



Guest Editors:

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Key Inforbits:



- 2024 New Drug Approvals
- Disease Categories with New Treatment Options in 2024
- Summary of Approved Drugs

New Drugs Approved in 2024

Brand Name Generic Name (Manufacturer) ¹	Approval Date ¹	Category ¹⁻³	FDA Indication ¹⁻³	Route ¹	Warnings/Precautions ¹⁻³	Orphan Drug ^{1,4}
<i>Zelsuvmi</i> berdazimer (Ligand Pharmaceuticals)	1/5/24	Nitric Oxide-Releasing Agent; Antiviral Agent	Molluscum contagiosum (adults and pediatrics ≥ 1 years of age)	TOP	No contraindications listed by manufacturer. Common side effects are application site reactions, including allergic contact dermatitis, and infection.	No
<i>Exblifep</i> cefepime, enmetazobactam (Allegra Therapeutics)	2/22/24	Combination Cephalosporin (4 th Generation) and Extended-Spectrum Beta-Lactamase (ESBL) Inhibitor	Complicated urinary tract infections (UTIs)	IV	Can cause neurotoxicity, which is more likely to happen in patients with impaired renal function. Common side effects include an increase in transaminases and bilirubin, headache, and infusion site reactions.	No
<i>Letybo</i> letibotulinumtoxinA-wlbg (Hugel America, Inc.)	2/29/24	Acetylcholine Release Inhibitor; Neuromuscular Blocker Agent, Toxin	Temporary improvement in the appearance of moderate to severe glabellar lines in adults	IM	<u>Boxed warning</u> for potential spread of toxin effects to produce botulinum toxin-like symptoms, including difficulties with swallowing and breathing. Contraindicated if patient is experiencing an infection at injection site. Use with caution in patients with pre-existing cardiovascular disease, compromised respiratory function, and dysphagia. Most common side effect is headache	No

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<i>Tevimbra</i> tislelizumab- jsgr (BeiGene, Ltd.)	3/13/24	Programmed Death Receptor-1 (PD-1) Blocking Monoclonal Antibody; Antineoplastic Agent, Immune Checkpoint Inhibitor	Unresectable or metastatic esophageal squamous cell carcinoma	IV	May cause immune-mediated adverse reactions, infusion-related reactions, and embryo-fetal harm. Can also cause complications of allogeneic hematopoietic stem cell transplantation. Most common lab abnormalities include decreased hemoglobin (Hgb), lymphocytes, sodium, and albumin, and increased alkaline phosphatase (ALP), aspartate aminotransferase (AST), and alanine aminotransferase (ALT). May also experience anemia, fatigue, musculoskeletal pain, weight loss, and cough.	Yes
<i>Rezdiffra</i> resmetirom (Madrigal Pharmaceuticals)	3/14/24	Thyroid Hormone Receptor-Beta (THR-beta) Agonist	Noncirrhotic, non- alcoholic steatohepatitis with moderate to advanced liver scarring	PO	Treatment is indicated in conjunction with diet and exercise. May cause elevations in liver tests and cholelithiasis or cholecystitis. Common side effects include diarrhea, constipation, nausea, vomiting, pruritus, abdominal pain, and dizziness.	No
<i>Tryvio</i> aprocitentan (Idorsia Pharmaceuticals, Ltd.)	3/19/24	Antihypertensive; Endothelin Receptor Antagonist	Used in combination with other antihypertensives to treat hypertension	PO	<u>Boxed warning</u> for embryo-fetal toxicity and is contraindicated in pregnancy. Only available through a REMS program. Do not use if aminotransferases >3x upper limit of normal (ULN) or in moderate to severe hepatic impairment. Common side effects are edema and anemia.	No
<i>Duvyzat</i> givinostat (ITF Therapeutics, LLC)	3/21/24	Histone Deacetylase Inhibitor	Duchenne muscular dystrophy (patients ≥6 years of age)	PO	Must be taken with food. Uses weight-based dosing. Dose adjustments may be needed for decreased platelets, increased triglycerides, QTc prolongation, or if moderate to severe diarrhea occurs.	Yes
<i>Winrevair</i> sotatercept -csrk (Merck & Co., Inc.)	3/26/24	Activin A Receptor IIA Ligand; Activin Receptor Ligand Trap	Pulmonary arterial hypertension	SubQ	Hgb and platelets should be monitored for needed dose modifications before each dose for the first 5 doses and periodically thereafter. Common side effects include headache, epistaxis, rash, telangiectasia, diarrhea, dizziness, and erythema. May cause impaired fertility for both genders.	Yes
<i>Vafseo</i> vadadustat (Akebia Therapeutics, Inc.)	3/27/24	Hypoxia-Inducible Factor Prolyl Hydroxylase (HIF PH) Inhibitor	Chronic kidney disease (CKD)- associated anemia	PO	Contraindicated in uncontrolled hypertension. Not recommended in active malignancy. AST, ALT, and bilirubin should be monitored prior to starting, monthly for the first 6 months, then as clinically indicated. Common side effects include hypertension and diarrhea.	No

