

New Drug Approval

Active Ingredient	Approval Date	FDA-approved use on approval date
Concizumab-mtci	12/20/2024	For routine prophylaxis to prevent bleeding episodes in hemophilia A and B
Vanzacaftor, tezacaftor, and deutevacaftor	12/20/2024	To treat cystic fibrosis
Olezarsen	12/19/2024	To treat familial chylomicronemia syndromeDrug Trials Snapshot
Ensartinib	12/18/2024	To treat non-small cell lung cancer
Cosibelimab-ipdl	12/13/2024	To treat cutaneous squamous cell carcinoma
Crinicerfont	12/13/2024	To treat classic congenital adrenal hyperplasia Press Release
Zenocutuzumab-zbco	12/4/2024	To treat non-small cell lung cancer and pancreatic adenocarcinoma
Iomeprol	11/27/2024	For use as a radiographic contrast agent
Acoramidis	11/22/2024	To treat cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis Drug Trials Snapshot
Landiolol	11/22/2024	To treat supraventricular tachycardia
Zanidatamab-hrii	11/20/2024	To treat unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer Drug Trials Snapshot
Revumenib	11/15/2024	To treat relapsed or refractory acute leukemia
Sulopenem etzadroxil, probenecid	10/25/2024	To treat uncomplicated urinary tract infections (uUTI) Drug Trial Snapshot
Zolbetuximab-clzb	10/18/2024	To treat gastric or gastroesophageal junction adenocarcinoma Drug Trials Snapshots: VYLOY
Marstacimab-hncq	10/11/2024	To prevent or reduce bleeding episodes related to hemophilia A or BPress ReleaseDrug Trials Snapshot
Inavolisib	10/10/2024	To treat locally advanced or metastatic breast cancer Drug Trials Snapshot
Flurpiridaz F 18	9/27/2024	A radioactive diagnostic drug to evaluate for myocardial ischemia and infarction
Xanomeline and trospium chloride	9/26/2024	To treat schizophrenia Press Release Drug Trials Snapshot
Levacetylleucine	9/24/2024	To treat Niemann-Pick disease type CPress Release Drug Trials Snapshot
Arimoclomol	9/20/2024	To treat Niemann-Pick disease type CPress Release Drug Trials Snapshot

Lebrikizumab-lbkz	9/13/2024	To treat moderate-to-severe atopic dermatitis Drug Trials Snapshot
Lazertinib	8/19/2024	To treat non-small cell lung cancer Drug Trials Snapshot
Axatilimab-csfr	8/14/2024	To treat chronic graft-versus-host disease (cGVHD) Drug Trials Snapshot
Seladelpar	8/14/2024	To treat primary biliary cholangitis (PBC) Drug Trials Snapshot
Nemolizumab-ilto	8/12/2024	To treat prurigo nodularis Drug Trials Snapshot
Palopegteriparatide	8/9/2024	To treat hypoparathyroidism Drug Trials Snapshot
Vorasidenib	8/6/2024	To treat Grade 2 astrocytoma or oligodendroglioma Drug Trials Snapshot
Deuruxolitinib	7/25/2024	To treat severe alopecia areata Drug Trials Snapshot
Donanemab-azbt	7/2/2024	To treat Alzheimer's disease Drug Trials Snapshot
Ensifentrine	6/26/2024	To treat chronic obstructive pulmonary disease Drug Trials Snapshot
Crovalimab-akkz	6/20/2024	To treat paroxysmal nocturnal hemoglobinuria Drug Trials Snapshot
Sofpironium	6/18/2024	To treat primary axillary hyperhidrosis Drug Trials Snapshot
Elafibranor	6/10/2024	To treat primary biliary cholangitis in combination with ursodeoxycholic acid Drug Trials Snapshot
Imetelstat	6/6/2024	To treat low- to intermediate-1 risk myelodysplastic syndromes Drug Trials Snapshot

References: Drugs.com

New Drug Indication Approval

Over the past six months (July 2024 to January 2025), the U.S. Food and Drug Administration (FDA) has approved several novel drug therapies. Here is a list of these newly approved drugs, along with their indications and approval dates:

Datroway (datopotamab deruxtecan-dlnk)

Indication: Treatment of advanced breast cancer in patients who have previously undergone treatment.

Approval Date: January 17, 2025

Lumakras (sotorasib) in combination with Vectibix (panitumumab)

Indication: Treatment of metastatic colorectal cancer in patients with a specific KRAS gene mutation, whose cancer has progressed despite chemotherapy.

Approval Date: January 16, 2025

Omvo

Indication: Treatment of adults with moderate-to-severe Crohn's disease.

