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Guest Editors:

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Key Objectives

- 2020 New Drug Approvals
- Summary of Approved Drugs
- Rare Disease Categories for New Drug Treatment

New Drugs Approved in 2020

Generic Name Trade Name (Manufacturer) ¹	Approval Date ¹	Category ¹	FDA Indication ¹	Route ¹	Warnings/Precautions ^{1,2}	Orphan Drug ¹
avapritinib Ayvakit (Blueprint Meds)	1/9/2020	Tyrosine kinase inhibitor	Metastatic gastrointestinal stromal tumor	Oral; Tablet	- CNS adverse events and intracranial hemorrhage - Fetal harm	X
teprotumumab Tepezza (Horizon Therapeutics)	1/21/2020	Insulin-like growth factor 1 receptor (IGF-1R) antagonist	Thyroid eye disease	Injection	- Hyperglycemia - Exacerbation of preexisting inflammatory bowel disease	X
tazemetostat Tazverik (Epizyme Inc)	1/23/2020	Methyltransferase and EZH2 inhibitor	Epithelioid sarcoma and Follicular lymphoma	Oral; Tablet	- Secondary malignancies, including myelodysplastic syndrome - May cause fetal harm	X
lacitol Pizensy (Braintree Labs)	2/12/2020	Laxative	Chronic idiopathic constipation	Oral; Solution	- Contraindications: gastrointestinal obstruction and galactosemia	
bempedoic acid Nexletol (Esperion theraps Inc.)	2/21/2020	Adenosine triphosphate-citrate lyase (ACL) inhibitor	Heterozygous familial hypercholesterolemia	Oral; Tablet	- Hyperuricemia resulting in cases of gout and tendon rupture	
eptinezuman-jjmr Vyepiti (Lundbeck Seattle Biopharm, Inc.)	2/21/2020	Monoclonal antibody- CGRP ligand inhibitor	Migraine prevention	Injection	- Hypersensitivity reactions	

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amisulpride Barhemsys (Acacia)	2/26/2020	Selective dopamine-2 and dopamine-3 antagonist	Nausea and vomiting post-surgery	IV Solution	- Congenital long QT syndrome - Avoid use in patients taking droperidol	
rimegepant Nurtec ODT (Biohaven Pharm)	2/27/2020	CGRP antagonist	Migraine treatment	Oral; ODT	- Hypersensitivity reactions	
isatuximab Sarclisa (Sanofi Aventis US)	3/2/2020	IgG1 derived monoclonal antibody	Multiple Myeloma	Injection	- Neutropenia - Infusion-related reactions - Secondary primary malignancies - May cause fetal harm	X
osilodrostat Isturisa (Recordati Rare)	3/6/2020	Cortisol synthesis inhibitor	Cushing's disease	Oral; Tablet	- Cardiac arrhythmias - QT interval prolongation - Hypocortisolism	X
ozanimod Zeposia (Celgene Intl)	3/25/2020	Sphingosine-1-phosphate (S1P) receptor modulator	Multiple sclerosis relapse	Oral; Capsule	- Contraindications: - ASCVD event or a decompensate heart failure within the last 6 months - Second degree or third-degree AV block - Severe untreated sleep apnea - Use of MAO inhibitor	
selumetinib Koselugo (Astrazeneca Pharms)	4/10/2020	Inhibitor of mitogen-activated protein kinase kinases 1 and 2 (MEK1/2)	Neurofibromatosis type 1	Oral; Capsule	- Asymptomatic cardiomyopathy and ↓ left ventricular ejection fraction - Skin toxicities - Increased CPK, rhabdomyolysis - May cause fetal harm	X
tucatinib Tukysa (Seagen)	4/17/2020	Tyrosine kinase inhibitor	Metastatic HER2-positive breast cancer	Oral; Tablet	- Severe diarrhea - Severe hepatotoxicity - May cause fetal harm	X
pemigatinib Pemazyre (Incyte Corp)	4/17/2020	Kinase inhibitor that targets fibroblast growth factor receptor (FGFR)1, 2, and 3	Cholangiocarcinoma	Oral; Tablet	- Hyperphosphatemia - Retinal pigment epithelial detachment with symptoms - May cause fetal harm	X
sacituzumab govitecan-hziy Trodelvy (Immunomedics)	4/22/2020	Trop-2 directed antibody and topoisomerase inhibitor conjugate	Metastatic triple-negative breast cancer	Injection	- Excessive cholinergic responses, neutropenic colitis, and febrile neutropenia - May cause fetal harm	