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<i>Voydeya</i> danicipan (Alexion Pharmaceuticals)	3/29/24	Complement Factor D Inhibitor	Used in combination with ravulizumab or eculizumab for extravascular hemolysis in adults with paroxysmal nocturnal hemoglobinuria	PO	<u>Boxed warning</u> for infections caused by encapsulated bacteria. Must have complete vaccination ≥2 weeks prior to first dose. Not effective as monotherapy. May cause increase in hepatic enzymes and hyperlipidemia. Most common side effect is headache.	Yes
<i>Zevtera</i> ceftobiprole medocaril sodium (Basilea Pharmaceutica International, Ltd.)	4/3/24	Cephalosporin (5th Generation)	Bloodstream infections caused by <i>Staphylococcus aureus</i> , acute bacterial skin and soft tissue infections (SSTIs), and adult and pediatric patients with community- acquired pneumonia	IV	Should not be used in patients with ventilator- associated pneumonia due to lack of efficacy and safety data. Has potential for neurotoxicity. Common side effects include nausea, vomiting, diarrhea, increased hepatic enzymes and bilirubin, fever, rash, headache, hypertension, and infusion site reactions.	No
<i>Lumisight</i> pegulicianine (Lumicell, Inc.)	4/17/24	Optical Imaging Agent	Indicated for fluorescence imaging in adults with breast cancer to detect cancerous tissue	IV	<u>Boxed warning</u> for anaphylaxis and other hypersensitivity reactions. Patients should be assessed for allergies to contrast media or polyethylene glycol (PEG). Weight based dosing. Common side effects include hypersensitivity and chromaturia.	No
<i>Anktiva</i> nogapendekin alfa inbakicept -pmln (ImmunityBio, Inc.)	4/22/24	Antineoplastic Agent, Biological Response Modulator, Interleukin-15 (IL- 15) Receptor Agonist	Bladder cancer in combination with Bacillus Calmette- Guérin (BCG)	IVES	Common side effects include increased creatinine, urinary symptoms (dysuria, hematuria, polyuria, increased urgency), UTIs, hyperkalemia, musculoskeletal pain, fever, and chills.	No
<i>Ojemda</i> tovorafenib (Day One Pharmaceuticals, Inc.)	4/23/24	Antineoplastic Agent, BRAF Kinase Inhibitor	Relapsed or refractory pediatric low- grade glioma	PO	May cause hemorrhaging, photosensitivity, hepatotoxicity, reduced growth velocity, and increased growth of neurofibromatosis (NF)1- associated tumors. Common side effects include rash, hair color changes, fatigue, viral infections, nausea, vomiting, headache, fever, dry skin, constipation, acne-like rash, and upper respiratory infections (URTIs).	Yes

