

Guest Editors:

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Key Inforbits:



- 2023 New Drug Approvals
- Disease Categories with New Treatment Options in 2023
- Summary of Approved Drugs

New Drugs Approved in 2023

Brand Name Generic Name (Manufacturer) ¹	Approval Date ¹	Category ^{1,2}	FDA Indication ^{1,2}	Route ¹	Warnings/Precautions ^{1,2}	Orphan Drug ^{1,3}
<i>Leqembi</i> lecanemab-irmb (Eisai Inc.)	1/6/23	Anti-Amyloid Monoclonal Antibody	To treat Alzheimer's disease	IV	Has a potential to cause brain bleeding or seizures due to amyloid related imaging abnormality (ARIA.) Most patients unaffected, though there is a genetic disposition. Common side effects include cough and diarrhea.	No
<i>Brenzavvy</i> bexagliflozin (TheracosBio, LLC)	1/20/23	Sodium-glucose cotransporter 2 inhibitor	Glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise	PO	Risk of UTI, acidosis, and low blood sugar.	No
<i>Jaypirca</i> pirtobrutinib (Eli Lilly and Company)	1/27/23	Tyrosine kinase inhibitor	Relapsed or refractory mantle cell lymphoma in adults who have had at least 2 lines of systemic therapy, including a BTK inhibitor	PO	May increase incidence of infection, certain vaccinations are required before the first dose. Increases risk of bleeding. Common side effects include nausea and vomiting, headache, mouth sores, and muscle pain	Yes
<i>Orserdu</i> elacestrant (Stemline Therapeutics, Inc.)	1/27/23	Estrogen receptor antagonist	Estrogen receptor- positive, human epidermal growth factor receptor 2- negative, ESR1- mutated, advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	PO	May cause dyslipidemia and is not recommended for use in patients with liver disease. Can affect fertility and is teratogenic. Common side effects include stomach upset, heartburn, and muscle pains.	No



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<i>Jesduvroq</i> daprodustat (GlaxoSmithKline)	2/1/23	Hypoxia-inducible factor prolyl hydroxylase inhibitor	Anemia caused by chronic kidney disease for adults on dialysis for at least 4 months	PO	Black box warning for the risk of increased cardiovascular events, such as stroke, MI, and thromboembolism. Not recommended for patients with recent history of ASCVD, hypertension, or cancer. Side effects include confusion, dizziness, imbalance, and seizures. Any side effect attributed to this drug is considered severe.	No
<i>Lamzede</i> velmanase alfatyvcv (Chiesi Farmaceutici S.p.A.)	2/16/23	Recombinant human lysosomal alpha-mannosidase	Non-central nervous system manifestations of alpha-mannosidosis	IV	Black box warning for increased risk of anaphylactic reaction to this drug. It is recommended that patients carry epinephrine and have allergy precautions at the ready while taking this medication. Consider pretreatment with histamine. Common side effects include headache, flu-like symptoms, joint pain, and bruising.	Yes
<i>Filspari</i> sparsentan (Traverse Therapeutics, Inc.)	2/17/23	Endothelin and angiotensin II receptor antagonist	Reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression	PO	Filspari REMS designed to help protect patients at risk due to boxed warnings for drug hepatotoxicity and teratogenicity. May cause angioedema and renal dysfunction. Common side effects include dizziness.	Yes
<i>Skyclarys</i> omaveloxolone (Reata Pharmaceuticals Inc.)	2/28/23	Nuclear factor erythroid 2-related factor 2 activator	Friedrich's ataxia	PO	Not recommended for patients with liver disease. Major CYP 3A4 substrate, monitor for drug interactions in any patient taking inducers or inhibitors. Common side effects include headache, weakness, muscle pain, and sore throat.	Yes
<i>Zavzpret</i> zavegepant (Pfizer Inc.)	3/9/23	Calcitonin gene-related peptide receptor antagonist	Migraine	Intranasal	Monitor patients with kidney or renal disease. Can cause change in taste and smell and can cause stomach upset.	No
<i>Daybue</i> trofinetide (Acadia Pharmaceuticals Inc.)	3/10/23	Glycine-Proline-Glutamate analogs	Rett syndrome	PO	Not recommended for patients with renal disease, not to be used with laxative. Commonly causes diarrhea. Other common side effects include anxiety, weight changes, and stomach upset,	Yes
<i>Zynyz</i> retifanlimab-dlwr (Incyte Corporation)	3/22/23	Programmed death receptor-1 blocking antibody	Metastatic or recurrent locally advanced Merkel cell carcinoma	IV	Patients should avoid breastfeeding for 4 months after the last dose of taking this medicine. Can cause liver problems, eye problems, and can induce SJS. Common side effects include fatigue, nausea, and back and neck pain	Yes

