



New Drugs Approved in 2020

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ABSTRACT

In 2020, the US Food and Drug Administration approved 53 novel drugs. Thirty-six of the 53 (68%) drugs were reviewed and approved through an expedited review pathway, and 31 of the 53 (58%) were approved for treatment of a rare disease. This review includes a summary of the novel drugs approved by the US Food and Drug Administration in 2020.

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In 2020, the US Food and Drug Administration (FDA) approved 53 novel drugs.¹ Several expedited review pathways, including accelerated approval, priority review, fast track, and breakthrough therapy, allow for approval processes that permit drugs to be available earlier than they could be with the traditional pathway. Ultimately, this allows for expedited approval of drugs that treat a serious condition or fill an unmet medical need. Of the novel drug approvals in 2020, 36 of the 53 (68%) drugs were processed via 1 of the expedited review pathways, and 31 of the 53 (58%) were approved for treatment of a rare disease.² The 53 novel drugs approved in 2020 are summarized in [Table 1](#).

The FDA also approved biologicals in 2020, which are not considered drugs and not reviewed in detail here. Notable among the approved biologicals are MenQuadfi (meningococcal (groups A, C, Y, and W) conjugate vaccine; Sanofi Pasteur Inc, Swiftwater, Penn) for prevention of invasive meningococcal disease, Tecartus (brexucabtagene autoleucel; Kite Pharma, Inc, Santa Monica, Calif) for mantle cell lymphoma, Sevenfact

(coagulation factor VIIa; Laboratoire Français du Fractionnement et des Biotechnologies SA, Les Ulis, France) for treatment of hemophilia A or B, and Audenz (influenza A (H5N1) monovalent vaccine; Seqirus Inc, Holly Springs, NC) for prevention of influenza A.

It is worth noting that Veklury[®] (remdesivir; Gilead Sciences, Inc., Foster City, Calif) was the first FDA-approved treatment for hospitalized patients with COVID-19. Veklury[®] (remdesivir) is an inhibitor of the SARS-CoV-2 RNA-dependent RNA polymerase, which is essential for viral replication. Additionally, Koselugo[®] (selumetinib) is the first FDA-approved treatment for neurofibromatosis type 1. Koselugo[®] (selumetinib, AstraZeneca [Cambridge, England] and Merck [Kenilworth, NJ]) is an inhibitor of mitogen-activated protein kinases 1 and 2, which lead to the development of different types of cancers.

The therapeutic area with the most drug approvals in 2020 was oncology, 23/53 (38%). Breast cancer and lung cancer accounted for 4 new drug approvals each. Interestingly, a recently published study found an association between National Institutes of Health funding and new drug approvals by the FDA between 2010-2016.³ The growth of oncology drug approvals and spending in the United States continues to increase. An economic evaluation of the oncology drug approvals in 2018 suggests an increase of \$39.5 billion in drug costs in the United States if those drugs were used in all eligible patients, a 75% increase from the total 2017 oncology drug costs.⁴ The average price per patient per treatment course for newly approved oncology therapies was \$150,384.⁴

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CLINICAL SIGNIFICANCE

- This summary of novel drugs approved by the US Food and Drug Administration in 2020 provides clinicians with pertinent prescribing information for each new drug.
- Clinicians will find this information useful when discussing these new drugs with their patients who may request them as part of their care.
- This information may be useful as clinicians work with hospitals and other healthcare organizations that are considering adding these drugs to their prescribing formularies.

