MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

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MC-Rx is dedicated to improved drug therapy vigilance, continuity of care, patient safety and effective formulary management. This edition is developed by our clinical team, which is comprised of registered clinical pharmacists, to provide you with continuous evaluation and insights of the drugs market and its impact as it evolves.

Here you will find

- Drug pipeline
- FDA drug approvals
- New indications
- Patent expirations
- Generic approvals
- FDA safety updates/recalls
- Drug shortages

Last Updated December 24, 2024.

Relationship between Autism and vaccines: myth vs reality

Autism Spectrum Disorder (ASD), as described by the World Health Organization (WHO, 2023), represents a diverse range of conditions associated with brain development, primarily involving varying levels of social interaction, communication, and behavioral challenges. Symptoms generally emerge in early childhood, but formal diagnosis may not occur until later (CDC, 2024). Today, it is widely understood that ASD results from a complex interaction of genetic and environmental factors, though definitive causative elements remain elusive. WHO estimates ASD affects approximately 1 in every 36 children worldwide (CDC, 2024). In addition to core symptoms, individuals with ASD frequently face comorbid conditions like anxiety disorders, attention deficit hyperactivity disorder (ADHD), obesity, and gastrointestinal issues (Hyman, S., 2020).

Despite extensive research indicating no connection between vaccines and autism, persistent myths linking them have led to significant public misunderstanding, often contributing to decreased vaccination rates and subsequent public health risks. These misconceptions originated in a 1998 study by Wakefield, published in The Lancet journal, which suggested a link between the MMR (measles, mumps, rubella) vaccine and autism (Cosenza and Sanna, 2021). Wakefield’s study claimed that the MMR vaccine caused intestinal inflammation, which in turn, led to developmental regression and autism-like symptoms due to translocation of nonpermeable peptides to the brain (Gerber and Offit, 2009). This study, however, was widely criticized, eventually leading to its retraction in 2010 (Cosenza and Sanna, 2021). Numerous follow-up studies have refuted any connection between the MMR vaccine and autism (Gerber and Offit, 2009).

Another vaccine-related myth is centered on thimerosal, a mercury-based preservative previously used in certain vaccines, which is toxic to the central nervous system (Gerber and Offit, 2009). Some believed that thimerosal exposure could result in autism-like symptoms. Research, however, has shown no significant difference in autism rates between children exposed to thimerosal-containing vaccines and those who were not (Gerber and Offit, 2009). To address public concerns, thimerosal was removed from childhood vaccines in the early 2000s, yet autism rates have continued to rise (Gerber and Offit, 2009).

The third prevalent myth is that administering multiple vaccines can “overwhelm” a child’s immune system, leading to ASD. This belief suggests that simultaneous exposure to multiple vaccines might induce developmental disruptions (Gerber and Offit, 2009). The infant immune system is capable of managing thousands of antigens daily through natural exposure, and vaccines represent only a fraction of this load (Miller and Reynolds, 2009). Studies have demonstrated that children receiving multiple vaccines simultaneously do not experience higher rates of autism (Gerber and Offit, 2009).

Over the past years, robust research has consistently demonstrated no link between vaccines and autism. Notably, a meta-analysis of studies found no correlation between vaccination and the development of autism (Taylor et al., 2014). In terms of public health, vaccine-preventable diseases pose far greater risks to health than the vaccines themselves. Notably, the CDC reported 17 measles outbreaks in 2011 due to unvaccinated persons (Taylor et al., 2014). For this reason, it is important to weigh the benefits and risks to determine the course forward. An increase in unvaccinated people endangers herd immunity, which is the indirect

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protection from an infectious disease that happens when a population is immune (Taylor et al., 2014).

In conclusion, extensive research unequivocally supports that there is no relationship between vaccines and autism. Studies on MMR, thimerosal, and multiple vaccine exposures have consistently shown no causal relationship with ASD. Over the years, vaccines have prevented several cases of diseases and saved millions of lives (CDC, 2024). It is known that vaccines prevent more than 20 life-threatening diseases and prevent 3.5 million to 5 million deaths every year from diseases like diphtheria, tetanus, pertussis, influenza and measles (WHO, n.d.). Bridging the gap in public understanding through education and transparent communication is vital to restoring confidence in vaccinations and maintaining high coverage rates.

