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Review Article

New Drugs Approved in 2023

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Abstract

In 2023, the US Food and Drug Administration (FDA) approved 55 novel drugs. Thirty six of the 55 (65%) novel drug approvals were reviewed and approved through an expedited review pathway and 28 of the 55 (51%) were approved for treatment of a rare disease. This review includes a summary of the novel drugs approved by the FDA in 2023.

Keywords: Novel drugs, FDA, Accelerated approval, Priority review, Fast track

Introduction

In 2023, the US Food and Drug Administration (FDA) approved 55 novel drugs [1]. This was the second highest novel drug approvals in 1 year due in part to several expedited review pathways, including accelerated approval, priority review, fast track, and breakthrough therapy, allow for approval processes that enable drugs to be available earlier than had they undergone review in the traditional pathway. Ultimately, expedited approval allows for availability of drugs that treat a serious condition or fill an unmet medical need.

Of the 55 novel drug approvals in 2023, 36 (65%) drugs were processed via one of the expedited review pathways, and 28 of the 55 (51%) were approved for treatment of a rare disease [2]. The Table includes a summary of the 55 novel drugs approved in 2023 (Table 1).

Brand (Generic)	Indication	Clinical Pearls	Package Insert
Cardiology			
Inpefa® (sotagliflozin)	Heart failure	Monitor hypoglycemia, volume depletion, and urinary tract infection	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216203s000lbl.pdf
Dermatology			
Bimzelx® (bimekizumab)	Moderate to severe plaque psoriasis	May increase risk of suicidal ideation and behavior	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761151s000lbl.pdf
Filsuvez® (birch triterpenes)	Dystrophic and junctional epidermolysis bullosa	Monitor for hypersensitivity reactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/215064s000lbl.pdf
Litfulo® (ritlecitinib)	Patchy hair loss	May increase risk of infection, thrombosis, or mortality	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/215830s000lbl.pdf

Endocrinology			
Brenzavvy® (bexagliflozin)	Type 2 diabetes	Contraindicated in patients on dialysis	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/214373s000lbl.pdf
Ngenla® (somatrogon-ghla)	Growth failure due to inadequate secretion of endogenous growth hormone	May increase risk of neoplasms, intracranial hypertension, glucose intolerance, and hypothyroidism	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761184Orig1s000 Corrected_lbl.pdf
Veozah® (fezolinetant)	Moderate-to-severe hot flashes	Monitor hepatic function	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216578s000lbl.pdf
Gastroenterology			
Omvoh® (mirikizumab-mrkz)	Ulcerative colitis	Monitor for hypersensitivity reactions, infections, and hepatotoxicity	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761279s000lbl.pdf
Velsipity® (etrasimod)	Ulcerative colitis	Contraindicated with recent cardiovascular events	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216956s000lbl.pdf
Genetic			
Agamree® (vamorolone)	Duchenne muscular dystrophy	Monitor for drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/215239s000lbl.pdf
Daybue® (trofinetide)	Rett Syndrome	Not recommended in moderate-severe renal impairment	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217026s000lbl.pdf
Elfabrio® (pegunigalsidase alfa-iwxj)	Fabry Disease	Monitor for infusion reactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761161s000lbl.pdf
Joenja® (leniolisib)	Activated phosphoinositide 3-kinase delta syndrome	Monitor for headaches, atopic dermatitis, and drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217759s000lbl.pdf
Lamzede® (valmanase alfa-tycv)	Non-central nervous system manifestations of alpha-mannosidosis	Monitor for infusion reactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761278s000lbl.pdf
Pombiliti® (cipaglucosidase alfa-atga)	Late-onset Pompe disease	Monitor for hypersensitivity reactions including anaphylaxis	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761204s000lbl.pdf
Sohonos® (palovarotene)	Fibrodysplasia ossificans progressiva	Contraindicated in pregnancy	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/215559s000lbl.pdf
Wainua® (eplontersen)	Polyneuropathy of hereditary transthyretin-mediated amyloidosis	May cause reduced vitamin A levels and supplementation is recommended	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217388s000lbl.pdf
Veopoz® (pozelimab-bbfg)	CD55-deficient protein-losing enteropathy	May increase risk of bacterial infections and systemic hypersensitivity reactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761339s000lbl.pdf