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opicapone Ongentys (Neurocrine)	4/24/2020	Selective and reversible inhibitor of catechol-o-methyltransferase (COMT)	Parkinson's disease	Oral; Capsule	- Contraindications: - Use of non-selective MAO inhibitors - Paraganglioma, pheochromocytoma, or other catecholamine-secreting neoplasms	
capmatinib Tabrecta (Novartis Pharm)	5/6/2020	Kinase inhibitor that targets mesenchymal-epithelial transition (MET)	Non-small cell lung cancer	Oral; Tablet	- Photosensitivity reactions - Hepatotoxicity - Fatal interstitial lung disease and pneumonitis - May cause fetal harm	X
selpercatinib Retevmo (Loxo Oncology Inc)	5/8/2020	Kinase inhibitor that inhibits wild type RET	Lung and thyroid cancers	Oral; Capsule	- QT interval prolongation - Serious hemorrhagic events - Serious hepatic events - May cause fetal harm	X
ripretinib Qinlock (Deciphera Pharms)	5/15/2020	Tyrosine kinase inhibitor that inhibits KIT proto-oncogene receptor kinase (KIT) and platelet derived growth factor receptor A (PDGFRA) kinase	Gastrointestinal stromal tumors	Oral; Tablet	- Cardiac dysfunction - Palmar-plantar erythrodysesthesia syndrome - Cutaneous squamous cell carcinoma, keratoacanthoma, and melanoma - May cause fetal harm	X
fluoroestradiol F18 Cerianna (Zionexa)	5/20/2020	Radioactive diagnostic agent	Imaging for breast cancer	IV Solution	- A negative scan does not exclude estrogen receptor (ER)-positive breast cancer - Increased risk of cancer	
artesunate Artesunate (Amivas)	5/26/2020	Inhibits protein and nucleic acid synthesis	Severe malaria	IV Powder	- Post-treatment hemolytic pneumonia - Hypersensitivity reactions	X
flortaucipir F18 Tauvid (Avid Radiopharms Inc)	5/28/2020	Diagnostic test	Diagnosis of Alzheimer's disease	IV Solution	- Dose-dependent increased risk of cancer - Misdiagnosis of Alzheimer's disease	
inebilizumab-cdon Uplizna (Viela Bio)	6/11/2020	Monoclonal antibody that causes antibody-dependent cellular cytotoxicity	Neuromyelitis optica spectrum disorder	Injection	- Contraindications: - History of life-threatening infusion reaction - Active hepatitis B infection - Active or untreated latent tuberculosis	X

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lurbinectedin Zepzelca (Jazz)	6/15/2020	Alkylating drug that binds guanine residues in the minor groove of DNA	Metastatic small cell lung cancer	IV Powder	- Myelosuppression, including anemia, neutropenia, and thrombocytopenia - Hepatotoxicity - May cause fetal harm	X
triheptanoin Dojolvi (Ultragenyx Pharm Inc)	6/30/2020	Medium-chain triglyceride	Molecularly long-chain fatty acid oxidation disorders	Oral; Liquid	- Feeding tube dysfunction. Not recommended for PVC feeding tubes - Avoid use in pancreatic insufficiency patients	X
remimazolam Byfavo (Acacia)	7/2/2020	Benzodiazepine	Sedation	IV Powder	- Use with opioid analgesics - Sedation in neonates - Neurotoxicity in pediatric patients	
fostemsavir Rukobia (Viiv Hlthcare)	7/2/2020	HIV-1 attachment inhibitor	HIV	Oral; ER Tablet	- QTc prolongation - Drug interactions may alter the concentrations - Autoimmune disorders	
decitabine and cedazuridine Inqovi (Otsuka)	7/7/2020	A combination of a nucleoside metabolic inhibitor and a cytidine deaminase inhibitor	Myelodysplas- tic syndromes	Oral; Tablet	- Serious cases of myelosuppression - Serious and fatal infections - May cause fetal harm	X
abametapir Xeglyze (Dr. Reddy's)	7/24/2020	Pediculicide	Head lice infestation	Lotion	- Benzyl alcohol toxicity with over- exposure in infants; or ingestion	
tafasitamab-cxix Monjuvi (Morphosys US Inc)	7/31/2020	Fc-modified monoclonal antibody; binds to CD19 antigen	Relapsed or refractory diffuse large B- cell lymphoma	Injection	- Severe myelosuppression - Fatal and serious infections - May cause fetal harm	X
belantamab mafodotin-blmf Blenrep (GlaxoSmith- Kline)	8/5/2020	Antibody-drug conjugate	Multiple myeloma	IV Inject- able	- Thrombocytopenia - Ocular toxicities - May cause fetal harm	X
nifurtimox Lampit (Bayer Healthcare)	8/6/2020	Antiprotozoal drug	Chagas disease	Oral; Tablet	- Contraindications: Alcohol consumption; Hypersensitivity Neurological disturbances; fetal harm	X