References:

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Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Acoramidis (BridgeBio Pharma)	NDA Filed	11/29/2024	Transthyretin (TTR) stabilizer for the treatment of patients with symptomatic transthyretin amyloidosis (ATTR) cardiomyopathy; oral
Concizumab (Novo Nordisk)	BLA Filed	12/20/2024	A humanized monoclonal antibody against tissue factor pathway inhibitor (TFPI) for the prevention and treatment of bleeding in patients 12 years and older with hemophilia A and B with inhibitors; subcutaneous injection
Crinecerfont (Neurocrine Biosciences)	NDA Filed	12/29/2024	Selective corticotropin-releasing factor type 1 receptor (CRF1) antagonist for the treatment of adult patients with classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency (21-OHD); oral solution
Datopotamab deruxtecan (Dato-DXd – Astra Zeneca/ Daiichi Sankyo)	BLA Filed	12/20/2024	Anti-Trop2 antibody-drug conjugate for the treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC); IV infusion
Depemokimab (GSK)	Phase 3	2025	Long-acting IL-5 monoclonal antibody for the treatment of severe eosinophilic asthma; subcutaneous (SC every 6 months)
Eladocagene exuparvovec (Upstaza - PTC Therapeutics)	BLA Filed	11/13/2024	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion
Garadacimab – (CSL Behring)	BLA Filed	2025	Humanized monoclonal antibody targeting interleukin 13 (IL-13) for the treatment of atopic dermatitis; SC
Linvoseltamab (Regeneron Pharmaceuticals)	Complete Response	2025	BCMAxCD3 bispecific antibody for the treatment of multiple myeloma; intravenous infusion
Marnetegragene autotemcel (Kresladi-Rocket Pharmaceuticals)	Complete Response	2025	Gene modified cell therapy for Leukocyte Adhesion Deficiency-I (LAD-I); IV infusion (one time)
Nipocalimab (Johnson & Johnson Innovative Medicine)	BLA Filed	8/29/2025	An Fc receptor (FcRn) inhibitor aglycosylated immunoglobulin G (IgG1) monoclonal antibody for the treatment of adults with generalized myasthenia gravis (gMG) who have (AChR) antibodies or anti-(Musk) antibodies; intravenous infusion
Obecabtagene autoleucel (obe-cel - Autolus Therapeutics)	BLA Filed	11/16/2024	Anti-CD19 CAR-T cell therapy for the treatment of acute lymphoblastic leukemia (ALL); intravenous infusion

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Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Odronextamab (Regeneron)	Complete Response	2025	CD20xCD3 bispecific antibody for the treatment of relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (B-NHL); intravenous infusion
Olezarsen (Ionis Pharmaceuticals)	NDA Filed	12/19/2024	Antisense drug that targets the ApoC-III protein to reduce serum triglycerides for the treatment of familial chylomicronemia syndrome (FCS); subcutaneous injection
Revumenib (Syndax Pharmaceuticals)	NDA Filed	12/26/2024	Menin inhibitor for the treatment of adult and pediatric patients with relapsed or refractory (R/R) acute leukemia harboring a KMT2A rearrangement (KMT2Ar); oral
Sebetralstat (KalVista Pharmaceuticals)	NDA Filed	6/17/2025	Plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE) attacks in adults and pediatric patients aged 12 years and older; oral
Sepiapterin (PTC Therapeutics)	NDA Filed	7/29/2025	Natural precursor of tetrahydrobiopterin (BH4), a cofactor for the enzyme phenylalanine hydroxylase, which breaks down phenylalanine for the treatment of phenylketonuria (PKU); oral
Sonpiretigene isteparvovec (Nanoscope Therapeutics)	Phase 2	2026	A gene therapy-based treatment involving an adeno associate virus carrying multi-characteristic opsin for the treatment of retinitis pigmentosa (RP); intravitreal injection
Vanzacaftor/tezacaftor/ deutivacaftor (vanza triple; VX-121/VX-661/VX- 561 - Vertex)	NDA Filed	1/2/2025	Triple combination for the treatment of patients with cystic fibrosis (CF) heterozygous for F508del and a minimal function mutation (F/MF); oral
Vusolimogene oderparepvec (Replimune)	Phase 2	2025	Oncolytic immunotherapy for the treatment of anti-PD-1 refractory melanoma; intratumoral
Zanidatamab (BeiGene/Jazz Pharmaceuticals)	BLA Filed	11/29/2024	HER2-targeted bispecific antibody in combination with chemotherapy as a therapeutic option for patients with previously treated HER2-amplified biliary tract cancers (BTC); intravenous infusion

