Serotonin 1F Receptor Agonist	Migraine with or without aura	Oral	– Driving Impairment	S
<b>lefamulin</b> Xenleta™ (Nabriva)	Pleuromutilin Antibacterial	Community Acquired Bacterial Pneumonia	Oral, Intravenous	– QT Prolongation – Embryo-fetal toxicity – C. diff associated diarrhea	P
<b>lemborexant</b> Dayvigo™ (Eisai Inc.)	Orexin receptor antagonist	Insomnia	Oral	– CNS depressant effects and daytime impairment – Sleep paralysis – hypnagogic/hypnopompic hallucinations and cataplexy-like symptoms – Complex sleep behaviors – Compromised respiratory function – Worsening depression/suicidal ideation	S
<b>lumateperone tosylate</b> Caplyta® (Intra-Cellular Therapies)	Atypical Antipsychotic	Schizophrenia	Oral capsule	– Cerebrovascular adverse reactions in elderly patients with dementia- related psychosis – Neuroleptic malignant syndrome – Tardive dyskinesia – Metabolic changes: Hyperglycemia/Diabetes mellitus, dyslipidemia, weight gain – Leukopenia, neutropenia, agranulocytosis – Orthostatic hypertension – Seizures – Potential for cognitive or motor impairment	S
<b>luspatercept-aamt</b> Reblozyl® (Calgene)	Erythroid maturation agent	Anemia due to beta thalassemia	Subcutaneous Injection	– Thrombosis/Thromboembolism – Hypertension – Embryo-fetal toxicity	Fa, O
<b>pitolisant</b> Wakix® (Harmony Biosciences)	Histamine-3 Receptor Antagonist/Inverse Agonist	Excessive daytime sleepiness in patients with narcolepsy	Oral	– QT Interval Prolongation	O, P
<b>pexidartinib</b> Turalio™ (Daiichi Sankyo)	Kinase inhibitor	Symptomatic tenosynovial giant cell tumor	Oral	– Embryo-fetal toxicity	B, O, P
<b>polatuzumab vedotin-piiq</b> Polivy™ (Genetech)	Anti-CD79B- directed antibody- drug conjugate	Relapsed or refractory diffuse large B-cell lymphoma	Intravenous	– Peripheral neuropathy – Infusion reactions – Myelosuppression – Serious and opportunistic infections – Progressive multifocal leukoencephalopathy – Tumor lysis syndrome – Hepatotoxicity – Embryo-fetal toxicity	B, O, P

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<b>prabotulinumtoxinA</b> -xvfs Jeuveau™ (Evolus)	Acetylcholine release Inhibitor Neuromuscular Blocker	Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity.	Intra-muscular	<ul style="list-style-type: none"> <li>– Potency units are not interchangeable with other botulinum toxin products.</li> <li>– Spread of toxin effect (difficulty breathing/swallowing)</li> <li>– Anaphylaxis</li> <li>– Caution with pre-existing cardiovascular disease.</li> <li>– Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.</li> <li>– Caution in patients with compromised respiratory function or dysphagia.</li> </ul>	N/A
<b>pretomanid</b> (Mylan)	Antimycobacterial	Pulmonary extensively drug resistant, treatment-intolerant or nonresponsive multidrug-resistant tuberculosis, to be used in combination with linezolid and bedaquiline	Oral	<ul style="list-style-type: none"> <li>– Hepatic adverse reactions,</li> <li>– Myelosuppression</li> <li>– Peripheral and optic neuropathy</li> <li>– QT prolongation</li> <li>– Reproductive effects</li> <li>– Lactic acidosis</li> </ul>	O, P
<b>risankizumab-rzaa</b> Skyrizi™ (Abbvie)	Interleukin-23 inhibitor	Moderate-to-severe plaque psoriasis	Subcutaneous	<ul style="list-style-type: none"> <li>– Infections</li> <li>– Tuberculosis</li> </ul>	N/A
<b>romosozumab-aqqg</b> Evenity® (Amgen)	Sclerostin Inhibitor	Osteoporosis in post-menopausal women at high risk of fracture	Subcutaneous	<ul style="list-style-type: none"> <li>– Major adverse cardiovascular event</li> <li>– Hypersensitivity reactions</li> <li>– Hypocalcemia</li> <li>– Osteonecrosis of the jaw</li> <li>– Atypical femoral fracture</li> </ul>	S
<b>selinexor</b> Xpovio™ (Karyopharm)	Nuclear export inhibitor	Relapsed or refractory multiple myeloma	Oral	<ul style="list-style-type: none"> <li>– Thrombocytopenia</li> <li>– Neutropenia</li> <li>– Gastrointestinal toxicity</li> <li>– Hyponatremia</li> <li>– Infections</li> <li>– Neurological toxicity</li> <li>– Embryo-fetal toxicity</li> </ul>	Fa, O
<b>siponimod</b> Mayzent® (Novartis)	Sphingosine 1-Phosphate Receptor Modulator	Relapsing forms of multiple sclerosis	Oral	<ul style="list-style-type: none"> <li>– Increased risk of infection</li> <li>– Macular edema</li> <li>– Bradyarrhythmia and atrioventricular conduction delays</li> <li>– Respiratory effects</li> <li>– Liver injury</li> <li>– Increased blood pressure</li> <li>– Fetal risk</li> </ul>	P