Hematology			
Aphexda® (motixafortide)	Autologous hematopoietic stem cell transplantation with multiple myeloma	May cause anaphylactic shock and hypersensitivity reactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217159s000lbl.pdf
Elrexfio® (elranatamab-bcmm)	Relapsed or refractory multiple myeloma	Monitor for cytokine release syndrome	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761345Orig1s000l bl.pdf
Fabhalta® (iptacopan)	Paroxysmal Nocturnal Hemoglobinuria	Risk evaluation and mitigation strategy program	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/218276s000lbl.pdf
Jaypirca® (pirtobrutinib)	Mantle Cell Lymphoma	Monitor for arrhythmias, cytopenias, hemorrhage, and infections	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216059Orig1s000lbl.pdf
Jesduvroq® (daprodustat)	Anemia of chronic kidney disease	Associated with increased risk of heart failure exacerbation	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216951s000lbl.pdf
Ojjaara® (momelotinib)	Intermediate or high-risk myelofibrosis	May increase risk of infection, hepatotoxicity, or cardiovascular event	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216873s000lbl.pdf
Talvey® (talquetamab-tgvs)	Relapsed or refractory multiple myeloma	Monitor for cytokine release syndrome	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761342s000lbl.pdf
Ryzneuta® (efbemalenograstim alfa- vuxw)	Neutropenia	May cause anemia and thrombocytopenia	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761134s000lbl.pdf
Vanflyta® (quizartinib)	Acute myeloid leukemia	Monitor for QTc prolongation Monitor for drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216993s000lbl.pdf
Infectious Diseases			
Beyfortus® (nirsevimab-alip)	Respiratory syncytial virus	Limited to children < 24 months of age	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761328s000lbl.pdf
Defencath® (taurolidine, heparin)	Prevent catheter-related bloodstream infections with hemodialysis	Monitor for heparin-induced thrombocytopenia	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/214520s000lbl.pdf
Paxlovid® (nirmatrelvir, ritonavir)	Mild-to-moderate COVID-19	Monitor for drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217188s000lbl.pdf
Rezzayo® (rezafungin)	Candidemia and invasive candidiasis	May cause infusion reactions, photosensitivity, or hepatic impairment	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217417s000lbl.pdf

Xacduro® (sulbactam, durlobactam)	Hospital-acquired and ventilator- associated bacterial pneumonia	Limited to Acinetobacter baumannii-calcoaceticus complex	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216974Orig1s000 Correctedlbl.pdf
Xdemvy® (lotilaner)	Demodex blepharitis	Do not administer while wearing contact lenses	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217603s000lbl.pdf
Nephrology			
Filspari® (sparsentan)	Reduce proteinuria in immunoglobulin A nephropathy	Contraindicated in pregnancy Monitor for drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216403s000lbl.pdf
Rivfloza® (nedosiran)	Lower urinary oxalate levels in patients with primary hyperoxaluria type 1	May cause injection site reaction(s)	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/215842s000lbl.pdf
Neurology			
Leqembi® (lecanemab-irmb)	Alzheimer's disease	Monitor for infusion reactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761269Orig1s000l bl.pdf
Qalsody® (tofersen)	Amyotrophic Lateral Sclerosis	May cause myelitis, aseptic meningitis, or elevated intracranial pressure	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/215887s000lbl.pdf
Rystiggo® (rozanolixizumab-noli)	Generalized myasthenia gravis	May cause infection	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761286s000lbl.pdf
Skyclarys® (omaveloxolone)	Friedreich's ataxia	Monitor for liver impairment and drug- drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216718Orig1s000l bl.pdf
Zavzpret® (zavegepant)	Migraine	Avoid use in severe hepatic or renal impairment	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216386s000lbl.pdf
Zilbrysq® (zilucoplan)	Generalized myasthenia gravis	Contraindicated in patients with unresolved Neisseria meningitidis infection	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216834s000lbl.pdf
Oncology			
Augtyro® (repotrectinib)	ROS1-positive non-small cell lung cancer	Monitor for drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/218213s000lbl.pdf
Columvi® (glofitamab-gxbm)	Diffuse large B-cell lymphoma	Monitor for cytokine release syndrome	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761309s000lbl.pdf
Epkinly® (epcoritamab-bysp)	Relapsed or refractory diffuse large B- cell lymphoma	Monitor for cytokine release syndrome	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761324s000lbl.pdf