Table 1 Summary of the Fifty-Three Novel Drugs Approved in 2020

Brand (Generic)	Indication	Clinical Pearls	Package Insert
Cardiology			
Nexletol [®] (bempedoic acid)	Heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease	May be associated with tendon rupture and hyperuricemia	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211616s000lbl.pdf
Dermatology			
Klisyri [®] (tirbanibulin)	Actinic keratosis of the face or scalp	May be associated with local skin reactions, application site pruritus, and application site pain	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213189s000lbl.pdf
Winlevi [®] (clascoterone)	Acne	Most common side effects are reddening, itching, and scaling or dryness of the skin	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213433s000lbl.pdf
Endocrine			
Isturisa [®] (osilodrostat)	Cushing's disease	May prolong QT interval	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212801s000lbl.pdf
Sogroya [®] (somapacitan-beco)	Growth hormone	Perform fundoscopic examination before initiating treatment to exclude preexisting papilledema	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761156s000lbl.pdf
Tepezza [®] (teprotumumab-trbw)	Thyroid eye disease	Monitor for signs and symptoms of infusion-related reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761143s000lbl.pdf
Zokinvy [®] (lonafarnib)	Premature aging	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213969s000lbl.pdf
Gastrointestinal			
Barhemsys [®] (amisulpride)	Prevent nausea and vomiting after surgery	May prolong QT interval	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209510s000lbl.pdf
Pizensy [®] (lactitol)	Chronic idiopathic constipation	May reduce the absorption of concomitantly administered oral medications	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211281s000lbl.pdf

Table 1 (Continued)

Brand (Generic)	Indication	Clinical Pearls	Package Insert
Genetic			
Dojolvi [®] (triheptanoin)	Molecularly long-chain fatty acid oxidation disorders	Do not administer alone to avoid gastrointestinal upset; not compatible with certain plastics such as PVC	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213687s000lbl.pdf
Imcivree [®] (setmelanotide)	Obesity and the control of hunger associated with pro-opiomelanocortin deficiency	Perform a full body skin examination prior to initiation and periodically during treatment to monitor pre-existing and new skin pigmentary lesions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213793s000lbl.pdf
Orladeyo [®] (berotralstat)	Hereditary angioedema	May prolong QT interval	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214094s000lbl.pdf
Oxlumo [®] (lumasiran)	Hyperoxaluria type 1	May cause injection site reactions	https://www.alnylam.com/wp-content/uploads/pdfs/OXLUMO-Prescribing-Information.pdf
Viltepso [®] (viltolarsen)	Duchenne muscular dystrophy	May cause nephrotoxicity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/2121540rig1s000lbl.pdf
Infectious Diseases			
Artesunate [®] (artesunate)	Severe malaria	May increase the risk of nephrotoxicity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213036s000lbl.pdf
Ebanga [®] (ansuvimab-zykl)	Ebola	Monitor for signs and symptoms of hypersensitivity reaction	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761172s000lbl.pdf
Inmazole [®] (atoltivimab, maftivimab, and odesivimab-ebgn)	Ebola virus	Monitor for signs and symptoms of infusion-related reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761169s000lbl.pdf
Lampit [®] (nifurtimox)	Chagas disease	Obtain a pregnancy test in females of reproductive potential prior to initiating treatment	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213464s000lbl.pdf
Rukobia [®] (fostemsavir)	HIV	May prolong QT interval	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212950s000lbl.pdf
Veklury [®] (remdesivir)	COVID-19	Perform hepatic laboratory testing prior to initiating treatment	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/2147870rig1s000lbl.pdf
Xeglyze [®] (abametapir)	Head lice	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/206966lbl.pdf
Neurology			
Byfavo [®] (remimazolam)	Sedation	May cause hypotension, hypertension, or hypoxia	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212295s000lbl.pdf
Enspryng [®] (satralizumab-mwge)	Neuromyelitis optica spectrum disorder	Test for HBV and TB before initiating treatment	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761149s000lbl.pdf
Evrysdi [®] (risdiplam)	Spinal muscular atrophy	May cause fever, diarrhea, or rash	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213535s000lbl.pdf
Gemtesa [®] (vibegron)	Overactive bladder	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213006s000lbl.pdf

Table 1 (Continued)

