REVIEW

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New Drugs Approved in 2021

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ABSTRACT

In 2021, the US Food and Drug Administration (FDA) approved 50 novel drugs. Thirty-seven of the 50 (74%) novel drug approvals were reviewed and approved through an expedited review pathway, and 26 of the 50 (52%) were approved for treatment of a rare disease. This review includes a summary of the novel drugs approved by the FDA in 2021.

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In 2021, the US Food and Drug Administration (FDA) approved 50 novel drugs.[1] Several expedited review pathways, including accelerated approval, priority review, fast track, and breakthrough therapy, allow for approval processes that allow drugs to be available earlier than had they undergone review in the traditional pathway. Ultimately, this allows for expedited approval and availability of drugs that treat a serious condition or fill an unmet medical need. Of the novel drug approvals in 2021, 37 of the 50 (74%) drugs were processed via one of the expedited review pathways, and 26 of the 50 (52%) were approved for treatment of a rare disease.[2] The 50 novel drugs approved in 2021 are summarized in the Table.

First-in-class is a classification indicating a mechanism of action different from existing therapies, occurring in 27 of the 50 (54%) approved drugs in 2021. One notable first-in-class example is Besremi (ropeginterferon alfa-2b-njft; PharmaEssentia USA, Burlington, Mass), indicated for treatment of polycythemia vera, a condition that causes the bone marrow to make too many red blood cells. Another first-in-class approval is LIVTENCITY (maribavir; Takeda Pharmaceuticals, Lexington, Mass), indicated for post-transplant cytomegalovirus infection that is refractory to treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet. The therapeutic area with the most novel drug approvals (16 of 50) in 2021 was oncology. Lung cancer accounts for 5 of the new drug approvals.

The FDA also approved biologicals in 2021, which are not considered drugs and not reviewed in detail here. Notable among the approved biologicals are PreHevbrio (hepatitis B vaccine [recombinant]; VBI Vaccines, Cambridge, Mass) for prevention of hepatitis B virus; Comirnaty (COVID-19 vaccine, mRNA; Pfizer, New York, NY) for prevention of coronavirus disease 2019; TICOVAC (Tick-Borne Encephalitis Vaccine; Pfizer, New York NY) for prevention of tick-borne encephalitis; VAXNEUVANCE (pneumococcal 15-valent conjugate vaccine; Merck, Whitehouse Station, NJ) for prevention of *Streptococcus pneumonia*; Prevnar 20 (pneumococcal 20-valent conjugate

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vaccine; Pfizer, New York, NY) for prevention of *Streptococcus pneumonia*; ABECMA (idecabtagene vicleucel; Bristol-Myers Squibb, Summit, NJ) for treatment of relapsed or refractory multiple myeloma; and Breyanzi (lisocabtagene maraleucel; Bristol-Myers Squibb, Summit, NJ) for treatment of relapsed or refractory large B-cell lymphoma.

Moreover, the FDA approved 4 biosimilar drugs. Among these are Semglee (insulin glargine-yfgn; Mylan, Morgantown, WV), Rezvoglar (insulin glargine-aglr; Ely Lilly, Indianapolis, Ind), Byooviz (ranibizumab-nuna, Biogen, Cambridge, Mass), and Yusimry (adalimumab-aqvh; Coherus BioSciences, Redwood City, Calif).

In 2017, the FDA announced the Drug Competition Action Plan to address the high drug costs through market competition of generic drugs. The 3 objectives were to improve the efficiency of the generic drug development, review, and approval process, maximize scientific and regulatory clarity, and close loopholes for brand-name drug companies that delay generic competition.[3] The Competitive Generic Therapy (CGT) designation qualifies a generic drug to receive an expedited development and review of its application.[4] Additionally, generic drug applications that receive a CGT designation may be eligible for a 180-day period of marketing exclusivity if it is the first approved product for that CGT and the product must be commercially marketed within 75 calendar days after the date of approval or the exclusivity will be forfeited.[4] This marketing exclusivity blocks approval of competitive abbreviated new drug applications, but only begins when the first CGT product is marketed. This provides an incentive to market the CGT quickly after it is first approved. Of the 80 first-time generic drug approvals in 2021, 51 received the CGT designation.[5,6] Since the program's inception, 119 generic drugs received the CGT designation.

CLINICAL SIGNIFICANCE

- This summary of novel drugs approved by the US Food and Drug Administration in 2021 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 health care organizations that are considering addition of these drugs to their prescribing formularies.

