





# AU Inf rMeD

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### Guest Editors:

Benjamin Marler, Steven Stadler, and Dw'Nesia Williams, Pharm.D. Candidates 2022;  
Bernie R. Olin, Pharm.D.

### Key Inforbits:



- 2021 New Drug Approvals
- Summary of Approved Drugs
- Rare Disease Categories for New Drug Treatment

### New Drugs Approved in 2021

Generic Name Trade Name (Manufacturer) <sup>1</sup>	Approval Date <sup>1</sup>	Category <sup>1</sup>	FDA Indication <sup>1,2</sup>	Route <sup>1</sup>	Warnings/Precautions <sup>1,2</sup>	Orphan Drug <sup>1</sup>
vericiguat Verquvo (Merck & Co, Inc)	1/20/2021	Soluble Guanylate Cyclase Stimulator	Heart failure with reduced ejection fraction	Oral; Tablets	High alert medication Embryo-fetal toxicity Avoid in pregnancy	
cabotegravir + rilpivirine Cabenuva (ViiV Healthcare)	1/21/2021	Integrase Inhibitor, Non-nucleoside Reverse Transcriptase Inhibitor	HIV-1	IM	Store in refrigerator Hepatotoxicity Depressive disorders <u>Contraindications:</u> CYP 3A inducers (carbamazepine, rifampin, St. John's wort), UGT inducers.	
voclosporin Lupkynis (Aurinia Pharmaceuticals, Inc)	1/22/2021	Calcineurin Inhibitor, Immunosuppressant	Lupus nephritis	Oral; Capsule	<u>BBW:</u> Malignancies, Serious infections <u>Contraindications:</u> CYP 3A4 inhibitors (ketoconazole, itraconazole, clarithromycin) <u>Warnings/Precautions:</u> QTc prolongation, hyperkalemia, hypertension, nephrotoxicity, neurotoxicity, pure red cell aplasia	
tepotinib Tepmetko (EMB Serono Inc)	2/03/2021	Tyrosine Kinase Inhibitor, MET Inhibitor	Non-Small Cell Lung Cancer	Oral; Tablet	Hepatotoxicity Peripheral edema Pulmonary toxicity/pneumonitis	x
umbralisib Ukoniq (TG Therapeutics)	2/05/2021	Phosphatidylinositol 3-Kinase Inhibitor	Marginal zone lymphoma, Follicular lymphoma	Oral; Tablet	Bone marrow suppression, dermatologic toxicity, GI toxicity, hepatotoxicity, serious and fatal infections	x
Evinacumab-dgnb Evkeeza (Regeneron Pharmaceuticals)	2/11/2021	Monoclonal antibody - ANGPTL3 inhibitor	Homozygous familial hypercholesterolemia	IV	Serious hypersensitivity reactions Embryo-fetal toxicity	x

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trilaciclib Cosela (G1 Therapeutics)	2/12/2021	Cyclin-dependent Kinase Inhibitor	Chemotherapy- induced myelosuppres- sion	IV	Infusion-site reactions Acute drug hypersensitivity reactions Pulmonary toxicity Embryo-fetal toxicity Interstitial lung disease/Pneumonitis	
casimersen Amondys 45 (Sarepta Therapeutics, Inc.)	2/25/2021	Antisense Oligonucleotide	Muscular Dystrophy	IV	Renal impairment	x
Fosdenopterin Nulibry (Alcami Carolinas Corporation)	2/26/2021	Molybdenum Cofactor	Reduce the risk of mortality in molybdenum cofactor deficiency Type A	IV	Photosensitivity	x
melphalan flufenamide Pepaxto (Oncopeptides AB)	2/26/2021	Alkylating Antineoplastic Agent	Relapsed or Refractory Multiple Myeloma	IV	Thrombocytopenia Neutropenia Anemia Secondary malignancies Embryo-fetal toxicity Infections	x
Serdexmethylpheni- date dexmethylphenidate Azstarys (Commave Therapeutics)	3/02/2021	Central Nervous System Stimulant	ADHD	Oral; capsule	Priapism Peripheral vasculopathy, including Raynaud's Phenomenon Cardiovascular events including MI and stroke	
tivozanib Fotivda (Aveo Pharmaceuticals)	3/10/2021	Tyrosine Kinase Inhibitor, VEGF Inhibitor	Renal Cell Carcinoma	Oral; capsule	Hypertension & Hypertensive Crisis Cardiac failure Thromboembolic events Proteinuria Thyroid dysfunction Risk of impaired wound healing Reversible posterior leukoencephalopathy syndrome Embryo-fetal Toxicity Allergic reaction to tartrazine	