Approval Date: January 15, 2025

Alhemo

Indication: Prevention or reduction of bleeding episodes in patients aged 12 and above with hemophilia and antibodies against clotting factor replacement treatments.

Approval Date: December 20, 2024

Zepbound (tirzepatide)

Indication: Treatment of obstructive sleep apnea in adults with obesity, to be used alongside a reduced-calorie diet and increased physical activity.

Approval Date: December 20, 2024

Alyftrek (vanzacaftor/tezacaftor/deutivacaftor)

Indication: Treatment of cystic fibrosis.

Approval Date: December 20, 2024

Tryngolza (olezarsen)

Indication: Adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome.

Approval Date: December 19, 2024

Ryoncil (remestemcel-L-rknd)

Indication: Treatment of steroid-refractory acute graft versus host disease in pediatric patients 2 months of age and older.

Approval Date: December 18, 2024

Ensacove (ensartinib)

Indication: Treatment of ALK-positive non-small cell lung cancer.

Approval Date: December 18, 2024

Steqeyma (ustekinumab-stba)

Indication: Treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.

Approval Date: December 17, 2024

Crenessity (crinecerfont)

Indication: Adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia.

Approval Date: December 13, 2024

Unloxcyt (cosibelimab-ipdl)

Indication: Treatment of cutaneous squamous cell carcinoma.

Approval Date: December 13, 2024

Bizengri (zenocutuzumab-zbco)

Indication: Treatment of neuregulin 1 fusion positive (NRG1+) non-small cell lung cancer and NRG1+ pancreatic adenocarcinoma.

Approval Date: December 4, 2024

Yesintek (ustekinumab-kfce)

Indication: Treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.

Approval Date: November 29, 2024

Attruby (acoramidis)

Indication: Treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

References: Drugs.com

Approval Date: November 22, 2024

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New Indication Approval for Existing Drugs

Here is a list of some recent drug approvals with new indications for existing drugs, highlighting their new indications, approval dates, and old indications:

Omvoh (etrasimod)

New Indication: Approved for moderate-to-severe Crohn's disease.

Approval Date: January 15, 2025.

Old Indication: Previously approved for moderate-to-severe active ulcerative colitis.

Zunveyl (benzgalantamine)

New Indication: Approved for mild to moderate Alzheimer's disease.

Approval Date: Expected by March 2025.

Old Indication: A reformulation of Razadyne, an Alzheimer's drug.

Lumakras (sotorasib) and Vectibix (panitumumab)

New Indication: Approved as a combination therapy for colorectal cancer with a specific KRAS gene mutation.

Approval Date: January 17, 2025.

Old Indications: Lumakras was initially approved for non-small cell lung cancer (NSCLC), while Vectibix is used for colorectal cancer without a KRAS mutation.

Datroway (datopotamab deruxtecan)

New Indication: Approved for advanced breast cancer in patients who have already undergone treatment.

Approval Date: January 17, 2025.

Old Indication: Initially approved for use in treating certain types of solid tumors.

References: Drugs.com

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Herbal Drug Approval

Over the past six months, several significant developments have emerged in the field of herbal medicine. Here are some notable updates:

1. FDA Advises Against Using Herbal Doctor Remedies' Products

In July 2024, the U.S. Food and Drug Administration (FDA) issued a warning against the use of products manufactured by Herbal Doctor Remedies. The company was found to produce unapproved new drugs, including Brain Forte, New Life, Lump Shrinker, Asma-F, Herpes-P, and Anemia, which have not been evaluated for safety and efficacy.

References: U.S. Food and Drug Administration

2. Kratom Linked to Health Risks

In August 2024, a study highlighted the potential liver risks associated with six popular herbal supplements, including green tea extract and curcumin. The research indicated that millions in the U.S. might be at risk of liver damage from these herbal remedies.

References: Medical News Today

3. Lianhua Qingwen's Use in COVID-19 Treatment

As of December 2024, Lianhua Qingwen, a traditional Chinese herbal medicine, has been promoted for the treatment of COVID-19 in various countries. However, its efficacy remains controversial, and health authorities in several regions have issued advisories regarding its use.

References: Medical News Today

4. Introduction of Sleepinox Herbal Supplement

In December 2024, Dr. David Mahjoubi, a board-certified anesthesiologist, introduced Sleepinox, a natural sleep supplement formulated with magnesium glycinate, valerian root, ashwagandha, borage oil, and L-theanine. The supplement aims to aid sleep, enhance cognitive function, and boost the immune system without the use of melatonin.

Reference: New York Post

References: Drugs.com

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