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Biosimilar Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Product Name / Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
aflibercept biosimilar	Celltrion	Eylea (aflibercept)	H2:2024	2024-2032
bevacizumab biosimilar (Aybintio)	Samsung Bioepis/ Organon	Avastin (bevacizumab)	H2:2024	Pending FDA Approval
bevacizumab biosimilar (Equidacent)	Centus	Avastin (bevacizumab)	H2:2024	Pending FDA Approval
denosumab biosimilar	Fresenius Kabi	Prolia (denosumab)	Q1:2025	TBD
denosumab biosimilar	Celltrion	Prolia (denosumab)	11/24	TBD
filgrastim biosimilar (Grastofil)	Apotex/Intas	Neupogen (filgrastim)	2024+	Pending FDA Approval
insulin aspart biosimilar	Sandoz/Gan & Lee	Novolog (insulin aspart)	H2:2024	Pending FDA Approval
insulin aspart biosimilar	Amphastar	Novolog (insulin aspart)	1/10/2025	Pending FDA Approval
insulin glargine biosimilar (Basalin)	Sandoz/Gan & Lee	Lantus (insulin glargine)	H2:2024	Pending FDA Approval
insulin lispro biosimilar (Prandilin)	Sandoz/Gan & Lee	Humalog (insulin lispro)	H2:2024	Pending FDA Approval
omalizumab biosimilar (Omlyclo)	Celltrion	Xolair (omalizumab)	3/10/2025	Upon FDA Approval
pegfilgrastim biosimilar (Armlupeg)	Lupin	Neulasta (pegfilgrastim)	H2:2024	Pending FDA Approval
pegfilgrastim biosimilar (Lapelga)	Apotex/Intas	Neulasta (pegfilgrastim)	2024+	Pending FDA Approval
trastuzumab biosimilar	Tanvex BioPharma	Herceptin (trastuzumab)	1/6/2025	Pending FDA Approval
ustekinumab biosimilar	Biocon	Stelara (ustekinumab)	Q4:2024	2/25
ustekinumab biosimilar	Celltrion	Stelara (ustekinumab)	H2:2024	3/7/2025
ustekinumab biosimilar	Hikma/Bio-Thera Solutions	Stelara (ustekinumab)	Q2:2025	TBD

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New Drug Entities

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Drug Entities	Details
Pivmecillinam (Pivya)	**Dosage form:** Tablets: 185 mg. **Indication:** Is an aminopenicillin class antibiotic indicated for the treatment of uncomplicated urinary tract infections (uUTI) in female patients aged 18 years or older. **Comparables:** first-line antibiotic agents utilized for the empiric treatment of uncomplicated urinary tract infections such as nitrofurantoin, trimethoprim-sulfamethoxazole, and fosfomycin. **Guidelines:** Anger, Jennifer, et al. "Recurrent Uncomplicated Urinary Tract Infections in Women: AUA/CUA/SUFU Guideline." 2019. Journal of Urology, vol.202, no. 2, Wolters Kluwer, Aug. 2019, pp. 282–289, doi:10.1097/JU.0000000000000296.
Deuruxolitinib (Leqselvi)	**Dosage form:** Tablets: 8 mg. **Indication:** Is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with severe alopecia areata. **Comparables:** Baricitinib (Olumiant), Ritlecitinib (Litfulo) **Guideline:** European Dermatology Forum (EDF): Evidence-based (S3) guideline for the treatment of androgenetic alopecia in women and in men, update (2017)
Benzgalantamine (Zunveyl)	**Dosage form:** Delayed-release tablets: 5 mg, 10 mg, and 15 mg. **Indication:** Is a cholinesterase inhibitor indicated for the treatment of mild-to-moderate dementia of the Alzheimer's type in adults. **Comparables:** galantamine (Razadyne®/generics), donepezil (Aricept®, generics) and rivastigmine (Exelon®, generics). **Guidelines:** American Academy of Neurology (AAN): Practice guideline on mild cognitive impairment, update (2018, reaffirmed 2021)
Denileukin diftitox-cxdl (Lymphir)	**Dosage form:** Injection: 300 mcg lyophilized cake in a single-dose vial. **Indication:** Is an interleukin-like (IL) 2-receptor-directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy. **Comparables:** Poteligeo (mogamulizumab-kpkc), Adcetris (brentuximab vedotin), and bexarotene **Guidelines:** T-cell lymphoma. National Comprehensive Cancer Network (NCCN) (Version 1.2025)
Aflibercept-abzv	**Dosage form:** Injection: 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose pre-filled syringe, Injection: 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial. **Indication:** Is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with: Neovascular (Wet) Age-Related Macular Degeneration (AMD). **Comparables:** Eylea and biosimilars **Guidelines:** Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern®. Ophthalmology. 2019;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024