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<i>Xolremdi</i> mavoxifafor (X4 Pharmaceuticals, Inc.)	4/26/24	CXC Chemokine Receptor 4 Antagonist	Warts, hypogamma- globulinemia, infections, and myelokathexis (WHIM) syndrome (in ≥12 years of age)	PO	May cause QTc prolongation. Concomitant use with CYP2D6 substrates is contraindicated. Not recommended for use in severe renal impairment, end stage renal disease (ESRD), or moderate to severe hepatic impairment. Must be taken on an empty stomach. Common side effects include thrombocytopenia, rash, rhinitis, epistaxis, vomiting, and dizziness.	Yes
<i>Imdelltra</i> tarlatamab- dlle (Amgen, Inc.)	5/16/24	Antineoplastic Agent, Delta-Like Ligand 3 (DLL3), Bispecific T-Cell Engager, (BiTE) Therapy	Extensive stage small cell lung cancer (ES-SCLC)	IV	Boxed warning for cytokine release syndrome and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). Must monitor complete blood count (CBC), liver enzymes, and bilirubin prior to treatment, before each dose, and as clinically indicated. Requires hospitalization for days 1 and 8 during cycle 1 and extensive outpatient monitoring with each dose thereafter. Common side effects include cytokine release syndrome, fatigue, fever, dysgeusia, decreased appetite, musculoskeletal pain, constipation, anemia, and nausea.	Yes
<i>Rytelo</i> imetelstat (Geron Corp.)	6/6/24	Oligonucleotide; Antineoplastic Agent, Telomerase Inhibitor	Low- to intermediate-1 risk myelodysplastic syndromes (MDS)	IV	No contraindications listed by manufacturer. May cause infusion-related reactions and requires premedication with diphenhydramine and hydrocortisone. Common side effects include decrease platelets, WBCs, neutrophils; increased AST, ALT, ALP; fatigue, prolonged partial thromboplastin time (PTT), arthralgia/myalgia, COVID-19 infections, and headache.	Yes
<i>Iqirvo</i> elafibranor (Ipsen Biopharmaceuticals)	6/10/24	Peroxisome Proliferator- Activated Receptor Agonist	Used in combination with ursodeoxycholic acid to treat primary biliary cholangitis	PO	Warnings for this medication include fractures, hypersensitivity (rash), livery injury, rhabdomyolysis, myalgias (with or without CPK elevation), and myopathy. Common side effects are diarrhea, nausea, arthralgia, weight fluctuations, abdominal pain, vomiting, constipation, muscle injury, fracture, dry mouth, rash, and gastroesophageal reflux disease. Avoid use in patients with known or suspected biliary obstruction.	Yes
<i>Sofdra</i> sofipronium bromide (Botanix Pharmaceuticals)	6/18/24	Anticholinergic Agent	Primary axillary hyperhidrosis	TOP	Warnings include heat illness, urinary retention, blurred vision which can impair operating machinery. Common side effects are dry mouth, blurry vision, application site reactions, urinary retention. Use with caution in hot environments, especially if the patient is unable to sweat.	No

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<i>Piasky</i> crovalimab-akkz (Genentech)	6/20/24	Complement C5 Inhibitor; Monoclonal Antibody	Paroxysmal nocturnal hemoglobinuria	IV; SubQ	<u>Boxed warning</u> for increased risk of meningococcal infections. Patient should be vaccinated for meningococcal ≥ 2 weeks prior to administration. Hypersensitivity reactions occurred in up to ¼ of patients who switched between C5 inhibitors including Type III reactions (arthralgia, myalgia, headache, fatigue, rash, fever, bruising, and/or abdominal pain). Allowing the prior C5 inhibitor to clear prior to initiation of an alternative C5 inhibitor agent should lower the risk of a reaction.	Yes
<i>Ohtuvayre</i> ensifentrine (Verona Pharma)	6/26/24	Phospho- diesterase-3 Enzyme/Phospho- diesterase-4 Enzyme Inhibitor	COPD	INH	Warnings include paradoxical bronchospasms and psychiatric reactions. Use with caution in patients with hepatic impairment. This drug is not indicated for initial (rescue) treatment of acute episodes of bronchospasm. Common side effects include back pain, hypertension, UTI, and diarrhea	No
<i>Kisunla</i> donanemab-azbt (Eli Lilly & Company)	7/2/24	Anti-Amyloid Monoclonal Antibody; Immune Globulin	Alzheimer's disease	IV	<u>Boxed warning</u> for amyloid related imaging abnormalities. Warnings include infusion reactions. Infusion reactions usually occur during infusion or within 30 minutes after infusion. Some dosage forms may contain polysorbate 80, known for hypersensitivity reactions. The most common side effect is headache.	No
<i>Leqselvi</i> deuruxolitinib (Sun Pharmaceutical Industries, Ltd.)	7/25/24	Janus Kinase Inhibitor	Severe alopecia areata	PO	<u>Boxed warnings</u> for serious infections, mortality, malignancy, major adverse cardiovascular event (MACE), and thrombosis. Warnings for this medication include increased risk of serious adverse reactions in patients who are CYP2C9 poor metabolizers or concomitantly using moderate to strong CYP2C9 inhibitors. Additional warnings include GI perforation, lymphopenia, anemia, neutropenia, and elevated triglycerides and total cholesterol. This medication should not be used in combination with other immunosuppressants. Common side effects are headache, acne, nasopharyngitis, blood creatinine phosphokinase increase, fatigue, SSTIs and herpes.	No
<i>Voranigo</i> vorasidenib (Servier Pharmaceuticals)	8/6/24	Antineoplastic Agent, IDH1 Inhibitor, IDH2 Inhibitor	Grade 2 astrocytoma or oligodendro- glioma with a susceptible IDH1 or IDH2 mutation	PO	Warnings for this medication include hepatotoxicity. Common side effects are fatigue, headache, COVID-19, musculoskeletal pain, diarrhea, nausea, and seizures. Common lab abnormalities include elevations in hepatic transaminases leading to hepatic failure, necrosis, or autoimmune hepatitis.	Yes