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ponesimod Ponvory (Janssen Pharmaceuticals, Inc)	3/18/2021	Sphingosine 1- Phosphate Receptor Modulator	Relapsing forms of Multiple Sclerosis	Oral; tablet	<u>Contraindications:</u> MI, unstable angina, stroke/TIA, decompensated HF, Class III or IV HF in the last 6 months; presence of a variety heart blocks  <u>Warnings/Precautions:</u> AV conduction delay, bradycardia, elevated LFTs, hypertension, increased risk of infections, macular edema, malignancy, neurotoxicity, progressive multifocal leukoencephalopathy, respiratory impairment	
dasiglucagon Zegalogue (Zealand Pharmaceuticals A/S)	3/22/2021	Hypoglycemia Antidote	Hypoglycemia	SubQ	<u>Contraindications:</u> pheochromocytoma, insulinoma  <u>Hypersensitivity reactions:</u> anaphylaxis, shock, rash, erythema, urticaria, hypotension, respiratory distress.	
viloxazine Qelbree (Catalent Pharma Solutions, LLC)	4/2/2021	Selective Norepinephrine Reuptake Inhibitor	Attention deficit hyperactivity disorder	Oral; Capsule	Increased suicidal thoughts and behaviors Increased heart rated Increased blood pressure Somnolence/Fatigue Activation of mania or hypomania	
drospirenone-estetrol Nexstellis (Mayne Pharmaceuticals)	4/15/2021	Estrogen and Progestin Combination, Contraceptive	Contraception	Oral; Tablet	<u>Contraindications:</u> adrenal insufficiency, renal impairment, co-administration of some Hep C medications, hepatic dysfunction, breast cancer  <u>BBW:</u> cigarette smoking increase risk of serious CV events  Warnings/Precautions: hormonally sensitive malignancy	
dostarlimab-gxly Jemperli (GlaxoSmithKline LLC)	4/22/2021	Anti-PD-1 Monoclonal Antibody, Checkpoint Inhibitor	Endometrial cancer, solid tumors	IV	Infusion-related reactions Endocrinopathies Immune-mediated ADRs Toxicities: dermatology, GI, hepatic, nephrology, ocular, pulmonary	
loncastuximab tesirine-lpyl Zynlonta (ADC Therapeutics)	4/23/2021	Anti-CD19, Antibody Drug Conjugate; Monoclonal Antibody	Large B-cell Lymphoma	IV	Bone marrow suppression Effusion/edema Extravasation Photosensitivity Dermatologic toxicity Increased risk of serious and fatal infections	x