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New Drug Entities

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Drug Entities	Details
Axatilimab-csfr (Niktimvo)	**Dosage form:** Injection: 50 mg/mL solution in a single-dose vial. **Indication:** Is a colony stimulating factor-1 receptor (CSF-1R) blocking antibody indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg. **Comparables:** none **Guidelines:** Hamilton BK. Updates in chronic graft-versus-host disease. Hematology Am Soc Hematol Educ Program. 2021;2021(1):648-654. doi:10.1182/hematology.2021000301
Ustekinumab-AAUZ (Otulfi) is biosimilar* to STELARA® (ustekinumab) and Ustekinumab-AAUZ (Imuldosa) is biosimilar* to STELARA® (ustekinumab)	**Dosage form:** Subcutaneous Injection • Injection: 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe Intravenous Infusion • Injection: 130 mg/26 mL (5 mg/mL) solution in a single-dose vial. **Indication:** Is a human interleukin-12 and -23 (IL-12, IL-23) antagonist indicated for the treatment of: Adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). • moderately to severely active Crohn's disease (CD). • moderately to severely active ulcerative colitis. • Pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use, injection 90 mg/mL single-dose prefilled syringe for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use, and injection 130 mg/26 mL single-dose vial for intravenous use as biosimilar to and interchangeable with Stelara ustekinumab injection 130 mg/26 mL single-dose vial for intravenous use. **Comparables:** Stelara and biosimilars **Guidelines:** Elston DM. American Academy of Dermatology and National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis. J Am Acad Dermatol. 2021;84(2):257-258. doi:10.1016/j.jaad.2020.09.013

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New Drug Entities

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Drug Entities	Details
Marstacimab-hncq (HYMPAVZI)	**Dosage form:** Injection: 150 mg/mL in a single-dose prefilled syringe, Injection: 150 mg/mL in a single-dose prefilled pen. **Indication:** Is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: - hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or - hemophilia B (congenital factor IX deficiency) without factor IX inhibitors. **Comparables:** none **Guidelines:** National Bleeding Disorders Foundation (NBDF): Medical and Scientific Advisory Council (MASAC) recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system (2024)
Sulopenem etzadroxil and probenecid (Orlynvah)	**Dosage form:** Tablets: 500 mg sulopenem etzadroxil and 500 mg probenecid. **Indication:** Is a combination of sulopenem etzadroxil, a penem antibacterial, and probenecid, a renal tubular transport inhibitor, indicated for the treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis in adult women who have limited or no alternative oral antibacterial treatment options. **Comparables:** amoxicillin/clavulanate **Guidelines:** Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. Clin Infect Dis. 2021;73(5):e1029-e1044. doi:10.1093/cid/ciab549

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New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Drug Formulations	Details
Aripiprazole (Opipza)	**New Dosage form:** Oral Film: 2 mg, 5 mg, 10 mg. **Indication:** Is a second-generation antipsychotic used for the following indications: • Treatment of schizophrenia in patients ages 13 years and older • Adjunctive treatment of major depressive disorder in adults • Irritability associated with autistic disorder in pediatric patients 6 years and older • Treatment of Tourette's disorder in pediatric patients 6 years and older **Comparables:** Aripiprazole **Guidelines:** American Psychiatric Association (APA): Practice guideline for the treatment of patients with schizophrenia, 3rd edition (2020)
Terazosin (Tezruly)	**New Dosage form:** Oral solution: 1 mg/mL of terazosin. **Indication:** Is an alpha-1 adrenoreceptor antagonist indicated for: • The treatment of signs and symptoms of benign prostatic hyperplasia (BPH). The treatment of hypertension alone or with other antihypertensive agents, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarction. **Comparables:** terazosin **Guidelines:** American Urological Association (AUA): Guidelines for the management of benign prostatic hyperplasia/lower urinary tract symptoms (2021, amended 2023)
Nalmefene injection (Zurnai)	**New Dosage form:** Autoinjector, Injection: 1.5 mg nalmefene base/0.5 mL in a prefilled, single-dose auto injector. **Indication:** Is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression. **Comparables:** nalmefene for injection, Opvee® (nalmefene) nasal spray. **Guidelines:** Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. MMWR Recomm Rep. 2022;71(3):1-95. Published 2022 Nov 4. doi:10.15585/mmwr.rr7103a1
Paliperidone palmitate (Erzofri)	**New Dosage form:** Extended-release injectable suspension. Extended-release injectable suspension: 39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL, 234 mg/1.5 mL, 351 mg/2.25 mL. **Indication:** Is a second-generation antipsychotic indicated for treatment of schizophrenia in adults, and treatment of schizoaffective disorder in adults as monotherapy, and as an adjunct to mood stabilizers or antidepressants. **Comparables:** injectable long-acting Invega® products Invega Sustenna®, Trinza™ and Hafyera™, which are administered as IM injections. Invega tablets are also available generically **Guidelines:** American Psychiatric Association (APA): Practice guideline for the treatment of patients with schizophrenia, 3rd edition (2020)