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<i>Yorvipath</i> palopegteriparatide (Ascendis Pharma)	8/9/24	Parathyroid Hormone Analog	Hypo- parathyroidism	SubQ	Warnings for this medication include hypercalcemia or hypocalcemia with more than one injection in one day. Additional warnings include osteosarcoma, orthostatic hypotension, and digoxin toxicity (due to hypercalcemia). Common side effects include injection site reactions, vasodilatory signs and symptoms, headache, diarrhea, back pain, and oropharyngeal pain.	Yes
<i>Nemluvio</i> nemolizumab-ilto (Galderma)	8/12/24	Interleukin-31 Receptor Alpha Antagonist; Monoclonal Antibody	Prurigo nodularis	SubQ	Warnings for this medication include hypersensitivity reactions, ensuring patients are up to date with all immunizations before starting therapy, and avoiding live vaccines during therapy. Common side effects include headache, atopic dermatitis, and eczema.	No
<i>Livdelzi</i> seladelpar (Gilead Sciences)	8/14/24	Peroxisome Proliferator- Activated Receptor Agonist	Used in combination with ursodeoxycholic acid to treat primary biliary cholangitis	PO	Warnings for this medication include fractures and elevated ALT/AST > 3 times the ULN. Avoid use in patients with known or suspected biliary obstruction. Poor CYP2C9 metabolizers will receive an increased exposure to seladelpar. Common side effects include headache, abdominal pain and distension, nausea, and dizziness.	Yes
<i>Niktimvo</i> axatilimab-csfr (Incyte and Syndax Pharmaceuticals)	8/14/24	Colony Stimulating Factor-1 Receptor (CSF-1R) Inhibitor; Monoclonal Antibody	Chronic graft- versus-host disease	IV	Warnings for this medication include infusion-related reactions and hypersensitivity to polysorbate 80. Polysorbate 80 may be included in some dosage forms which could increase the risk of hypersensitivity reactions. Common lab abnormalities include decreased serum phosphate, hypercalcemia, and increased lipase and amylase. Common side effects include edema and increased risk of infection.	Yes
<i>Lazcluze</i> lazertinib (Janssen Biotech, Inc.)	8/19/24	Antineoplastic Agent; Epidermal Growth Factor Receptor (EGFR) Inhibitor; Tyrosine Kinase Inhibitor	Used in combination with amivantamab to treat locally advanced or metastatic NSCLC	PO	Warnings for this medication include venous thrombotic events, interstitial lung disease/pneumonitis, ocular toxicity, and severe rash. It may cause fetal harm. Common side effects include lab abnormalities, rash, nail toxicity, musculoskeletal pain, edema, diarrhea, constipation, and hemorrhage.	No
<i>Ebglyss</i> lebrikizumab-lbkz (Eli Lilly & Company)	9/13/24	Interleukin-13 Antagonist; Monoclonal Antibody	Moderate-to- severe atopic dermatitis	SubQ	Warnings for this medication include Hypersensitivity reactions, conjunctivitis, keratitis, and Helminth infections. Avoid live vaccines. Common side effects include conjunctivitis, injection site reactions, and Herpes-Zoster.	No