<i>Rezzayo</i> rezafungin (Patheon Italia S.p.A.)	3/22/23	Echinocandin antifungal	Candidemia and invasive candidiasis	IV	Patients may experience sunburn more easily. Not recommended for use in pregnancy. Common side effects include nausea, vomiting, diarrhea, and tremors.	Yes
<i>Joenja</i> leniolisib (Pharming Group N.V.)	3/24/23	Phosphatidylinositol 3-kinase inhibitor	Activated phosphoinositide 3-kinase delta syndrome	PO	Not recommended for use in patients with liver disease. Patients should avoid breastfeeding for 1 week after the last dose. Common side effects include headache, nasal congestion, diarrhea, and hair loss.	Yes
<i>Qalsody</i> tofersen (Biogen MA Inc.)	4/25/23	Antisense oligonucleotide	Amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation	Intrathecal	Not recommended for use if the patient is pregnant. Can cause spinal cord issues such as numbness and tingling down spine, as well as aseptic meningitis. Common side effects are joint and muscle pain, and fatigue.	Yes
<i>Elfabrio</i> pegunigalsidase alfa-iwxj (Chiesi Farmaceutici S.p.A.)	5/9/23	Hydrolytic lysosomal neutral glycosphingolipid-specific enzyme	Confirmed Fabry disease	IV	Black box precaution for hypersensitivity reactions, recommended to pretreat with antihistamines and keep epinephrine on hand. Can cause sciatica and infusion site reactions. Common side effects include upset stomach, diarrhea, and generalized aches.	No
<i>Veozah</i> fezolinetant (Astellas Pharma US, Inc.)	5/12/23	Neurokinin 3 receptor antagonist	Moderate to severe hot flashes caused by menopause	PO	Not recommended for use in patients with kidney or liver disease or those taking fluvoxamine, mexiletine, or cimetidine. Common side effects include stomach pain, diarrhea, and trouble sleeping.	No
<i>Miebo</i> perfluorhexyloctane (Bausch & Lomb)	5/18/23	Semifluorinated alkane	Signs and symptoms of dry eye disease	Ophthalmic	No contraindications listed by manufacturer. Remove contact lenses before taking.	No
<i>Epkinly</i> epcoritamab-bysp (Genmab US, Inc.)	5/19/23	Bispecific CD20-directed CD3 T-cell engager	Relapsed or refractory diffuse large B-cell lymphoma (not otherwise specified) and high-grade B-cell lymphoma after two or more lines of systemic therapy	SubQ	May cause a serious, life threatening release of cytokines. Must increase dose slowly to increase tolerance. Can cause immune effector cell-associated neurotoxicity syndrome, which is a deadly neurological condition that needs to be monitored for. Common side effects include headaches, nausea and vomiting, and fatigue.	No
<i>Xacduro</i> sulbactam,	5/23/23	Beta-lactam antibacterial and	Hospital-acquired bacterial pneumonia	IV	Contraindicated for use with probenecid. Can cause kidney issues and unusual bleeding or	No