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New Drug Formulations

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New Drug Formulations	Details
Octreotide acetate (Bynfezia Pen)	**New Dosage form:** Injection, for subcutaneous use. Injection: 7,000 mcg/2.8 mL (2,500 mcg/mL) octreotide (as acetate) in a 2.8 mL single-patient-use prefilled pen. **Indication:** Is a somatostain analog "New Formulation" or New Manufacturer: For subcutaneous use for the following indications: • Acromegaly: To reduce blood levels of growth hormone (GH) and insulin growth factor 1 (IGF-1; somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. • Carcinoid Tumors: For the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease. • Vasoactive Intestinal Peptide Tumors (VIPomas): For the treatment of profuse watery diarrhea associated with VIP-secreting tumors. **Comparables:** Octreotide **Guidelines:** Neuroendocrine and Adrenal tumors. National Comprehensive Cancer Network (NCCN) (Version 2.2024)
Docetaxel (Beizray)	**New Dosage form:** Injection, for subcutaneous use. Injection: 7,000 mcg/2.8 mL (2,500 mcg/mL) octreotide (as acetate) in a 2.8 mL single-patient-use prefilled pen. **Indication:** Is a microtubule inhibitor indicated for: • Breast Cancer (BC): single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC (1.1) • Non-small Cell Lung Cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC (1.2) • Castration-Resistant Prostate Cancer (CRPC): with prednisone in metastatic castration-resistant prostate cancer (1.3) • Gastric Adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction (1.4) • Squamous Cell Carcinoma of the Head and Neck (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN (1.5) **Comparables:** Docetaxel **Guidelines:** National Comprehensive Cancer Network (NCCN). https://www.nccn.org/guidelines/category_1

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New Indications

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New Indications	Details
Vonoprazan (Voquezna)	For the addition of the indication: for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.
Ribociclib (Kisqali)	For the expansion of the indication: indicated for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer at high risk of recurrence in combination with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.
Cerliponase alfa (Brineura)	For the expansion of the treatment population to birth. Is a hydrolytic lysosomal N-terminal tripeptidyl peptidase indicated to slow the loss of ambulation in pediatric patients with neuronal ceroid lipofuscinosis type 2 (CLN2 disease), also known as tripeptidyl peptidase 1 (TPP1) deficiency.
Durvalumab (Imfinzi)	For the expansion of the indication: for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery. For the addition of the indication: for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).
Daratumumab and hyaluronidase fihj (Darzalex Faspro)	For the expansion of the indication: for the treatment of adult patients with multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant.
Iptacopan (Fabhalta)	For the addition of the indication: for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.
Furosemide (Furoscix Infusor)	For the expansion of the indication: for the treatment of congestion due to fluid overload in adult patients with chronic heart failure.
Protonix IV (pantoprazole sodium)	For the expansion of the indication: for the treatment of gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) for up to 10 days in adults and up to 7 days in pediatric patients 3 months and older
Anacaulase-bcbd (NexoBrid)	For the expansion of the indication: for eschar removal in adults and pediatric patients with deep partial thickness and/or full thickness thermal burns.
Respiratory Syncytial Virus Vaccine, Adjuvanted (Arexvy)	For the expansion of the indication: to include use in individuals 50 through 59 years of age who are at increased risk for Lower Respiratory Tract Disease (LRTD) caused by Respiratory Syncytial Virus (RSV).
Peanut (Arachis hypogaea) Allergen Powder-dnfp (Palforzia)	For the expansion of the indication: to extend the age indication to include patients 1 through 3 years of age with a confirmed diagnosis of peanut allergy.

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New Indications

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New Indications	Details
Fibrinogen Human (Fibryga)	For the addition of the indication: to include the fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency indication, and to update the US prescribing information to expand the indication to include fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency indication.
Adalimumab-aaty (Yuflyma)	For the expansion of the indication: for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.
Amivantamab-vmjw (Rybrevant)	For the expansion of the indication: for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations in combination with lazertinib. For the addition of the indication: in combination with carboplatin and pemetrexed, is indicated for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations
Dostarlimab-gxly (Jemperli)	For the expansion of the indication: for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent.
Sparsentan (Filspari)	For the expansion of the indication: indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.
Guselkumab (Tremfya)	For the addition of the indication: for the treatment of adult patients with moderately-to-severely active ulcerative colitis.
Phentermine and topiramate extended-release (Qsymia)	For the expansion of the indication: indicated in combination with a reduced-calorie diet and increased physical activity to decrease excess body weight and maintain weight reduction long term in: • Adults and pediatric patients aged 12 years and older with obesity • Adults with overweight in the presence of at least one weight-related comorbid condition.
Certolizumab pegol (Cimzia)	For the addition of the indication: For the treatment of active polyarticular Juvenile Idiopathic Arthritis (pJIA) for patients 2 years of age and older, and corresponding pediatric labeling updates pursuant to the Pediatric Research Equity Act (PREA). This approval is in response to a PREA post marketing requirement (PMR).
Lanreotide	For addition of an indication: for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
Pembrolizumab (Keytruda)	For the addition of the indication: in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM).