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<i>Miplyffa</i> arimoclomol (Zevra Therapeutics)	9/20/24	Pharmacologic Chaperone; Heat Shock Protein Inducer	Used in combination with miglustat to treat neurological manifestations of Niemann-Pick disease Type C	PO	Warnings for this medication include hypersensitivity reactions and serum creatinine elevations. Serum creatinine increase does not affect glomerular filtration. Use alternative methods for assessing renal function. Common side effects include decreased weight, diarrhea, and URTIs. May cause fetal harm.	Yes
<i>Aqneursa</i> levacetylleucine (IntraBio Inc)	9/26/24	Amino Acid Derivative	Niemann-Pick disease type C	PO	Use effective contraception during therapy and 7 days after treatment. Common side effects include URTIs. Other potential side effects include exacerbation of rosacea, abdominal pain, vomiting, and thrombocytopenia.	Yes
<i>Cobenfy</i> xanomeline, trospium chloride (Bristol Myers Squibb)	9/26/24	Anticholinergic Agent; Antipsychotic Agent	Schizophrenia	PO	Common side effects for this medication include angioedema, anticholinergic, GI motility, liver impairment, tachycardia, urinary retention. Use is contraindicated in moderate renal impairment, urinary retention, gastric retention, untreated narrow angle glaucoma or mild hepatic impairment.	No
<i>Flyrcado</i> flurpiridaz F18 (GE Healthcare)	9/27/24	Radio- pharmaceutical	IV radioactive diagnostic drug to evaluate for myocardial ischemia and infarction	IV	Warnings for this medication include cardiopulmonary events and malignancy. Common side effects include headache or dyspnea. Other potential side effects include abdominal pain, GI upset, flushing, chest pain, and angina pectoris. Patients should be adequately hydrated before administration.	No
<i>Itovebi</i> inavolisib (Genentech)	10/10/24	Antineoplastic Agent, Anti- CLDN18.2; Monoclonal Antibody	Locally advanced or metastatic breast cancer	PO	Warnings for this medication include GI toxicity and hyperglycemia. Common side effects include alopecia, skin rash, xeroderma, GI upset, UTI, decreased hemoglobin, decreased neutrophils, decreased platelet count, lymphocytopenia, and fatigue. It is classified as a high alert medication.	No
<i>Hympavzi</i> marstacimab-hncq (Pfizer)	10/11/24	Antihemophilic Agent	Reduce bleeding episodes related to hemophilia A or B	SubQ	Warnings for this medication include hypersensitivity and thromboembolic events. Side effects include antibody development, pruritus, injection-site reaction, and headache. Some dosages may contain polysorbate 80.	Yes

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<i>Vyloy</i> zolbetuximab-clzb (Astellas Pharmaceuticals)	10/18/24	Antineoplastic Agent	Gastric or gastroesophageal junction adenocarcinoma	IV	Warnings for this medication include hypersensitivity, nausea and vomiting. Nausea and vomiting occurred more often during the first treatment cycle. Potential side effects include peripheral edema, decreased serum albumin, decreased serum glucose, constipation, abdominal pain, and hypersensitivity reactions.	Yes
<i>Orlynvah</i> sulopenem etzadroxil, probenecid (Iterum Therapeutics)	10/25/24	Antibiotic, Penem; Uricosuric Agent	Uncomplicated UTIs	PO	Warnings for this medication include hypersensitivity reactions and superinfection. Potential side effects include abdominal pain, headache, vomiting, vulvovaginal candidiasis, skin rash, abdominal distention, and flushing. Use is not recommended when CrCl <15 mL/min or for patients on hemodialysis.	No
<i>Ziihera</i> zanidatamab-hrii (Jazz Pharmaceuticals)	11/20/24	Antineoplastic Agent, Anti-HER2; Monoclonal Antibody	Unresectable or metastatic HER2- positive biliary tract cancer	IV	<u>Boxed warning</u> for fetal toxicity. Warnings for this medication include cardiotoxicity, diarrhea, and infusion reactions. Patients must verify they are not pregnant prior to starting treatment. Common side effects include skin rash, decreased serum albumin, abdominal pain, diarrhea, nausea, decreased hemoglobin fatigue and infusion-reactions.	Yes
<i>Revuforj</i> revumenib (Syndax Pharmaceuticals)	11/15/24	Antineoplastic Agent, Menin Inhibitor	Relapsed or refractory acute leukemia	PO	<u>Boxed warning</u> for differentiation syndrome. Warnings for this medication include differentiation syndrome and QT prolongation. Potential adverse reactions include edema, heart failure, QT prolongation, skin rash, GI upset, febrile neutropenia, hemorrhage, increased serum alanine aminotransferase, hypersensitivity reactions, infections, fatigue, musculoskeletal pain, cataracts or renal impairment.	Yes
<i>Attruby</i> acoramidis (BridgeBio)	11/22/24	Transthyretin Stabilizer	Amyloid cardiomyopathy	PO	Warnings for this medication include anaphylaxis, hyperkalemia, hypotension, infusion site reactions and metabolic acidosis. Caution with pregnancy due to unknown effects. Common side effects include diarrhea and upper abdominal pain. It cannot be cut, crushed or chewed.	Yes
<i>Rapiblyk</i> landiolol (AOP Orphan Pharmaceuticals)	11/22/24	Antiarrhythmic Agent, Class II; Beta-Blocker, Beta-1 Selective	Supraventricular arrhythmia	IV	This is for short term use only. Common side effects include hypotension and infusion site reactions.	No