durlobactam (Entasis Therapeutics Ltd.)		beta lactamase inhibitor	and ventilator-associated bacterial pneumonia caused by susceptible isolates of <i>Acinetobacter baumannii-calcoaceticus complex</i>		bruising. Common side effects include diarrhea or constipation.	
<i>Paxlovid</i> nirmatrelvir, ritonavir (Pfizer Inc.)	5/25/23	Severe acute respiratory syndrome coronavirus (main protease inhibitor and HIV-1 protease inhibitor and CYP3A inhibitor)	Mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19	PO	Strong CYP 3A4 inhibitor, recommended to assess drug-drug interactions and to make a decision on clinical usefulness given patients conditions. Common side effects include changes in taste, diarrhea, and muscle pain.	No
<i>Posluma</i> flutufolostat F 18 (Blue Earth Diagnostics Ltd.)	5/25/23	Radioactive diagnostic agent	Use with positron emission tomography imaging in certain patients with prostate cancer	IV	Teratogenic. Recommended for patients to limit exposure to medication, and to drink lots of non caffeinated liquids.	No
<i>Inpefa</i> sotagliflozin (Lexicon Pharmaceuticals, Inc.)	5/26/23	Sodium-glucose cotransporter 2 inhibitor	Heart failure	PO	Risk of UTI, acidosis, and low blood sugar.	No
<i>Columvi</i> glofitamab-gxbm (Genentech, Inc.)	6/15/23	Biospecific CD20-directed CD3 T-cell engager	Diffuse large B-cell lymphoma, not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy	IV	May cause a serious, life threatening release of cytokines. Must increase dose slowly to increase tolerance. Contraindicated to use in patients with active infections. Common side effects include headache, constipation, and body aches.	No
<i>Litfulo</i> ritlecitinib (Pfizer Inc.)	6/23/23	Tyrosine kinase inhibitor	Severely patchy hair loss	PO	Increased risk of infection, including opportunistic infections. Contraindicated for use in patients with rheumatoid arthritis. Risk of venous thromboembolism. Common side effects include diarrhea, headache, and acne.	No
<i>Rystiggo</i> rozanolixizumab	6/26/23	Neonatal Fc receptor blocker	Generalized myasthenia gravis in	SubQ	Contraindicated for use in patients with an active infection. Patients may need certain	Yes



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-noli (UCB, Inc.)			adults who are anti-acetylcholine receptor- or anti-muscle-specific tyrosine kinase antibody-positive		vaccines before initiating treatment. Common side effects include headache, upset stomach, and joint pain.	
<i>Ngenla</i> somatrogonghla (Pfizer Inc.)	6/27/23	Human growth hormone analog	Growth failure due to inadequate secretion of endogenous growth hormone	SubQ	Can cause eye problems. Not recommended for use in patients with diabetes, patients must monitor blood sugar while taking medication. Common side effects include nausea, cough, stomach pain, and throat irritation.	Yes
<i>Beyfortus</i> nirsevimab-alip (AstraZeneca)	7/17/23	Respiratory syncytial virus F protein-directed fusion inhibitor	Prevent respiratory syncytial virus lower respiratory tract disease	IM	Currently being distributed per patient needs due to national shortage of drugs. May cause muscle weakness and cyanosis.	No
<i>Vanflyta</i> quizartinib (Daiichi Sankyo, Inc.)	7/20/23	Tyrosine kinase inhibitor	Use as part of a treatment regimen for newly diagnosed acute myeloid leukemia that meets certain criteria	PO	Can cause QT prolongation and torsades de pointes. Not recommended for use in any patient with a history of arrhythmia. Due to this risk the drug has a REMS program. Common side effects include mouth sores, headache, and insomnia.	Yes
<i>Xdemvy</i> lotilaner (Tarsus Pharmaceuticals, Inc.)	7/25/23	Ectoparasiticide	Demodex blepharitis	Ophthalmic	No contraindications, warnings or precautions present. Less frequent side effects include burning of eyes, chalazion, hordeolum, punctate keratitis, and stinging of eyes.	No
<i>Zurzuvae</i> zuranolone (Biogen Inc.)	8/4/23	Neuroactive steroid gamma-aminobutyric acid A receptor positive modulator	Postpartum depression	PO	Major psychiatric warnings present including increased risk of suicidal thinking. May cause CNS depression and increases risk for falls.	No
<i>Izervay</i> avacincaptad pegol (Iveric Bio, Inc.)	8/4/23	Complement C5 inhibitor	Geographic atrophy secondary to age-related macular degeneration	Intravitreal injection	Contraindications to ocular or periocular infections as well as active intraocular inflammation. Can cause endophthalmitis and retinal detachments, increased ocular pressure, and neovascular age-related macular degeneration and choroidal neovascularization.	No
<i>Talvey</i> talquetamab-	8/9/23	Bispecific GPRC5D-directed CD3 T-cell	Adults with relapsed or refractory multiple myeloma who have	SubQ	REMS program in place. Can cause cytokine release syndrome, serious skin reactions, neutropenia, thrombocytopenia,	Yes