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New Indications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Indications	Details
Ribociclib (Kisqali)	For the expansion of the indication: indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence. For the addition of the indication: for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine-based therapy; or • fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.
Ribociclib in combination with letrozole (Kisqali Femara Co-Pack)	For the expansion of the indication: for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.
Benralizumab (Fasenra)	For the addition of the indication: for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis.
Isatuximab-irfc (Sarclisa)	For the addition of the indication: For the treatment of adults with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT) with bortezomib, lenalidomide, and dexamethasone for adults
Bimekizumab-bkzx (Bimzelx)	For the addition of the indication: for the treatment of adults with active psoriatic arthritis (PsA) For the addition of the indication: for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. For the addition of the indication: for the treatment of adults with active ankylosing spondylitis (AS).
Osimertinib (Tagrisso)	For the addition of the indication: for the treatment of adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. For the addition of the indication: first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations
Selpercatinib (Retevmo)	For the expansion of the indication: as a treatment of adult and pediatric patients 2 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy.
Dupilumab (Dupixent)	For the expansion of the indication: for use as an add-on maintenance treatment in adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. For the expansion of the indication: as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

Last Updated December 24, 2024.

New Indications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Indications	Details
Nivolumab (Opdivo)	For the addition of the indication: For the treatment as neoadjuvant with platinum-doublet chemotherapy, followed by single-agent nivolumab after surgery as adjuvant treatment, for adults with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
Dapagliflozin (Farxiga)	For the expansion of the indication: as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus to include pediatric patients aged 10 years and older.
Dapagliflozin and metformin hydrochloride (Xigduo RX)	For the expansion of the indication: as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus to include pediatric patients aged 10 years and older.
Isatuximab-irfc (Sarclisa)	For the expansion of the indication: With bortezomib, lenalidomide, and dexamethasone for adults with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT).
Dalteparin Sodium (Fragmin)	For the expansion of the indication: treatment of symptomatic venous thromboembolism (VTE) to reduce the recurrence in pediatric patients from 1 month of age down to birth (gestational age of at least 35 weeks).
Sodium oxybate (Lumryz)	For the expansion of the indication: to include pediatric patients 7 years of age or older with narcolepsy.
Filgrastim-sndz (Zarxio)	For the addition of the indication: to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)

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In-Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

In-Market-Brands	Details
Vorasidenib (Voranigo)	**Dosage form:** Tablets: 10 mg and 40 mg. **Indication:** Is an isocitrate dehydrogenase-1 (IDH1) and isocitrate dehydrogenase-2 (IDH2) inhibitor indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection. **Comparables:** none **Guidelines:** Central Nervous System Cancers. National Comprehensive Cancer Network (NCCN) (Version 3.2024)
Palopegteriparatide (Yorvipath)	**Dosage form:** Injection: single-patient-use prefilled pen • 168 mcg/0.56 mL pen, labeled doses of 6, 9, or 12 mcg • 294 mcg/0.98 mL pen, labeled doses of 15, 18, or 21 mcg • 420 mcg/1.4 mL pen, labeled doses of 24, 27, or 30 mcg. **Indication:** Is a parathyroid hormone analog (PTH) indicated for the treatment of hypoparathyroidism in adults. **Comparables:** none **Guidelines:** Schafer AL, Shoback DM. Hypocalcemia: Definition, Etiology, Pathogenesis, Diagnosis, and Management. In: Primer on the Metabolic Bone Diseases and Disorders of Mineral Metabolism, 9th, Bilezikian JP (Ed), American Society for Bone and Mineral Research, Hoboken, NJ 2018. p.646.
Nemolizumab-ilto (Nemluvio)	**Dosage form:** Injection: single-dose prefilled dual chamber pen containing 30 mg of nemolizumab-ilto lyophilized powder and diluent, water for injection. **Indication:** Is an interleukin-31 receptor antagonist indicated for the treatment of adults with prurigo nodularis. **Comparables:** Dupixent® (dupilumab) **Guidelines:** Practical approaches for diagnosis and management of prurigo nodularis – United States expert panel consensus (2021)
Seladelpar (Livdelzi)	**Dosage form:** Capsules: 10 mg. **Indication:** Is a peroxisome proliferator-activated receptor (PPAR)-delta agonist indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. **Comparables:** Iqirvo (elafibranor), Ocaliva (obeticholic acid) **Guidelines:** American Association for the Study of Liver Diseases (AASLD): Primary biliary cholangitis – Practice guidance update (2021)

