

Novel Drug Approvals for 2020

Innovation drives progress. When it comes to innovation in the development of new drugs and therapeutic biological products, FDA's Center for Drug Evaluation and Research (CDER) supports the pharmaceutical industry at every step of the process. With its understanding of the science used to create new products, testing and manufacturing procedures, and the diseases and conditions that new products are designed to treat, CDER provides scientific and regulatory advice needed to bring new therapies to market.

The availability of new drugs and biological products often means new treatment options for patients and advances in health care for the American public. For this reason, CDER supports innovation and plays a key role in helping to advance new drug development.

Each year, CDER approves a wide range of new drugs and biological products:

- Some of these products are innovative new products that never have been used in clinical practice. Below is a listing of new molecular entities and new therapeutic biological products approved by CDER in 2020. This listing does not contain vaccines, allergenic products, blood and blood products, plasma derivatives, cellular and gene therapy products, or other products approved in 2020 by the Center for Biologics Evaluation and Research ([/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year](#)).
- Others are the same as, or related to, previously approved products, and they will compete with those products in the marketplace. See [Drugs@FDA](#) (<https://www.accessdata.fda.gov/scripts/cder/daf/>) for information about all of CDER's approved drugs and biological products.

Certain drugs are classified as new molecular entities ("NMEs") for purposes of FDA review. Many of these products contain active moieties that have not been approved by FDA previously, either as a single ingredient drug or as part of a combination product; these products frequently provide important new therapies for patients. Some drugs are characterized as NMEs for administrative purposes, but nonetheless contain active moieties that are closely related to active moieties in products that have previously been approved by FDA. For example, CDER classifies biological products submitted in an application under section 351(a) of the Public Health Service Act as NMEs for purposes of FDA review, regardless of whether the Agency previously has approved a related active moiety in a different product. FDA's classification of a drug as an "NME" for review purposes is distinct from FDA's determination of whether a drug product is a "new chemical entity" or "NCE" within the meaning of the Federal Food, Drug, and Cosmetic Act.

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
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No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
48	Orladeyo (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=214094)	berotralstat	12/4/2020	To treat patients with hereditary angioedema
47.	Gallium 68 PSMA-11 (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212642)	Gallium 68 PSMA-11	12/1/2020	For detection and localization of prostate cancer Press Release (/news-events/press-announcements/fda-approves-first-psma-targeted-pet-imaging-drug-men-prostate-cancer)
46.	Danyelza (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761171)	naxitamab-gqgk	11/25/2020	To treat high-risk refractory or relapsed neuroblastoma
45.	Imcivree (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213793)	setmelanotide	11/25/2020	To treat obesity and the control of hunger associated with pro-opiomelanocortin deficiency, a rare disorder that causes severe obesity that begins at an early age Drug Trials Snapshot (/drugs/drug-trials-snapshots-imcivree)
44.	Oxlumo (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=214103)	lumasiran	11/23/2020	To treat hyperoxaluria type 1 Press Release (/news-events/press-announcements/fda-approves-first-drug-treat-rare-metabolic-disorder)

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43.	Zokinvy (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213969)	lonafarnib	11/20/2020	To treat rare conditions related to premature aging Press Release (/news-events/press-announcements/fda-approves-first-treatment-hutchinson-gilford-progeria-syndrome-and-some-progeroid-laminopathies) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-zokinvy)
42.	Veklury (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=214787)	remdesivir	10/22/2020	To treat COVID-19 Press Release (/news-events/press-announcements/fda-approves-first-treatment-covid-19) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-veklury)
41.	Inmaze (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761169)	atoltivimab, maftivimab, and odesivimab-ebgn	10/14/2020	To treat ebola virus Press Release (/news-events/press-announcements/fda-approves-first-treatment-ebola-virus) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-inmaze)

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40.	Gavreto (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213721)	pralsetinib	9/4/2020	To treat non-small lung cancer Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-gavreto)
39.	Detectnet (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213227)	copper Cu 64 dotatate injection	9/3/2020	To help detect certain types of neuroendocrine tumors Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-detectnet)
38.	Sogroya (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761156)	somapacitan-beco	8/28/2020	Growth hormone Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-sogroya)
37.	Winlevi (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213433)	clascoterone	8/26/2020	To treat acne Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-winlevi)
36.	Enspryng (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761149)	satralizumab-mwge	8/14/2020	To treat neuromyelitis optica spectrum disorder Press Release (/news-events/press-announcements/fda-approves-treatment-rare-disease-affecting-optic-nerves-spinal-cord) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-enspryng)