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tgvs (Janssen Biotech, Inc.)		engager	received at least four prior therapies		hepatotoxicity, severe infections, neurologic toxicity, oral toxicity, and weight loss.	
<i>Elrexio</i> elranatamab-bcmm (Pfizer Inc.)	8/14/23	Bispecific B-cell maturation antigen-directed CD3 T-cell engager	Adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy	SubQ	REMS program in place. Can cause cytokine release syndrome, neutropenia, hepatotoxicity, serious infections, and neurologic toxicity.	Yes
<i>Sohonos</i> palovarotene (Ipsen Biopharmaceuticals, Inc.)	8/16/23	Retinoic acid receptor gamma agonist	Reduce the volume of new heterotopic ossification in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva	PO	Contraindicated in patients with hypersensitivities to palovarotene and in pregnancy. Can cause bone toxicity, mucocutaneous reactions, night blindness, photosensitivity reactions, and psychiatric effects.	Yes
<i>Veopoz</i> pozelimab-bbfg (Regeneron Pharmaceuticals, Inc.)	8/18/23	Complement C5 inhibitor	Patients 1 year old and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease	IV, SubQ	Contraindicated in patients with unresolved <i>N. meningitidis</i> infection. Can increase the risk of bacterial infections and cause infusion reactions. Common side effects include increased blood pressure, bone fractures, and upper respiratory tract infections.	Yes
<i>Aphexda</i> motixafortide (BioLineRx Ltd)	9/8/23	Hematopoietic stem cell mobilizer	Use with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma	SubQ	Contraindicated in patients with serious hypersensitivity reactions to motixafortide. Can cause anaphylactic shock/hypersensitivity reactions, injection site reactions, and leukocytosis.	Yes
<i>Ojjaara</i> momelotinib (GlaxoSmithKline)	9/15/23	Tyrosine kinase inhibitor	Intermediate or high-risk myelofibrosis in adults with anemia	PO	Can cause an increase in the risk of major adverse cardiovascular events, thrombocytopenia and neutropenia, hepatotoxicity, serious infections, an increased risk of secondary malignancies, and thrombosis risk.	Yes
<i>Exxua</i> gepirone (Mission Pharmacal)	9/22/23	Serotonin 5-HT1A Receptor Agonist	Major depressive disorder	PO	Contraindicated in patients with a hypersensitivity to gepirone, prolonged QTc interval >450 msec at baseline, patients receiving strong CYP34A inhibitors, severe	No