Table Summary of 50 Novel Drugs Approved in 2021

Brand (Generic)	Indication	Clinical Pearls	Package Insert
Cardiology			
Verquvo (vericiguat)	To reduce cardiovascular death and heart failure hospitalization in adults with symptomatic chronic HF and EF <45%	Contraindicated in pregnancy	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214377s000lbl.pdf
Dermatology			
Adbry (tralokinumab-ldrm)	Atopic dermatitis	Monitor for hypersensitivity reactions or conjunctivitis	https://www.leo-pharma.us/Files/Billeder/US%20Website%20Product%20PIs/AdbryPI.pdf
Bylvay (odevixibat)	Pruritus	May increase the risk hepatotoxicity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215498s000lbl.pdf
Korsuva (difelikefalin)	Pruritus with chronic kidney disease undergoing hemodialysis	May cause somnolence	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214916s000lbl.pdf
Livmarli (maralixibat)	Cholestatic pruritus associated with Alagille syndrome	May increase the risk of hepatotoxicity or gastrointestinal adverse reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214662s000lbl.pdf
Endocrine			
Kerendia (finerenone)	Reduction of kidney and heart complication in chronic kidney disease associated with type 2 diabetes	Check for drug–drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215341s000lbl.pdf
Skytrofa (lonapegsomatropin-tcgd)	Short stature due to inadequate endogenous growth hormone	Monitor for hypersensitivity reactions or intracranial hypertension	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761177Orig1s000lbl.pdf
Voxzogo (vosoritide)	Achondroplasia	Not recommended in renal impairment	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214938s000lbl.pdf
Zegalogue (dasiglucagon)	Severe hypoglycemia	Check for drug–drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214231s000lbl.pdf
Genetic			
Amondys 45 (casimersen)	Duchenne muscular dystrophy	May cause nephrotoxicity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213026lbl.pdf
Evkeeza (evinacumab-dgnb)	Homozygous familial hypercholesterolemia	May cause hypersensitivity reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761181s000lbl.pdf
Leqvio (inclisiran)	Heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease	The effect on cardiovascular morbidity and mortality has not been determined	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf
Nexviazyme (avalglucosidase alfa-ngpt)	Late-onset Pompe disease	Risk of acute cardiorespiratory failure	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761194s000lbl.pdf
Nulibry (fosdenopterin)	Molybdenum cofactor deficiency type A	May cause photosensitivity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214018s000lbl.pdf

Table (*Continued*)