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In-Market Brand

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In-Market-Brands	Details
Lazertinib (Lazcluze)	**Dosage form:** Tablets: 80 mg and 240 mg. **Indication:** Is a kinase inhibitor indicated in combination with amivantamab for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test. **Comparables:** Tagrisso (osimertinib) **Guidelines:** Non-Small Cell Lung Cancer. National Comprehensive Cancer Network (NCCN) (version 11.2024)
Afamitresgene autoleucel (Tecelra)	**Dosage form:** Suspension for Intravenous Infusion **Indication:** Is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy used for the treatment of adults with unresectable or metastatic synovial sarcoma. **Comparables:** **Guidelines:** Soft Tissue Sarcoma. National Comprehensive Cancer Network (NCCN) (version 4.2024)
Lebrikizumab-lbkz (Ebglyss)	**Dosage form:** Injection: 250 mg/2 mL in a single-dose prefilled pen, 250 mg/2 mL in a single-dose prefilled syringe with needle shield. **Indication:** Is an interleukin-13 antagonist indicated for the treatment of adult and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. EBGLYSS can be used with or without topical corticosteroids. **Comparables:** Dupilumab (Dupixent), Tralokinumab (Adbry), Abrocitinib (Cibinqo), Upadacitinib (Rinvoq) **Guidelines:** American Academy of Allergy, Asthma, and Immunology (AAAAI) and American College of Allergy, Asthma, and Immunology (ACAAI): Atopic dermatitis (eczema) guidelines – GRADE- and Institute of Medicine-based recommendations (2023)
Arimoclomol (Miplyffa)	**Dosage form:** 47 mg capsule; oral **Indication:** is indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older. **Comparables:** none **Guidelines:** Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet J Rare Dis. 2018;13(1):50. Published 2018 Apr 6. doi:10.1186/s13023-018-0785-7

Last Updated December 24, 2024.

In-Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

In-Market-Brands	Details
Norethindrone acetate and ethinyl estradiol (Femlyv)	**New Dosage form:** orally disintegrating tablets 24 ODTs each containing 1 mg norethindrone acetate and 0.02 mg ethinyl estradiol, 4 inert ODTs. **Indication:** Is a combination of norethindrone acetate, a progestin, and ethinyl estradiol, an estrogen, indicated for use by females of reproductive potential to prevent pregnancy. **Comparables:** Oral Contraceptives that contain progestin and an estrogen **Guidelines:** The American College of Obstetricians and Gynecologist. https://www.acog.org/clinical/clinical-guidance/clinical-practice-guideline
Epinephrine nasal spray (Neffy)	**New Dosage form:** Nasal spray: 2 mg/0.1 mL of epinephrine per spray. **Indication:** Is an alpha- and beta-adrenergic receptor agonist indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater. **Comparables:** epinephrine injection **Guidelines:** American Academy of Allergy Asthma & Immunology (AAAAI). https://www.aaaai.org
Sitagliptin and metformin hydrochloride extended release (Zituvimet XR)	**New Dosage form:** Sitagliptin 100 mg and metformin HCl 1,000 mg extended-release, sitagliptin 50 mg and metformin HCl 500 mg extended-release, sitagliptin 50 mg and metformin HCl 1,000 mg extended-release. **Indication:** Is a combination of sitagliptin, a dipeptidyl peptidase-4 (DPP 4) inhibitor, and metformin hydrochloride (HCl), a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Comparables:** Alogliptin/metformin **Guidelines:** ADA Standards of Care in Diabetes—2024
Maralixibat (Livmarli)	**New Dosage form:** Oral Solution. **Indication:** New Patient Population: provides for a new indication for maralixibat oral solution 19 mg/mL to include the treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). **Comparables:** none **Guidelines:** American Association for the Study of Liver Diseases (AASLD): Primary biliary cholangitis – Practice guidance update (2021)
Letermovir (Prevymis)	**New Dosage form:** Oral Pellets: 20 mg or 120 mg per packet. Other dosage form: Tablet: 240 mg; 480 mg, Injection: 240 mg/12 mL (20 mg/mL) or 480 mg/24 mL (20 mg/mL) in a single-dose vial. **Indication:** Prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients (6 months of age and older and weighing at least 6 kg) who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). Prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients (12 years of age and older and weighing at least 40 kg) who are kidney transplant recipients at high risk (Donor CMV seropositive/recipient CMV seronegative [D+/R-]). **Comparables:** acyclovir, ganciclovir, valacyclovir, **Guidelines:** American Society of Transplantation (AST): Transplant infectious diseases guidelines (2019)

Last Updated December 24, 2024.