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pegcetacoplan Empaveli (Apellis Pharmaceuticals, Inc.)	5/14/2021	Complement Inhibitor	Paroxysmal nocturnal hemoglobinuria	SubQ Infusi- on	REMS Program Serious infections caused by encapsulated bacteria, such as meningococcal infections Infusion-related reactions	x
amivantamab-vmjw Rybrevant (Janssen Biotech, Inc)	5/21/2021	EGFR Inhibitor, MET Inhibitor, Monoclonal Antibody	Non-small cell lung cancer	IV	Dermatologic toxicity, infusion reactions, ocular toxicity, photosensitivity, pulmonary toxicity	
piflufolastat F 18 Pylarify (Progenics Pharmaceuticals, Inc.)	5/26/2021	Radiopharm- aceutical	Prostate-specific Diagnostic Imaging	IV	Radiopharmaceutical handling Radiation accumulation Hypersensitivity	
sotorasib Lumakras (Amgen Inc.)	5/28/2021	KRAS Inhibitor	Non-small cell lung cancer	Oral; Tablet	Hepatotoxicity, pulmonary toxicity.	x
infigratinib Truseltiq (QED Therapeutics, Inc)	5/28/2021	FGFR Inhibitor; Tyrosine Kinase Inhibitor	Cholangiocarcin oma, unresectable locally advanced or metastatic	Oral; Capsule	Hyperphosphatemia Ocular toxicity Embryo-fetal toxicity	x
olanzapine and samidorphan Lybalvi (Alkermes, Inc.)	5/28/2021	Atypical Antipsychotic; Opioid Antagonist	Schizophrenia and certain features of Bipolar I disorder	Oral; Tablet	Accidental opioid overdose, anticholinergic effects, blood dyscrasias, cerebrovascular effects, CNS depression, dermatologic reactions, esophageal dysmotility, extrapyramidal symptoms, falls, hyperglycemia, hyperlipidemia, hyperprolactinemia, opioid withdrawal, orthostatic hypotension, neuroleptic malignant syndrome, temperature regulation, weight gain	
ibrexafungerp Brexafemme (Scynexis)	6/1/2021	Antifungal; Triterpenoid	Vulvovaginal candidiasis	Oral; Tablet	Hypersensitivity, reproductive considerations - ensure patients are not pregnant or breast feeding	
aducanumab-avwa Aduhelm (Biogen Inc.)	6/7/2021	Anti-Amyloid Monoclonal Antibody	Alzheimer's Disease	IV	Amyloid related imaging abnormalities (obtain brain MRI prior to therapy)	
asparaginase erwinia chrysanthemii (recombinant)-rywn Rylaze (Jazz Pharmaceuticals Ireland Limited)	6/30/2021	Antineoplastic Agent	Acute lymphoblastic leukemia	IM	Hepatotoxicity, hypersensitivity reactions, pancreatitis, thrombosis, and hemorrhage	x

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finerenone Kerendia (Bayer HealthCare Pharmaceuticals Inc.)	7/9/2021	Nonsteroidal Mineralocorticoid (Aldosterone) Receptor Antagonist	CKD associate with type 2 diabetes	Oral; Tablet	Hyperkalemia, hepatic impairment	
fexinidazole Fexinidazole (Drugs for Neglected Diseases <i>initiative</i> )	7/16/2021	Antiprotozoal, Nitroimidazole, Antitrypanosomal	Human African trypanosomiasis	Oral; Tablet	Neuropsychiatric effects, neutropenia, QT prolongation, hepatic impairment, renal impairment, reproductive considerations - ensure patients are not pregnant or breastfeeding	<b>x</b>
belumosudil Rezurock (Kadmon Pharmaceuticals, LLC)	7/16/2021	ROCK-2 Inhibitor	Graft-vs-Host Disease	Oral; Tablet	Patients should use contraception during therapy and at least 1 week after last dose, exposure may cause fetal harm. Breastfeeding is not recommended.	<b>x</b>
odevixibat Bylvy (Albireo Pharma, Inc.)	7/20/2021	Ileal Bile Acid Transporter Inhibitor	Pruritus	Oral; Capsule	Diarrhea, fat-soluble vitamin deficiency, hepatic issues - may cause LFT variability, obtain baseline labs prior to initiation	<b>x</b>
anifrolumab-fnia Saphnelo (AstraZeneca)	7/30/2021	Monoclonal Antibody; Immunoglobulin; Interferon Receptor Antagonist, Type 1	Systemic lupus erythematosus	IV	Hypersensitivity reactions Increased risk of serious/fatal infections Infusion reactions Malignancy Not recommended to use with other biologic therapies	
avalglucosidase alfa- ngpt Nexviazyme (Genzyme Corporation)	8/6/2021	Enzyme	Late onset Pompe Disease	IV	BBW: Hypersensitivity reactions, infusion- associated reactions, risk of acute cardiorespiratory failure in susceptible patients	<b>x</b>
belzutifan Welireg (Merck & Co, Inc)	8/13/2021	HIF-2 alpha Inhibitor	von Hippel- Lindau disease	Oral; Tablet	BBW: Embryo-fetal toxicity Warnings/Precautions: Anemia, Hypoxia	<b>x</b>
difelikefalin Korsuva (Cara Therapeutics, Inc.)	8/23/2021	Kappa Opioid Receptor Agonist	CKD associated pruritus	IV	CNS effects such as mental status change, gait disturbance  Hepatic impairment	
lonapegsomatropin- tcgd Skytrofa (Ascendis Pharma Endocrinology Division A/S)	8/25/2021	Growth Hormone	Short Stature; Growth Hormone Deficiency	SubQ	Increased Mortality in patients with acute critical illness Severe Hypersensitivity Increased Risk of Neoplasms Intracranial Hypertension	<b>x</b>