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35.	Viltepso (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212154)	viltolarsen	8/12/2020	To treat Duchenne muscular dystrophy Press Release (/news-events/press-announcements/fda-approves-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-viltepso)
34.	Olinvyk (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=210730)	oliceridine	8/7/2020	To manage acute pain in certain adults Press Release (/news-events/press-announcements/fda-approves-new-opioid-intravenous-use-hospitals-other-controlled-clinical-settings) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-olinvyk)
33.	Evrysdi (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213535)	risdiplam	8/7/2020	To treat spinal muscular atrophy Press Release (/news-events/press-announcements/fda-approves-oral-treatment-spinal-muscular-atrophy) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-evrysdi)

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32.	Lampit (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213464)	nifurtimox	8/6/2020	To treat Chagas disease in certain pediatric patients younger than age 18 Drug Trials Snapshot (/drugs/development-approval-process-drugs/drug-trials-snapshots-lampit)
31.	Blenrep (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761158)	belantamab mafodotin-blmf	8/5/2020	To treat multiple myeloma Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-blenrep)
30.	Monjuvi (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761163)	tafasitamab-cxix	7/31/2020	To treat relapsed or refractory diffuse large B-cell lymphoma Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshots-monjuvi)
29.	Xeglyze (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206966)	abametapir	7/24/2020	To treat head lice Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-xeglyze)
28.	Inqovi (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212576)	decitabine and cedazuridine	7/7/2020	To treat adult patients with myelodysplastic syndromes Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-inqovi)

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
27.	Rukobia (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212950)	fostemsavir	7/2/2020	To treat HIV Press Release (/news-events/press-announcements/fda-approves-new-hiv-treatment-patients-limited-treatment-options) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-rukobia)
26.	Byfavo (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212295)	remimazolam	7/2/2020	For sedation Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-byfavo)
25.	Dojolvi (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213687)	triheptanoin	6/30/2020	To treat molecularly long-chain fatty acid oxidation disorders Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-dojolvi)
24.	Zepzelca (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213702)	lurbinectedin	6/15/2020	To treat metastatic small cell lung cancer Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-zepzelca)

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
23.	Uplizna (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761142)	inebilizumab-cdon	6/11/2020	To treat neuromyelitis optica spectrum disorder Press Release (/news-events/press-announcements/fda-approves-new-therapy-rare-disease-affecting-optic-nerve-spinal-cord) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-uplizna)
22.	Tauvid (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212123)	flortaucipir F18	5/28/2020	Diagnostic agent for patients with Alzheimer's disease Press Release (/news-events/press-announcements/fda-approves-first-drug-image-tau-pathology-patients-being-evaluated-alzheimers-disease) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-tauvid)
21.	Artesunate (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213036)	artesunate	5/26/2020	To treat severe malaria Press Release (/news-events/press-announcements/fda-approves-only-drug-us-treat-severe-malaria)

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20.	Cerianna (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212155)	fluoroestradiol F18	5/20/2020	Diagnostic imaging agent for certain patients with breast cancer Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-cerianna)
19.	Qinlock (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213973)	ripretinib	5/15/2020	To treat advanced gastrointestinal-stromal tumors Press Release (/news-events/press-announcements/fda-approves-first-drug-fourth-line-treatment-advanced-gastrointestinal-stromal-tumors) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-qinlock)
18.	Retevmo (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213246)	selpercatinib	5/8/2020	To treat lung and thyroid cancers Press Release (/news-events/press-announcements/fda-approves-first-therapy-patients-lung-and-thyroid-cancers-certain-genetic-mutation-or-fusion) Drug Trials Snapshot (/drugs/development-approval-process-drugs/drug-trials-snapshots-retevmo)

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17.	Tabrecta (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213591)	capmatinib	5/6/2020	To treat patients with non small cell lung cancer Press Release (/news-events/press-announcements/fda-approves-first-targeted-therapy-treat-aggressive-form-lung-cancer) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-tabrecta)
16.	Ongentys (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212489)	opicapone	4/24/2020	To treat patients with Parkinson's disease experiencing "off" episodes Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-ongentys)

