

FDA Drug Approvals for 2022

Investors pay close attention to the FDA's approval process. The FDA's stance on innovation as it relates to safety and efficacy is crucial to any investment in therapeutic drug development. Innovation in drug development moves at the pace of the FDA. The table below lists novel FDA approvals in 2022 spanning innovation from gene therapy to antibodies to small molecule drugs.

Table 2: Novel FDA Drug Approvals for 2022 (CDER)

Approval Date in 2022	Drug Name & Company	Drug Modality	Indication & Mechanism of Action
28-Dec	NexoBrid (anacaulase); MediWound/ Vericel	Enzyme	"(Dermatology) Proteolytic enzymes enriched in bromelain for removing eschar caused by thermal burns "
28-Dec	Briumvi (ublituximab); TG Therapeutics	Antibody	(Neurology) Briumvi, anti-CD20 mAb (ublituximab) for relapsed MS
23-Dec	Xenoview (hyperpolarized Xe-129); Polarean Imaging	Contrast Agent, SM	(Evaluation of Lung Ventilation) Xenon Xe 129 Gas Blend, hyperpolarized contrast agent for use with MRI; Drug device combination
22-Dec	Lunsumio (mosunetuzumab); Roche	Bispecific antibody	(Oncology) Lunsumio. CD20xCD3 T-cell engager for R/R follicular lymphoma
22-Dec	Sunlenca (Lenacapavir); Gilead	Small molecule antiviral	(Infectious Disease) HIV-1 capsid inhibitor for multidrug resistant HIV-1 infection
12-Dec	Krazati (adagrasib); Mirati	Small molecule	(Oncology) KRAS-G12C inhibitor (adagrasib) for KRASG12C + NSCLC after at least one prior systemic therapy
1-Dec	Rezlidhia (olutasidenib); Rigel	Small molecule	(Oncology) Rezlidhia, IDH1 inhibitor (olutasidenib) for R/R AML with susceptible IDH1 mutation
18-Nov	Tzield (teplizumab); Provention Bio & Sanofi	Antibody	(Endocrinology) Tzield, CD3-directed immunosuppressant to delay the onset of Stage 3 Type 1 diabetes
14-Nov	Elahere (mirvetuximab soravtansine); Immunogen	Antibody -drug conjugate (ADC)	"(Oncology) FRa-binding maytansinoid ADC for ovarian cancer resistant to platinum"
25-Oct	Tecvayli (teclistamab); Janssen/ JNJ	Bspecific Antibody	(Oncology) Tecvayli, BCMA-directed CD3 T-cell engager for R/R multiple myeloma
21-Oct	Imjudo (tremelimumab); Astra Zeneca	Antibody	(Oncology) Imjudo CTLA-4 checkpoint inhibitor (tremelimumab) for hepatocellular carcinoma with durvalumab
30-Sep	Lytgobi (futibatinib); Taiho	Small molecule	(Oncology) Lytgobi, irreversible FGFR1-4 inhibitor for Intrahepatic cholangiocarcinoma with FGFR2 rearrangements
29-Sep	Relyvrio (sodium phenylbutyrate/taurursodiol); Amylyx Pharma	Small molecule	(Neurology) Relyvrio (sodium phenylbutyrate and taurursodiol*) ALS
22-Sep	Omlonti (oomidenepag isopropyl); Santen	Small molecule	(Ophthalmology) Omlonti, EP2 receptor agonist for open-angle glaucoma and ocular hypertension
21-Sep	Elucirem (gadopiclenol); Guerbet	Contraast agent, Small Molecule	(Contrast Agent, Vascularity in the CNS) Elucirem, gadolinium-based contrast agent for MRI imaging of lesions with abnormal vascularity diagnostic
14-Sep	Terlivaz (terlipressin); Mallinckrodt	Small molecule	(Hepatorenal) Terlivaz, vasopressin receptor agonist for hepatorenal syndrome in patients with reduced kidney function hepatology
9-Sep	Rolvedon (eflapegrestim); Spectrum Pharma	Fusion protein	"(Hematology/ Oncology) Rolvedon, rhG-CSF for infection related to neutropenia in cancer "
9-Sep	Sotyktu (deucravacitinib); BMS	Small molecule	(Dermatology) Sotyktu, TYK2 allosteric inhibitor for moderate-to-severe plaque psoriasis
7-Sep	Daxxify (daxibotulinumtoxinA); Revance Therapeutics	Protein - purified botulinum toxin type A	"(Dermatology) Daxxify, acetylcholine release inhibitor (botulinum toxin formulation) for moderate to severe glabellar lines"
1-Sep	Spevigo (spesolimab-sbzo); Boehringer Ingelheim	Antibody	(Dermatology) Spevigo, interleukin-36 receptor (IL1RL2/IL1RAP) antibody (spesolimab-sbzo) for psoriasis symptoms
31-Aug	Xenpozyme (Olipudase alfa); Sanofi	Enzyme	(Rare Disease) Xenpozyme, acid sphingomyelinase replacement
13-Jun	Amvuttra (vutrisiran); Alnylam	Nucleotide/ siRNA	"(Neurology, Rare Disease) Amvuttra, TTR siRNA for polyneuropathy of hereditary transthyretin-mediated amyloidosis"
23-May	Vtama (tapinarof); Dermavent Sciences	Small molecule	"(Dermatology) Vtama, AhR agonist (tapinarof) for plaque psoriasis"
13-May	Mounjaro (tirzepatide); Eli Lilly	Peptide, subcutaneous	(Endocrinology)Mounjaro, GIP and GLP-1 receptor agonist for diabetes
3-May	Voquezna (vonoprazan, amoxicillin, clarithromycin); Takeda	Small molecule	(Infectious Disease) Voquezna, K+/H+-ATPase potassium channel blocker for H. pylori infection
28-Apr	Camzyos (mavacamten); BMS	Small molecule	(Cardiology) Camzyos, cardiac myosin inhibitor for obstructive Hypertrophic cardiomyopathy (HCM) cardiology
26-Apr	Vivjoa (oteseconazole); Mycovia	Small molecule	(Infectious Disease) Vivjoa, antifungal (CYP51 inhibitor) for RVVC in non-reproductive females
23-Mar	Pluvicto (lutetium (177Lu) vipivotide tetraxetan); Novartis	Small molecule - radiolabelled	(Oncology) Pluvicto, PSMA-targeted radiotherapy for PSMA-positive prostate cancer
18-Mar	Opdualag (nivolumab and relatlimab);BMS	Antibody	(Oncology) Opdualag, Lag-3 checkpoint inhibitor (nivolumab (PD-1i) and relatlimab-rmbw*) for melanoma
18-Mar	Ztalmy (ganaxolone); Marinus	Small molecule	"(Neurology) Ztalmy, GABAA PAM for seizures in CDKL5 deficiency disorder"
28-Feb	Vonjo (ganaxolone)CTI Biopharma	Small molecule	"(Oncology) JAK2/IRAK1 inhibitor for myelofibrosis "
17-Feb	Pyrukynd (mitapivat); Agios	Small molecule	(Hemolytic Anemia) Pyrukynd, PK activator for hemolytic anemia in PK deficiency hematology
4-Feb	Enjaymo (sutimlimab-jome); Sanofi	Antibody	(Hematology) Enjaymo, complement component (C1s) inhibitor for cold agglutinin disease
28-Jan	Vabysmo (faricimab-svoa); Genentech/Roche	Bispecific Antibody	(Ophthalmology) Vabysmo, VEGF and Ang-2 inhibitor for neovascular AMD and diabetic macular edema
25-Jan	Kimtrak (tebentafusp-tebn); Immunocore	Bspecific Antibody	(Oncology) Injectable bispecific gp100 peptide-HLA-directed CD3 T cell engager; for uveal melanoma
14-Jan	Cibinqo (abrocitinib); Pfizer	Small molecule	(Dermatology) Cibinqo, JAK1 inhibitor for refractory atopic dermatitis
7-Jan	Quviviq (daridorexant); Idorsia	Small molecule	(Neurology) Quviviq, OX1/2 dual antagonist for insomnia