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<i>Iomervu</i> iomeprol (BIPSO GmbH)	11/27/24	Contrast Agent	Intravascular imaging	IV	Warnings for this medication include allergic reactions, contrast-induced kidney disease, CNS effects, extravasation, ischemia, seizures, and thromboembolic events. Common side effects include headache, hypertension, nausea, vomiting, dizziness, and back pain.	No
<i>Bizengri</i> zenocutuzumab- zbco (Partner Therapeutics)	12/4/24	Antineoplastic Agent, Anti-HER2 and HER3; Bispecific Antibody; Monoclonal Antibody	Non-small cell lung cancer (NRG1 fusion positive), pancreatic adenocarcinoma (NRG1 fusion positive)	IV	Boxed warning for fetal toxicity. Warnings include cardiovascular toxicity, hypersensitivity and pulmonary toxicity. Common side effects include edema, skin rash, abdominal pain, GI upset, decreased hemoglobin, decreased platelets, fatigue, and dyspnea. Select patients who ace NRG1 gene fusion.	Yes
<i>Crenessity</i> crinecerfont (Neurocrine Biosciences)	12/13/24	Corticotropin- releasing Factor Type 1 Receptor Antagonist	Congenital adrenal hyperplasia	PO	Warnings include hypersensitivity and adrenal crisis. Common side effects include abdominal pain, decreased neutrophils, fatigue, headache, decreased appetite and dizziness. This medication should be taken with meals.	Yes
<i>Unloxcyt</i> cosibelimab-ipdl (Checkpoint Therapeutics)	12/13/24	Antineoplastic Agent, Anti-PD-L1 Monoclonal Antibody	Metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC who are not candidates for curative surgery or curative radiation	IV	Common side effects include edema, pruritus, skin rash, hypothyroidism, increased serum potassium, increased serum calcium, constipation, diarrhea, decreased hemoglobin, fatigue, headache, and muscle pain. There are no contraindications listed in the manufacturers labeling.	No
<i>Ensacove</i> ensartinib (Xcovery Holdings)	12/18/24	Tyrosine Kinase Inhibitor; Anaplastic Lymphoma Kinase Inhibitor; Antineoplastic Agent	Non-small cell lung cancer, anaplastic lymphoma kinase positive, locally advanced or metastatic	PO	Warnings include bradycardia, CPK elevation, dermatologic toxicity, hepatotoxicity, hyperglycemia, hyperuricemia, ocular toxicity, and pulmonary toxicity. A higher incidence of serious adverse events was observed in patients 65 years old and older. Common side effects include edema, alopecia, rash, GI upset, cough, respiratory tract infections, dizziness, and fatigue.	No