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<b>solriamfetol</b> Sunosi™ (Jazz Pharma)	Dopamine and norepinephrine reuptake inhibitor	Improve excessive daytime sleepiness in patients with narcolepsy or obstructive sleep apnea	Oral	– Blood pressure and heart rate increases – Psychiatric symptoms	O, S
<b>tafamidis meglumine</b> Vyndaqel® <b>tafamidis</b> Vyndamax™ (Pfizer)	Transthyretin Stabilizer	Cardiomyopathy caused by transthyretin mediated amyloidosis	Oral	– The two dosage forms are not equivalent and should not be interchanged	B, Fa, O, P
<b>tenapanor</b> Ibsrela® (Ardelyx)	Sodium/hydrogen exchanger 3 inhibitor	Irritable bowel syndrome with constipation	Oral	– Diarrhea	S
<b>triclabendazole</b> Egaten™ (Novartis)	Anthelmintic	Fascioliasis	Oral	– QT Prolongation	O, P
<b>trifarotene</b> Aklief® (Galderma Laboratories)	Topical Acne Agent, Retinoid-like Agent	Acne vulgaris in patients 9 years and older	Topical	– Skin irritation – Ultraviolet light and environmental exposure	S
<b>ubrogepant</b> Ubrelvy™ (Allergan)	Calcitonin Gene-Related Peptide Receptor Antagonist	Acute migraine with or without aura	Oral	– None	S
<b>upadacitinib</b> Rinvoq™ (AbbVie)	Janus Kinase Inhibitor	Moderately to severe active rheumatoid arthritis	Oral	– Serious infections – Malignancy – Thrombosis – Gastrointestinal perforations – Laboratory monitoring – Embryo-fetal toxicity – Live Vaccines	P
<b>voxelotor</b> Oxbryta™ (Global Blood Therapeutics)	Hemoglobin S Polymerization Inhibitor	Sickle Cell Disease	Oral	– Hypersensitivity reaction – Laboratory test interference	A, Fa, O
<b>zanubrutinib</b> Brukinsa™ (BeiGene USA)	Kinase Inhibitor	Mantle cell lymphoma (relapsed or refractory)	Oral	– Hemorrhage – Infections – Cytopenias – Secondary/primary malignancies – Cardiac arrhythmias can occur – Embryo-fetal toxicities	A, B, O

**Risk Classifications\***

A= Accelerated Approval

B= Breakthrough

Fa= Fast Track Approval

O= Orphan Drug

P = Priority Approval

N/A = Not Applicable

S = Standard Approval

## Summary:

The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) reviews innovative new drug therapies and approves those that are safe and effective each year. In 2019, there were 48 novel drugs approved.<sup>1</sup> This is slightly less than the record breaking 59 approved therapies in 2018<sup>2</sup>, yet more than the ten-year average of 37 approvals per year.<sup>3</sup> In addition, in 2019, CDER approved a variety of therapies including: new and expanded uses, biosimilars, new formulations, and new dosage forms.

An impressive 42% (20 of the 48 of the new drugs) were identified as first-in-class including drugs for the treatment of bladder cancer, postpartum depression, and schizophrenia.<sup>3</sup> "Orphan drugs" used to treat rare diseases, including erythropoietic protoporphyria, and tenosynovial giant cell tumor, made up 21 of the 48 new novel therapies (44%). More than one-third of the new therapies are indicated for cancer treatments.<sup>4</sup> Out of these new drugs, 15 of these have a warning for fetal toxicity. The 2019 new approvals also include new antibiotics including Recarbrio™ (imipenem, cilastin, relebactam) indicated for complicated urinary tract infections and complicated intra-abdominal bacterial infections, Pretomanid, used in combination with linezolid and bedaquiline, for the treatment of multi-drug resistant tuberculosis, as well as Xenleta™ (lefamulin) indicated for the treatment of adults with community-acquired bacterial pneumonia.

To end, CDER states, "Our drug therapy approvals of 2019 will help many patients in need for years to come. However, CDER's mission goes well beyond critically reviewing the safety and efficacy of drug applications we receive from industry. We also look to advance the science and technology that can lead to future innovative drugs --- many of which may not yet be conceived. We are working to develop more innovative and efficient approaches for the development and study of the drug therapies that will emerge from these technological advances."

## References:

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4. Brennan Z. FDA: 2019 continues uptick in orphan drug approvals. Regulatory Affairs Professionals Society (RAPS) [Internet]. 2020 Jan 6 [cited 2020 Jan 17]; [about 2 screens]. Available from: <https://www.raps.org/news-and-articles/news-articles/2020/1/fda-2019-continues-uptick-in-orphan-drug-approval>



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TO TRANSFORM THE World.  
WE CARRY all THE POWER WE NEED  
INSIDE Ourselves ALREADY.”**

**-J.K. Rowling**

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