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mocertinib Exkivity (Takeda Pharmaceuticals America, Inc.)	9/15/2021	EGFR Inhibitor, Tyrosine Kinase Inhibitor	Non-small Cell Lung Cancer	Oral; Capsule	QTC Prolongation Torsades de Pointes Intestinal Lung Disease Cardiac Toxicity Diarrhea Embryo-Fetal Toxicity	x
tisotumab vedotin- tftv Tivdak (Seagen Inc.)	9/20/2021	Monoclonal Antibody; Anti- Tissue Factor; Antibody Drug Conjugate; Antimicrotubu-lar	Cervical cancer	IV	Ocular Adverse Reactions Peripheral Neuropathy Hemorrhage Pneumonitis Embryo-Fetal Toxicity	
atogepant Qulipta (Forest Laboratories Ireland Ltd.)	9/28/2021	CGRP Antagonist	Migraine prevention	Oral; Tablet	Nausea	
maralixibat Livmarli (Mirum Pharmaceuticals, Inc.)	9/29/2021	Ileal Bile Acid Transporter Inhibitor	Cholestatic pruritus due to Alagille syndrome	Oral; Solutio n	Liver Test Abnormalities Gastrointestinal Adverse Effects Fat Soluble Vitamin Deficiency Diarrhea	x
avacopan Tavneos (Thermo Fisher Scientific)	10/7/2021	Complement Inhibitor	Antineutrophil cytoplasmic autoantibody- associated vasculitis	Oral; Capsule	Hypersensitivity Reaction Hepatotoxicity Hepatitis B Virus Reactivation Increase chance of serious infections	x
asciminib Scemblix (Novartis Pharmaceuticals Corporation)	10/29/2021	BCR-ABL Tyrosine Kinase Inhibitor; STAMP Inhibitor	Chronic myeloid leukemia	Oral; Tablet	Myelosuppression Pancreatic Toxicity Embryo-Fetal Toxicity Hypertension	x
ropeginterferon alfa- 2b-njft Besremi (PharmaEssentia Corporation)	11/12/2021	Interferon; Biological Response Modulator	Polycythemia vera	SubQ	Depression and Suicide warning Endocrine and Cardiovascular Toxicity Flu-like symptoms Arthralgia Fatigue	x
vosoritide Voxzogo (BioMarin Pharmaceutical Inc.)	11/19/2021	C-type Natriuretic Peptide	Achondroplasia	SubQ	Risk of Hypotension Injection site reaction Vomiting	x

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maribavir Livtency (Takeda Pharmaceuticals)	11/23/2021	Benzimidazole Riboside	Cytomegalovirus	Oral; Tablet	Reduced Antiviral effect when treated with Ganciclovir and Valganciclovir Nausea	x
pafolacianine Cytalux (Grand River Aseptic Manufacturing)	11/29/2021	Ovarian cancer Diagnostic Imaging	Optical imaging agent (ovarian cancer)	IV	Embryo Fetal Toxicity Infusion Site Reactions Nausea Drug interaction with folic acid	x
tezepelumab-ekko Tezpire (AstraZeneca)	12/17/2021	Monoclonal Antibody; Anti- asthmatic	Asthma	SubQ	Risk associated with Abrupt Reduction of Corticosteroid use Pharyngitis Back Pain	
efgartigimod alfa-fcab Vyvgart (Argenx BV)	12/17/2021	Neonatal Fc Receptor Antagonist	Myasthenia gravis	IV	Respiratory Tract Infection Headache Paresthesia Hypersensitivity Reactions	x
inclisiran Leqvio (Novartis Pharmaceuticals Corporation)	12/22/2021	Antilipemic siRNA Agent	Heterozygous familial hypercholesterol emia, Secondary prevention of cardiovascular events	SubQ	Injection site Reactions Arthralgia Urinary Tract Infections Discontinue in Pregnancy	
tralokinumab-ldrm Adbry (Leo Pharmaceuticals)	12/27/2021	Monoclonal Antibody; Interleukin-13 Antagonist	Atopic Dermatitis	IV	Eye and Eyelid Swelling Injection Site Reactions Eosinophilia	