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Company)					hepatic impairment, taking or within 14 days of stopping a monoamine oxidase inhibitor. Common side effects include nausea, dizziness, drowsiness, and fatigue.	
<i>Pombiliti</i> cipaglucoasidase alfa-atga (Amicus Therapeutics US, LLC)	9/28/23	Hydrolytic lysosomal glycogen-specific enzyme	Late-onset Pompe disease	IV	Contraindicated in pregnancy when used in combination with miglustat. Significant drug interactions exist. Common side effects include hypersensitivity reactions.	Yes
<i>Rivfloza</i> nedosiran (Pyramid Laboratories)	9/29/23	LDHA-directed small interfering RNA	Lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function	SubQ	Can cause injection-site reactions (erythema, pain, bruising, and rash).	Yes
<i>Velsipity</i> etrasimod (Pfizer Inc.)	10/12/23	Sphingosine 1- phosphate receptor modulator	Moderately to severe active ulcerative colitis in adults	PO	Contraindicated in patients with a history of myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or class III or IV heart failure in the last 6 months, Mobitz type II second-degree or third-degree atrioventricular block, sinus syndrome, or sino-atrial block, unless a functioning pacemaker is present.	No
<i>Zilbrysq</i> zilucoplan (UCB, Inc.)	10/17/23	Complement C5 inhibitor	Generalized myasthenia gravis in adults who are anti- acetylcholine receptor (AChR) antibody positive	SubQ	Contraindicated in unresolved <i>Neisseria meningitidis</i> infection. REMS program in place due to risk of meningococcal infection. Can cause pancreatitis in addition to increased lipase and amylase.	Yes
<i>Bimzelx</i> bimekizumab (UCB, Inc.)	10/17/23	Humanized interleukin-17A and F antagonist	Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	SubQ	Can increase the risk of infections, increased liver serum transaminases >3x upper limit of normal, suicidal ideation. Not to be used in patients with tuberculosis disease.	No
<i>Agamree</i> vamorolone (Santhera Pharmaceuticals)	10/26/23	Corticosteroid	Duchenne muscular dystrophy	PO	Contraindicated in patients with a hypersensitivity to vamorolone. Common side effects include Cushingoid appearance, vitamin D deficiency, weight gain, vomiting, and psychiatric signs and symptoms.	Yes



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, Inc.)						
<i>Omvo</i> mirikizumab- mrkz (Eli Lilly and Company)	10/26/23	Interleukin-23 antagonist	Ulcerative colitis	IV, SubQ	Contraindicated in patients with a serious hypersensitivity reaction to mirikizumab. Can cause livery injury, hypersensitivity reactions, increased infection risk. Should not be used in patients with tuberculosis.	No
<i>Loqtorzi</i> toripalimab-tpzi (Coherus BioSciences, Inc.)	10/27/23	Programmed death receptor-1 blocking antibody	Recurrent or metastatic nasopharyngeal carcinoma when used together with or following other therapies	IV	Can cause cardiotoxicity, immune-mediated rash or dermatitis, immune-mediated endocrinopathies, diarrhea, hepatitis, infusion-related reactions, kidney toxicity, ocular toxicity, and pulmonary toxicity.	Yes
<i>Fruzaqla</i> fruquintinib (Takeda Pharmaceuticals U.S.A., Inc.)	11/8/23	Tyrosine kinase inhibitor	Refractory, metastatic colorectal cancer	PO	Can cause skin reactions, GI perforation, severe or life-threatening hemorrhage, hepatic dysfunction/liver injury, elevated blood pressure, an increased risk of infection, increased risk of proteinuria, posterior reversible encephalopathy syndrome, arterial thromboembolic events, and impaired wound healing.	No
<i>Defencath</i> taurolidine, heparin (CorMedix Inc.)	11/15/23	Thiadiazinane antimicrobial and anti-coagulant	Reduce the incidence of catheter-related bloodstream infections in adults with kidney failure receiving chronic hemodialysis through a central venous catheter	Central venous cathete r	Contraindicated in patients with a hypersensitivity to taurolidine, heparin, and pork products. Can cause heparin-induced thrombocytopenia and hypersensitivity reactions.	No
<i>Augtyro</i> reprotrectinib (Bristol-Myers Squibb Company)	11/15/23	Tyrosine kinase inhibitor	ROS1-positive non- small cell lung cancer	PO	Can cause CNS effects, increased AST/ALT, hyperuricemia, myalgias, interstitial lung disease/pneumonitis, and skeletal fractures	Yes
<i>Ryzneuta</i> efbemalenogras tim alfa-vuxw (Evide Biotechnology PTE. LTD.)	11/16/23	Leukocyte growth factor	Neutropenia	SubQ	Contraindicated in patients with a history of serious allergic reactions to granulocyte-stimulating factors. Can cause aortitis, capillary leak syndrome, leukocytosis, thrombocytopenia, serious allergic reactions, myelodysplastic syndrome, glomerulonephritis, acute respiratory distress syndrome, and splenic rupture	No