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risdiplam Evrysdi (Genentech Inc)	8/7/2020	SMN2 splicing modifier	Spinal muscular atrophy	Oral; Solution		X
oliceridine Olinvyk (Trevena)	8/7/2020	Relatively selective opioid agonist with affinity for mu- opioid receptors	Acute pain	IV Solution	- Contraindications: - Acute or severe bronchial asthma - Gastrointestinal obstruction - Respiratory depression	
viltolarsen Viltepso (Nippon Shinyaku)	8/12/2020	Binds to exon 53 during mRNA processing	Duchenne muscular dystrophy	IV Solution	- Kidney toxicity - Serum creatinine may not be a reliable measure of kidney function	X
satralizumab- mwge Enspryng (Genentech)	8/14/2020	Interleukin 6 (IL- 6) receptor monoclonal antibody	Neuromyelitis optica spectrum disorder	Injection	- Contraindications: - History of life-threatening reaction to any ingredients - Active hepatitis B infection - Active or untreated latent tuberculosis	X
clascoterone Winlevi (Cassiopea Spa)	8/26/2020	Androgen receptor inhibitor	Acne	Topical; Cream	- Hypothalamic-pituitary-adrenal (HPA) axis suppression	
somapacitan- beco Sogroya (Novo Nordisk Inc)	8/28/2020	Growth hormone	Growth hormone	SubQ Solution	- Acute critical illness - Active malignancy - Hypersensitivity to any ingredients - Active proliferative or severe non- proliferative diabetic retinopathy	
copper Cu 64 dotatate injection Detectnet (Radiomex)	9/3/2020	PET imaging solution	Detect neuroendocrine tumors	IV Solution	- Increased risk of cancer	X
pralsetinib Gavreto (Blueprint Medicines)	9/4/2020	Tyrosine kinase inhibitor	Non-small lung cancer	Oral; Capsule	- Severe and fatal interstitial lung disease/pneumonitis - TLS in patients with medullary thyroid carcinoma - May cause fetal harm	X
atoltivimab, maftivimab, and odesivimab-ebgn Inmazeb (Regeneron)	10/14/2020	Antiviral drug combination	Ebola virus	Inject- able; Solution	- Hypersensitivity reactions	X

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remdesivir Veklury (Gilead Sciences Inc)	10/22/2020	Adenosine nucleotide prodrug	COVID-19	IV powder and solution	- Transaminase elevations - Not recommended in patients with GFR less than 30 ml/min	
lonafarnib Zokinvy (Eiger Biopharms)	11/20/2020	Farnesyltransferase inhibitor	Conditions related to premature aging	Oral; Capsule	- Review concomitant medications for drug interactions - Electrolyte abnormalities and increased liver enzymes - Potentially nephrotoxic - May impair fertility and may cause fetal harm	X
lumasiran Oxlumo (Alnylam Pharms Inc)	11/23/2020		Hyperoxaluria type 1	SubQ Solution		X
Imcivree setmelanotide (Rhythm)	11/25/2020		Pro-opiomelanocortin deficiency-treats obesity with this disease	SubQ Solution	- New or worsening depression - Not recommended with moderate to severe renal impairment - Sexual adverse effects	X
naxatamab-gqgk Danyelza (Y-MABS Therapeutics Inc)	11/25/2020	GD2 binding recombinant monoclonal antibody	Neuroblastoma	IV Solution	- May cause fetal harm and urinary retention	X
gallium 68 PSMA-11 Gallium 68 PSMA-11 (Univ CA Los Angeles)	12/1/2020	Diagnostic agent	Detect and localize prostate cancer	IV Solution		
berotralstat Orladeyo (Biocryst)	12/3/2020	Plasma kallikrein inhibitor	Hereditary angioedema	Oral; Capsule	- QT prolongation - Avoid in patients with end stage renal disease	X
tirbanibulin Klisyri (Almirall)	12/14/2020	microtubule inhibitor	Actinic keratosis of the face or scalp	Topical; Ointment	- Local skin irritation including severe reactions	
margetuximab Margenza (Macrogenics Inc)	12/16/2020	HER2 receptor antagonist	HER2 positive breast cancer	Injection	- Use during pregnancy resulted in cases of oligohydramnios	