IV: intravenous IM: intramuscular SubQ: subcutaneous BBW: black box warning

### Disease Categories with New Treatment Options in 2021<sup>3</sup>

- **Heart, Blood, Kidney, and Endocrine diseases:** diabetes, severe hypoglycemia, CKD with T2DM, chronic weight management, chemotherapy-induced bone marrow suppression, homozygous familial hypercholesterolemia, paroxysmal nocturnal hemoglobinuria, achondroplasia, polycythemia vera, and sickle cell disease
- **Autoimmune, Inflammatory, and Lung Diseases:** pruritus associated with CKD, cystic fibrosis ages 6-11 years, systemic sclerosis-associated interstitial lung disease, prevent organ rejection in patients receiving lung transplant, anti-neutrophil cytoplasmic antibody-associated vasculitis
- **Infectious diseases:** human smallpox, post-transplant cytomegalovirus infection, Human African trypanosomiasis
- **Neurological and Psychiatric Disorders:** opioid overdose, Alzheimer's disease, episodic migraines, Duchenne muscular dystrophy, myasthenia gravis
- **Cancers:** Cholangiocarcinoma, von Hippel-Lindau disease, light chain amyloidosis, locally advanced unresectable or metastatic perivascular epithelioid cell tumor
- **Other rare diseases:** Late onset Pompe Disease, neurogenic detrusor overactivity

### Summary of Newly Approved Drugs:

Each year to further advance disease management in the United States, the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) reviews and approves a variety of new drugs and biological products.<sup>1</sup> For the year of 2021, CDER approved 50 novel drugs. Typically, that is the average of drugs approved based on the past two years. The new medications were approved with the potential for a positive impact and unique contribution to patient care.<sup>3</sup>

In 2021, there was a variety of focus on disease states such as infectious diseases, neurological and psychiatric disorders, and oncology. Of the new medications approved, 54% (27 of the 50 new drugs) are considered to be "first-in-class" novel drugs due to their unique mechanism of action that differs from those of existing therapies.<sup>3</sup> Some of the novel drugs provide new therapy for endocrine diseases, for example, diabetes to treat conditions such as severe hypoglycemia, CKD associated with type 2 diabetes, and CKD at risk of progression. There were 26 "orphan drugs" approved to treat rare diseases, for instance, Pompe disease, molybdenum cofactor deficiency type A, and sleeping sickness (Human African trypanosomiasis).

In conclusion, CDER collaborated with the medical community, patient advocacy groups, and caregivers to enhance patient health with the 2021 new medications. CDER states that "throughout 2021, the COVID-19 pandemic continued to present significant challenges to our entire staff. In spite of these hardships, we have approved many therapies that will advance health for the American public. As in the past, the 2021 new drug therapies span many areas of medicine and disease areas."<sup>3</sup>

### References:

1. FDA: novel drug approvals for 2021 [Internet]. Silver Spring, MD: U.S. Food and Drug Administration; FDA's center for drug evaluation and research; 2021 Jan 13 [cited 2021 Jan 29]; [about 55 p]. Available from: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021>
2. Lexicomp [AUHSOP Intranet]. Hudson, OH: Wolters Kluwer Health. cited 2022 Jan 12]. Available from: <https://online.lexi.com/lco/action/home>
3. New Drug Therapy Approvals 2021. FDA's Center for Drug Evaluation and Research. Release 2022 Jan [cited 2022 Jan 18]. Available from: <https://www.fda.gov/media/155227/download>



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### **Health Professional with a Question? Drugs – Therapeutics – Pharmacy Practice?**

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