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
15.	Trodelvy (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761115)	sacituzumab govitecan-hziy	4/22/2020	To treat adult patients with metastatic triple-negative breast cancer who received at least two prior therapies for metastatic disease Press Release (/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-sacituzumab-govitecan-hziy-metastatic-triple-negative-breast-cancer) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-trodelvy)
14.	Pemazyre (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213736)	pemigatinib	4/17/2020	To treat certain patients with cholangiocarcinoma, a rare form of cancer that forms in bile ducts Press Release (/news-events/press-announcements/fda-approves-first-targeted-treatment-patients-cholangiocarcinoma-cancer-bile-ducts) Drug Trials Snapshot (Drug Trials Snapshot: PEMAZYRE)

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13.	Tukysa (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213411)	tucatinib	4/17/2020	To treat advanced unresectable or metastatic HER2-positive breast cancer Drug Trials Snapshot (Drug Trials Snapshot: TUKYSA)
12.	Koselugo (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=213756)	selumetinib	4/10/2020	To treat neurofibromatosis type 1, a genetic disorder of the nervous system causing tumors to grow on nerves Drug Trials Snapshot (/drugs/resources-information-approved-drugs/drug-trials-snapshots-koselugo)
11.	Zeposia (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=209899)	ozanimod	3/25/2020	To treat relapsing forms of multiple sclerosis Drug Trials Snapshot (/drugs/development-approval-process-drugs/drug-trials-snapshots-zeposia)
10.	Isturisa (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212801)	osilodrostat	3/6/2020	To treat adults with Cushing's disease who either cannot undergo pituitary gland surgery or have undergone the surgery but still have the disease Press Release (/news-events/press-announcements/fda-approves-new-treatment-adults-cushings-disease) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-is-100)

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
9.	Sarclisa (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761113)	isatuximab	3/2/2020	To treat multiple myeloma Press Release (/news-events/press-announcements/fda-approves-new-therapy-patients-previously-treated-multiple-myeloma) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-sarclisa)
8.	Nurtec ODT (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212728)	rimegepant	2/27/2020	To treat migraine Drug Trials Snapshot (/drugs/development-approval-process-drugs/drug-trials-snapshots-nurtec-odt)
7.	Barhemsys (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=209510)	amisulpride	2/26/2020	To help prevent nausea and vomiting after surgery Drug Trial Snapshot (/drugs/development-approval-process-drugs/drug-trials-snapshots-barhemsys)
6.	Vyepti (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761119)	eptinezumab-jjmr	2/21/2020	For the preventive treatment of migraine in adults Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-vyepti)

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
5.	Nexletol (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=211616)	bempedoic acid	2/21/2020	To treat adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C Drug Trials Snapshot (/drugs/resources-information-approved-drugs/drug-trials-snapshots-nexletol)
4.	Pizensy (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=211281)	lactitol	2/12/2020	To treat chronic idiopathic constipation (CIC) in adults Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-pizensy)
3.	Tazverik (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=211723)	tazemetostat	1/23/2020	To treat epithelioid sarcoma Press Release (/news-events/press-announcements/fda-approves-first-treatment-option-specifically-patients-epithelioid-sarcoma-rare-soft-tissue) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trials-snapshots-tazverik)

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2.	Tepezza (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761143)	teprotumumab-trbw	1/21/2020	To treat Thyroid eye disease Press Release (/news-events/press-announcements/fda-approves-first-treatment-thyroid-eye-disease) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-tepezza)
1.	Ayvakit (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=212608)	avapritinib	1/9/2020	To treat adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) FDA Information (/drugs/resources-information-approved-drugs/fda-approves-avapritinib-gastrointestinal-stromal-tumor-rare-mutation) Drug Trials Snapshot (/drugs/drug-approvals-and-databases/drug-trial-snapshot-ayvakit)

*The listed “FDA-approved use” on this website is for presentation purposes only. To see the FDA-approved conditions of use [e.g., indication(s), population(s), dosing regimen(s)] for each of these products, see the most recent FDA-approved Prescribing Information (click on the Drug Name) .