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relugolix Orgovyx (Myovant Sciences)	12/18/2020	Gonadotropin- releasing hormone (GnRH) receptor antagonist	Advanced prostate cancer	Oral; Tablet	- QT/QTc prolongation - Suppression of pituitary gonadal system - May cause fetal harm	
ansuvimab-zyki Ebanga (Ridgeback Biotherapeutics)	12/21/2020	Recombinant monoclonal antibody	Ebola virus	IV Powder		X
vibegron Gemtesa (Urovant)	12/23/2020	Selective beta-3 adrenergic receptor agonist	Overactive bladder	Oral; Tablet	- Urinary retention	

IV – Intravenous SubQ – Subcutaneous

Summary of Newly Approved Drugs:

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 each year to further advance disease management in the United States.¹ Despite a major focus on identifying treatment regimens and a vaccine for an overwhelming pandemic, the year 2020 saw the approval of 53 novel drugs.^{1,3} This is slightly greater than 2019 which had a total of 48 new drug approvals and, also, greater than the typical ten-year average of 40 approvals per year.^{1,3}

In addition, in 2020, CDER approved a variety of therapies including: new and expanded uses, biosimilars, new formulations, and new dosage forms.³ For comparison, 40% (21 of the 53 new drugs) were identified as first-in-class including drugs for the treatment of HIV-1 and neurofibromatosis type 1.³ “Orphan drugs”, drugs used to treat rare diseases, including spinal muscular atrophy, Chagas disease, and hereditary angioedema, made up 31 of the 53 novel therapies (53%).³ More than one-third of the new therapies are indicated for cancer treatments.³ The 2020 novel approvals also include the first medication in the U.S. for the treatment of COVID-19, Veklury (remdesivir), and two new drugs, Ebanga (ansuvimab-zykl) and Inmazeb (atoltivimab, maftivimab, odesivimab-ebgn) for certain patients infected with Ebola virus.³

Lastly, CDER states, “In 2020, despite severe challenges from the COVID-19 pandemic, the FDA’s Center for Drug Evaluation and Research (CDER) approved many new drug therapies to help a wide range of patients suffering from many different medical conditions to gain new hope for improved quality of life, and in some cases, improved chances of surviving life-threatening illnesses. Many of these new therapies were approved for patients with rare diseases, which, as shown below, span a broad spectrum of disease categories.”³

Rare Disease Categories with New Treatment Options in 2020

- **Infectious disease:** *severe malaria, Ebola virus, Chagas disease*
- **Neurology:** *spinal muscular atrophy, Duchenne muscular dystrophy, tuberous sclerosis complex, Dravet syndrome, neuromyelitis optica spectrum disorder*
- **Autoimmune, inflammatory, and lung diseases:** *lupus nephritis, Still's disease, hereditary angioedema, deficiency of interleukin-1 receptor antagonist*
- **Heart, blood, kidney, and endocrine diseases:** *hypereosinophilic syndrome, pro-opiomelanocortin deficiency, Cushing's disease, primary hyperoxaluria type 1*
- **Cancers:** *multiple myeloma, neuroblastoma, myelodysplastic syndromes, chronic myelomonocytic leukemia, gastrointestinal stromal tumor, epithelioid sarcoma, metastatic cholangiocarcinoma, neurofibromatosis type 1, mesothelioma*
- **Other rare diseases:** *Hutchinson-Gilford Progeria Syndrome, thyroid eye disease*

References:

1. FDA: novel drug approvals for 2020 [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 screens]. Available from: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020>
2. In: Lexi-Comp Online [AUHSOP Intranet]. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc [updated Jan 26, 2021, cited 2021 Jan 29]. [about 106 p.]. Available from http://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/6393
3. 2020: another strong year for innovation and advances [Internet]. Silver Spring, MD: U.S. Food and Drug Administration; FDA's center for drug evaluation and research; 2020 Jan 6 [cited 2021 Jan 29]; [about 43 screens]. Available from: <https://www.fda.gov/media/144982/download>



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