Table 3: Novel FDA Drug Approvals for 2022 (CBER)

Approval Date in 2022	Drug Name & Company	Drug Modality	Indication & Mechanism of Action
16-Dec	ADSTILADRIN (nadofaragene firadenovec); Ferring Pharma	Gene Therapy	(Cancer) Replicating adenovirus vector-based gene therapy containing the gene interferon alfa-2b for immune stimulation for non-muscle invasive bladder cancer
30-Nov	REBYOTA (fecal microbiota, live); Ferring Pharma	Live fecal microbiota suspension	(Infectious Disease) Mechanism not known - delivery of tested fecal microbiota via rectal administration. Fecal matter from human donors. For Clostridioides difficile infection
22-Nov	HEMGENIX (etranacogene dezaparovec); CSL Behring	Gene Therapy	(Hemophilia B - congenital Factor IX deficiency) Adeno-associated virus vector-based gene therapy - delivers a gene for human coagulation factor IX
16-Sep	SKYSONA (elivaldogene autotemcell); Bluebird Bio	Gene Therapy	(Neurology) Cerebral adrenoleukodystrophy (CALD); rare diseaseLentivirus vector. Adds functional copies of the ABCD1 cDNA into patients' hematopoietic stem cells (HSCs) through transduction of autologous CD34+ cells with Lenti-D Lentivirus vebtor (LW).
17-Aug	ZYNTEGLO (betibeglogene autotemcel); Bluebird Bio	Gene Therapy	(β-thalassemia) Lenti virus vector. Adds functional copies of a modified β-globin gene into patients' hematopoietic stem cells (HSCs) through transduction of autologous CD34+ cells
3-Jun	PRIORIX Measles, Mumps & Rubella Vaccine Live; GSK	Live vaccine	(Infectious Disease) Immune response to Measles, Mumps, and Rubella antigens in vaccine
28-Feb	CARVYKTI (ciltacabtagene autoleucl); Janssen/JNJ	CAR- T cell	(Oncology) Relapsed or refractory multiple myeloma. CAR- T cell CARVYKTI is a BCMA-directed, genetically modified autologous T cell immunotherapy.
31-Jan	SPIKEVAX (COVID-19 Vaccine, mRNA); Moderna	mRNA Vaccine	(Infectious Disease) Coronavirus disease 2019 Active immunization to prevent COVID-19 with mRNA that codes for COVID-19 antigens