<i>Truqap</i> capivasertib (AstraZeneca Pharmaceuticals LP)	11/16/23	Tyrosine kinase inhibitor	Breast cancer that meets certain disease criteria	PO	Contraindicated in patients with severe hypersensitivity to capivasertib. Can cause cutaneous adverse reactions, severe diarrhea associated with dehydration, severe hyperglycemia, and ketoacidosis.	No
<i>Ogsiveo</i> nirogacestat (SpringWorks Therapeutics, Inc.)	11/27/23	Gamma secretase inhibitor	Adults with progressing desmoid tumors who require systemic treatment	PO	Can cause alterations in potassium and phosphate levels, diarrhea, AST/ALT elevations, and the occurrence of new nonmelanoma skin cancers	Yes
<i>Fabhalta</i> iptacopan (Novartis Pharmaceuticals Corporation)	12/5/23	Complement factor B inhibitor	Paroxysmal nocturnal hemoglobinuria	PO	Not recommended in patients with serious hypersensitivity to iptacopan or in unresolved serious infections caused by encapsulated bacteria. Can increase total cholesterol, LDL and serum triglycerides. REMS program in place due to serious infections caused by encapsulated bacteria.	Yes
<i>Filsuvez</i> birch triterpenes (Lichtenheldt GmbH)	12/18/23	Topical skin product	Wounds associated with dystrophic and junctional epidermolysis bullosa	Topical	Local hypersensitivity and skin reactions, including dermatitis and urticaria, have been reported	Yes
<i>Wainua</i> eplontersen (AstraZeneca Pharmaceuticals LP)	12/21/23	Transthyretin- directed antisense oligonucleotide	Polyneuropathy of hereditary transthyretin- mediated amyloidosis	SubQ	May cause a decrease in serum vitamin A. Supplement at recommended daily allowance of vitamin A during treatment	Yes

IV: intravenous IM: intramuscular SubQ: subcutaneous

Disease Categories with New Treatment Options in 2023:⁴

- **Infectious Diseases:** COVID-19, respiratory syncytial virus, pneumonia, HIV-1
- **Neurological Conditions:** amyotrophic lateral sclerosis, Alzheimer’s disease, migraine
- **Heart, blood, kidney, and endocrine diseases:** type 2 diabetes, anemia, pediatric hormone deficiency
- **Cancer:** colorectal, prostate, lung
- **Women’s health:** postpartum depression, hot flashes due to menopause

Summary of Newly Approved Drugs:⁴

Over 2023, there have been 55 new drugs approved for use in the US by the FDA. This is a much larger number of approvals since last year’s 37. Over the last 10 years, the average number of new drug approvals is 42.9 indicating that this year’s number of approvals is above average. As drug development increases, it is important for health care professionals to periodically review new approvals. This month, let’s all take time to reflect upon the new drugs approved last year.

Out of the 55 drugs, 20 of them are first-in-class medications meaning their mechanisms of action are different from existing therapies. The most common indication among all drugs approved is cancer of some type.



A majority of the drugs that were approved last year were orphan drugs, which is defined as a drug for a disease that affects less than 200,000 people. Out of the 55 total drugs approved, 28 of them (about 51%) were orphan drugs. This is about consistent with the percentage of orphan drugs approved in 2022 (58%). A study conducted in 2023 on rare diseases targeted by orphan drug designations and approvals following the Orphan Drug Act (ODA) concludes that the increase in the number of orphan drug approvals is due to financial incentives provided by the ODA along with several scientific advances.⁵

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