Brand (Generic)	Indication	Clinical Pearls	Package Insert
Welireg (belzutifan)	von Hippel-Lindau disease	May cause anemia or hypoxia	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215383s000lbl.pdf
Hematology			
Besremi (ropeginterferon alfa-2b-njft)	Polycythemia vera	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761166s000lbl.pdf
Empaveli (pegcetacoplan)	Paroxysmal nocturnal hemoglobinuria	Available only through a restricted program called Empaveli Risk Evaluation and Mitigation Strategy	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215014s000lbl.pdf
Rezurock (belumosudil)	Chronic graft-versus-host disease	Check for drug-drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214783s000lbl.pdf
Infectious diseases			
Brexafemme (ibrexafungerp)	Vulvovaginal candidiasis	Contraindicated in pregnancy	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214900s000lbl.pdf
Cabenuva (cabotegravir and rilpivirine)	HIV	Monitor for allergic and post-injection reactions, increase in liver enzymes, and depression	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212888s000lbl.pdf
Fexinidazole (fexinidazole)	Trypanosomiasis	May cause hepatotoxicity, neuropsychiatric adverse reactions, or QT prolongation	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214429s000lbl.pdf
Livtencity (maribavir)	Cytomegalovirus	Check for drug—drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215596lbl.pdf
Neurology			
Aduhelm (aducanumab-avwa)	Alzheimer disease	May cause hypersensitivity reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf
Ponvory (ponesimod)	Relapsing forms of multiple sclerosis	May increase the risk of infections, bradyarrhythmias/AV conduction delays or macular edema	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213498s000lbl.pdf
Qulipta (atogepant)	Prevent episodic migraines	Check for drug—drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215206Orig1s000lbl.pdf
Vyvgart (efgartigimod alfa-fcab)	Myasthenia gravis	Delay administration in patients with an active infection	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761195s000lbl.pdf
OB/GYN			
Nextstellis (drospirenone and estetrol)	To prevent pregnancy	Decreased efficacy with body mass index $\geq$30 kg/m^2	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214154s000lbl.pdf
Oncology			
Cosela (trilaciclib)	To mitigate chemotherapy-induced myelosuppression in small cell lung cancer	Monitor for hypersensitivity reactions or pneumonitis	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214200s000lbl.pdf
Cytalux (pafolacianine)	Diagnostic agent for ovarian cancer	Use only 5% dextrose injection for dilution	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214907s000lbl.pdf
Exkivity (mobocertinib)	Non-small cell lung cancer	Monitor for cardiac toxicity or pneumonitis	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215310s000lbl.pdf
Fotivda (tivozanib)	Renal cell carcinoma	Monitor for signs or symptoms of cardiac failure	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212904s000lbl.pdf
Jemperli (dostarlimab-gxly)	Endometrial cancer	May increase risk of immune-related adverse reaction in any organ system or tissue	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761174s000lbl.pdf
Lumakras (sotorasib)	Non-small cell lung cancer	May increase the risk hepatotoxicity or pneumonitis	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214665s000lbl.pdf
Pepaxto (melphalan flufenamide)	Relapsed or refractory multiple myeloma	Monitor for signs and symptoms of myelosuppression	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214383s000lbl.pdf
Pylarify (piflufolastat F 18)	Diagnostic agent for men with prostate cancer	May increase risk for image misinterpretation	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214793s000lbl.pdf
Rybrevant (amivantamab-vmjw)	Subset of non-small cell lung cancer	Monitor for signs and symptoms of infusion-related reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761210s000lbl.pdf
Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn)	Acute lymphoblastic leukemia or Lymphoblastic lymphoma	Monitor for hypersensitivity reactions, hepatotoxicity, or pancreatitis	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761179s000lbledt.pdf
Scemblix (asciminib)	Chronic myeloid leukemia	Monitor for signs and symptoms of myelosuppression and cardiac toxicity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215358s000Orig1lbl.pdf
Tepmetko (tepotinib)	Non-small cell lung cancer	May increase the risk hepatotoxicity or pneumonitis	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214096s000lbl.pdf
Tivdak (tisotumab vedotin-tftv)	Recurrent metastatic cervical cancer	Monitor for signs and symptoms of peripheral neuropathy	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761208Orig1s000lbledt.pdf
Truseltiq (infigratinib)	Cholangiocarcinoma	May cause retinal pigment epithelial detachment	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214622s000lbl.pdf
Ukoniq (umbralisib)	Marginal zone lymphoma and follicular lymphoma	May increase the risk of infections, neutropenia or hepatotoxicity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213176s000lbl.pdf
Zynlonta (loncastuximab tesirine-lpyl)	Certain types of relapsed or refractory diffuse large B-cell lymphoma	Monitor for signs and symptoms of myelosuppression and cutaneous reactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761196s000lbl.pdf
Psychiatry			
Azstarys (serdexmethylphenidate and dexmethylphenidate)	ADHD	Pretreatment screening for cardiac disease	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212994s000lbl.pdf
Lybalvi (olanzapine and samidorphan)	Schizophrenia and bipolar type 1	Check for drug—drug interactions	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213378s000lbl.pdf
Qelbree (viloxazine)	ADHD	May increase suicidal thoughts and behavior	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211964s000lbl.pdf

Table (*Continued*)

Brand (Generic)	Indication	Clinical Pearls	Package Insert
Respiratory			
Tezspire (tezepelumab-ekko)	Asthma	Do not discontinue corticosteroids use abruptly	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761224s000lbl.pdf
Rheumatology			
Lupkynis (voclosporin)	Lupus nephritis	Monitor for prolonged QT interval, nephrotoxicity, neurotoxicity, or hypertension. Contraindicated with strong CYP 3A4 inhibitors.	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213716s000lbl.pdf
Saphnelo (anifrolumab-fnia)	Moderate to severe systemic lupus erythematosus	Monitor for hypersensitivity reactions or serious infections	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761123s000lbl.pdf
Tavneos (avacopan)	Anti-neutrophil cytoplasmic autoantibody-associated vasculitis	May increase the risk of infections, HBV reactivation, or hepatotoxicity	https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214487s000lbl.pdf

ADHD = attention-deficit/hyperactivity disorder; AV = atrioventricular; CYP = cytochrome P450; EF = ejection fraction; HBV = hepatitis B vaccine; HF = heart failure; HIV = human immunodeficiency virus; OB/GYN = Obstetrics/Gynecology.

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