Fruzaqla® (fruquintinib)	Refractory, metastatic colorectal cancer	May cause or worsen hypertension	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217564s000lbl.pdf
Loqtorzi® (toripalimab-tpzi)	Recurrent or metastatic nasopharyngeal carcinoma	Monitor for immune-mediated reactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761240s000lbl.pdf
Ogsiveo® (nirogacestat)	Desmoid tumors	Monitor for drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217677s000lbl.pdf
Orserdu® (elacestrant)	ER+ advanced or metastatic breast cancer	May cause dyslipidemia Monitor for drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217639s000lbl.pdf
Posluma® (flotufolastat F 18)	Prostate cancer	Minimize radiation exposure with appropriate safety measures	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216023s000lbl.pdf
Truqap® (capivasertib)	Breast cancer	May cause hyperglycemia Monitor for drug-drug interactions	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/218197s000lbl.pdf
Zynyz® (retifanlimab-dlwr)	Merkel Cell Carcinoma	Monitor for immune-mediated reactions (hepatitis, nephritis, endocrinopathies)	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/761334s000lbl.pdf
Ophthalmology			
Izervay® (avacincaptad pegol)	Atrophy secondary to age-related macular degeneration	May increase risk of intraocular pressure and retinal detachment	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217225s000lbl.pdf
Miebo® (perfluorhexyloctane)	Dry eye disease	Do not administer while wearing contact lenses	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/216675s000lbl.pdf
Psychiatry			
Exxua® (gepirone)	Major depressive disorder	Monitor for QTc prolongation	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/021164s000lbl.pdf
Zurzuvae® (zuranolone)	Postpartum depression	May cause CNS depressant effects	https://www.accessdata.fda.gov/drugsat fda_docs/label/2023/217369s000lbl.pdf

Table 1: Summary of 55 Novel Drugs Approved in 2023.

Twenty (36%) of the approved drugs include a first-in-class classification, which indicates a mechanism of action different from existing therapies. One notable first-in-class example is defencath® (taurolidine, heparin) indicated to reduce the incidence of catheter-related bloodstream infections in adult patients with kidney failure receiving chronic haemodialysis through a central venous catheter. Another first-in-class approval is fabhalta® (iptacopan) indicated for the treatment of adults with paroxysmal nocturnal haemoglobinuria. The therapeutic area with the most novel drug approvals (10 of 55) in 2023 was oncology.

The FDA also approved biologics in 2023, which are considered large, complex molecules made from living sources. Notable among the approved biologics are Casgevy (exagamglogene autotemcel; Vertex Pharmaceuticals, Boston, MA) for treatment of sickle cell disease, Adzynma (ADAMTS13, recombinant-krhn; Takeda Pharmaceuticals, Lexington, MA) for prevention or treatment of congenital thrombotic thrombocytopenic purpura, Ixchiq (Chikungunya Vaccine, Live; Valneva, Bethesda, MD) for active immunization of chikungunya virus, and Abrysvo (Respiratory Syncytial Virus Vaccine; Pfizer, New York, NY) for active immunization of respiratory syncytial virus. Additionally, Cyfendus (Anthrax Vaccine Adsorbed, Adjuvanted; Emergent BioSolutions, Gaithersburg, MD) for post-exposure prevention of Bacillus anthracis, Lantidra (donislecel-jujn; CellTrans, Chicago, IL) for treatment of type 1 diabetes, and Elevidys (delandistrogene moxeparvovec-rokl; Sarepta Therapeutics, Cambridge, MA) for treatment of Duchenne muscular dystrophy.

Moreover, the FDA approved biosimilar medications, which are considered highly similar and have no clinically meaningful differences from an existing FDA-approved biologic. Among these are Yuflyma (adalimumab-aaty; Celltrion, Incheon, Republic of Korea), Tyruko (natalizumab-sztn; Sandoz, Princeton, NJ), Tofidence (tocilizumab-bavi; Biogen, Cambridge, MA), Wezlana (ustekinumab-auub; Amgen, Thousand Oaks, CA), and Avzivi (bevacizumab-tnjn; Bio-Thera Solutions, Guangzhou, China).

Clinical Significance

- This summary of novel drugs approved by the FDA in 2023 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 addition of these drugs to their prescribing formularies.

References

1. US Food and Drug Administration (FDA) Novel drug approvals for 2023.
2. US Food and Drug Administration (FDA) New Drug Therapy Approvals 2023.