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<i>Tryngolza</i> olezarsen (Ionis Pharmaceuticals)	12/19/24	ASO-GaINAc3 Conjugate; Antisense Oligonucleotide	Adjunct therapy for patients with familial chylomicronemia syndrome	SubQ	Warnings include hematologic effects, hepatic impairment, hypercholesterolemia, immunogenicity, injection site reactions, and musculoskeletal effects. Common side effects include hyperglycemia, decreased platelets, antibody development, injection site reactions, and arthralgia.	Yes
<i>Alhemo</i> concizumab-mtci (Novo Nordisk)	12/20/24	Tissue Factor Pathway Inhibitor Antagonist; Antihemophilic Agent; Monoclonal Antibody	To reduce frequency of bleeding episodes in patients with hemophilia A and B	IM	Common side effects include antibody development and injection-site reaction. Other potential side effects include urticaria, hypersensitivity reaction, thromboembolism, and renal infarction.	Yes
<i>Alyftrek</i> vanzacaftor, tezacaftor, deutivacaftor (Vertex Pharmaceuticals)	12/20/24	CFTR Modulator; Cystic Fibrosis Transmembrane Conductance Regulator Potentiator	Cystic fibrosis patients ≥ 6 years old with a responsive CFTR mutation	PO	Boxed warning for liver injury or liver failure. Warnings for this medication include cataracts and hypersensitivity reactions. Common side effects include influenza, skin rash, fatigue, headache, cough, nasopharyngitis, and URTIs.	Yes

IM: intramuscular INH: inhalation IV: intravenous IVES: intravesical PO: by mouth SubQ: subcutaneous TOP: topical

Disease Categories with New Treatment Options in 2024:⁴

Conditions of Interest	Approved Medications
Infectious Diseases	Zelsuvmi (berdazimer), Exblifep (cefepime, enmetazobactam), Zevtera (ceftobiprole medocaril sodium), Xolremdi (Mavoxifafor), Orlynvah (ulopenem etzadroxil, probenecid)
Neurologic Conditions	Kisunla (donaemab-azbt), Miplyffa (arimoclomol), Aqneursa (levacetylleucine)
Oncologic Conditions	Tevimbra (tislelizumab- jsgr), Anktiva (nogapendekin alfa inbakicept –pmln), Ojemda (tovorafenib), Imdelta (tarlatamab- dlle), Rytelo (imetelstat), Voranigo (vorasidenib), Lazcluze (lazertinib), Itovebi (inavalisib), Vyloy (zolbetuximab-clzb), Ziihera (zanidatamab-hrii), Revuforj (revumenib), Bizengri (zenocutuzumab-zbco), Unloxcyt (cosibelimab-ipdl), Ensacove (ensartinib)
Cardiovascular Conditions	Tryvio (aprocitentan), Attriby (acoramidis), Rapiblyk (landiolol)
Endocrine Conditions	Rezdiffra (resmetirom), Yorvipath (palopegteriparatide), Crenessity (crinecerfront)
Blood Disorders	Vafseo (vadadustat), Voydeya (danicopan), Piasky (crovalimab-akkz), Hympavzi (marstacimab-hncq), Alhemo (conicizumab-mtci)

Pulmonary Conditions	Alyftrek (vanzacaftor, tezacaftor, and deuterivacaftor), Ohtuvayre (ensifentrine), Winrevair (sotatercept-csrk)
Imaging Agents	Lumisight (pegulicainine), Flyrcado (fluripiridaz F 18), Iomervu (iomeprol)
Dermatologic Conditions	Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilt), Leqaelvi (deuruxolitinib), Xolremdi (mavorixafor)

Summary of Newly Approved Drugs:⁴

It is crucial for healthcare providers to practice lifelong learning, such as staying up to date on novel drug approvals. As we transition to the new year, let's reflect on the new drugs brought to the market last year. Over 2024, there were 50 new drugs approved for use in the US by the FDA. This is slightly less than the 55 approvals in 2023 but remained higher than the average number of new drug approvals over the last 10 years, which is 47.

Out of the 50 drugs, 26 (52%) were first-in-class medications with mechanisms of actions that differ from current existing therapies. First-in-class medications provide a unique opportunity for alternative treatment options and potentially improved results. Novel mechanisms of actions are especially important for patients who have not achieved desired results from available treatment options. In addition to first-in-class medications, 26 out of 50 (52%) medications were orphan drugs. In 2023, 28 out of 55 (51%) approved drugs were orphan drugs. Over the past 10 years, the average percentage of orphan drugs approved by the FDA, out of all approved drugs, has been 49.3%.^{4,5}

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