Brand (Generic)	Indication	Clinical Pearls	Package Insert
Koselugo [®] (selumetinib)	Neurofibromatosis type 1	Assess ejection fraction by echocardiogram prior to initial treatment and periodically afterward	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213756s000lbl.pdf
Nurtec ODT [®] (rimegepant)	Migraine	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212728s000lbl.pdf
Olinvyk [®] (oliceridine)	Acute pain	Contraindicated in patients with gastrointestinal obstruction	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210730s000lbl.pdf
Ongentys [®] (opicapone)	Parkinson's disease	May cause dyskinesia, constipation, blood creatine kinase increase, hypotension, or weight loss	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212489s000lbl.pdf
Tauvid [®] (flortaucipir F18)	Alzheimer's disease diagnostic agent	May increase the risk of radiation exposure	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212123s000lbl.pdf
Uplizna [®] (inebilizumab-cdon)	Neuromyelitis optica spectrum disorder	May cause urinary tract infections	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761142s000lbl.pdf
Vyepti [®] (eptinezumab-jjmr)	Migraine prevention	May cause hypersensitivity reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761119s000lbl.pdf
Zeposia [®] (ozanimod)	Relapsing forms of multiple sclerosis	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209899s000lbl.pdf
Oncology			
Ayvakit [®] (avapritinib)	Unresectable or metastatic gastrointestinal stromal tumor	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212608s000lbl.pdf
Blenrep [®] (belantamab mafodotin-blmf)	Multiple myeloma	May be associated with ocular toxicity, thrombocytopenia, or infusion-related reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761158s000lbl.pdf
Cerianna [®] (fluoroestradiol F18)	Breast cancer diagnostic agent	May cause injection site pain or changes in taste	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212155s000lbl.pdf
Danyelza [®] (naxitamab-gqqg)	Refractory or relapsed neuroblastoma	Monitor for hypertension	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761171lbl.pdf
Detectnet [®] (copper Cu 64 dotatate injection)	Neuroendocrine tumor diagnostic agent	Caution with elderly dosing	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213227s000lbl.pdf
Gallium 68 PSMA-11	Prostate cancer diagnostic agent	Can be seen in a variety of tumor types and in non-malignant processes	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212642s000lbl.pdf
Gavreto [®] (pralsetinib)	Non-small cell lung cancer	May increase the risk of liver toxicity or pneumonitis	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213721s000lbl.pdf
Inqovi [®] (decitabine and cedazuridine)	Myelodysplastic syndromes	Monitor for signs and symptoms of myelosuppression	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212576s000lbl.pdf
Margenza [®] (margetuximab-cmkb)	HER2+ breast cancer	Monitor for signs and symptoms of infusion-related reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761150s000lbl.pdf

Table 1 (Continued)

Brand (Generic)	Indication	Clinical Pearls	Package Insert
Monjuvi [®] (tafasitamab-cxix)	Relapsed or refractory diffuse large B-cell lymphoma	Monitor for signs and symptoms of infusion-related reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761163s000lbl.pdf
Qinlock [®] (ripretinib)	Gastrointestinal-stromal tumor	Monitor for signs and symptoms of heart failure	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213973s000lbl.pdf
Orgovyx [®] (relugolix)	Advanced prostate cancer	May prolong QT interval	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214621s000lbl.pdf
Pemazyre [®] (pemigatinib)	Cholangiocarcinoma	Monitor for retinal pigment epithelial detachment and hyperphosphatemia	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213736s000lbl.pdf
Retevmo [®] (selpercatinib)	Lung and thyroid cancers	May increase the risk of hepatotoxicity or prolong QT interval	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213246s000lbl.pdf
Sarclisa [®] (isatuximab-irfc)	Multiple myeloma	Monitor for signs and symptoms of infusion-related reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761113s000lbl.pdf
Tabrecta [®] (capmatinib)	Non-small cell lung cancer	May increase the risk of hepatotoxicity or pneumonitis	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213591s000lbl.pdf
Tazverik [®] (tazemetostat)	Epithelioid sarcoma	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211723s000lbl.pdf
Trodely [®] (sacituzumab govitecan-hziy)	Refractory metastatic triple-negative breast cancer	Monitor for neutropenia and diarrhea	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761115s000lbl.pdf
Tukysa [®] (tucatinib)	Unresectable or metastatic HER2-positive breast cancer	May increase the risk of hepatotoxicity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213411s000lbl.pdf
Zepzelca [®] (lurbinectedin)	Metastatic small-cell lung cancer	Monitor for signs and symptoms of liver toxicity and myelosuppression	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213702s000lbl.pdf

COVID-19 = coronavirus disease; HBV = hepatitis B virus; HIV = human immunodeficiency virus; PVC = polyvinyl chloride; TB = tuberculosis.

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