In-Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

In-Market-Brands	Details
Atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza)	**New Dosage form:** Injection: 1,875 mg atezolizumab and 30,000 units hyaluronidase per 15 mL (25 mg/2,000 units per mL) solution in a single-dose vial. **Indication:** Is a combination of atezolizumab, a programmed death-ligand 1 (PD-L1) blocking antibody, and hyaluronidase, an endoglycosidase indicated: Non-Small Cell Lung Cancer (NSCLC) • As adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test. • For the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells[TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC]covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA approved test, with no EGFR or ALK genomic tumor aberrations. • In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations. • In combination with paclitaxel protein-bound and carboplatin for the first line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations. • For the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing hemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving TECENTRIQ HYBREZA. Small Cell Lung Cancer (SCLC) • In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). Hepatocellular Carcinoma (HCC) • In combination with bevacizumab for the treatment of adult patients with unresectable or metastatic HCC who have not received prior systemic therapy. Melanoma • In combination with cobimetinib and vemurafenib for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma as determined by an FDA-approved test. Alveolar Soft Part Sarcoma (ASPS) • For the treatment of adult patients with unresectable or metastatic ASPS. **Comparables:** tecentriq IV **Guidelines:** National Comprehensive Cancer Network (NCCN). https://www.nccn.org/guidelines/category_1
Inavolisib (ITOVEBI))	**Dosage form:** Tablets: 3 mg and 9 mg. **Indication:** Is a kinase inhibitor indicated in combination with palbociclib and fulvestrant for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy. **Comparables:** none **Guidelines:** Invasive breast cancer. National Comprehensive Cancer Network (NCCN) (Version 6.2024)

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In-Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

In-Market-Brands	Details
Levacetylleucine (Aqneursa)	**Dosage form:** For oral suspension: 1 gram L-Acetylleucine in a unit-dose packet. **Indication:** Is indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighting > 15 kg. **Comparables:** Miplyffa **Guidelines:** Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet Journal of Rare Diseases. 2018;13(1). doi:10.1186/s13023-018-0785-7
Xanomeline and trospium chloride (Cobenfy)	**Dosage form:** Capsules (xanomeline/trospium chloride): 50 mg/20 mg, 100 mg/20 mg, 125 mg/30 mg. **Indication:** Is a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, indicated for the treatment of schizophrenia in adults. **Comparables:** none **Guidelines:** APA Releases New Practice Guideline on Treatment of Patients with Schizophrenia. https://www.psychiatry.org/news-room/news-releases/apa-releases-new-practice-guideline-on-treatment-o
Vyloy (zolbetuximab-czlf)	**Dosage form:** For injection: 100 mg lyophilized powder in a single-dose vial. **Indication:** Is a claudin 18.2-directed cytolytic antibody and is indicated in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test. **Comparables:** None. **Guidelines:** Esophageal and Esophagogastric Junction Cancers. National Comprehensive Cancer Network (NCCN) (Version 4.2024)

Last Updated December 24, 2024.

New Generics

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Tromethamine injection solution	B Braun Medical Inc.	Tham	12/9/2024	For the prevention and correction of metabolic acidosis.
Drosperidone tablets	Lupin Limited	Slynd	9/30/2024	For use by females of reproductive potential to prevent pregnancy
Amantadine Extended-Release Capsules	Zydus Worldwide DMCC	Gocovri	8/26/2024	For the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications
Methylnaltrexone Bromide injection	Actavis LLC	Relistor injection	8/26/2024	For the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation For the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care
Riluzole Oral suspension	Alkem Laboratories Limited	Tiglutik	8/22/2024	For the treatment of amyotrophic lateral sclerosis (ALS)
Lofexidine Tablets	Indoco Remedies limited	Lucemyra	8/20/2024	For the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults
Valbenazine Capsules	Zydus Worldwide DMCC	Ingrezza	8/7/2024	For the treatment of adults with tardive dyskinesia
Trametinib Tablets	Novugen Oncology Sdn. Bhd.	Mekinist	8/6/2024	For the treatment of BRAF-inhibitor treatment-naive patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations; patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation; patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation; adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation; pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation

Last Updated December 24, 2024.

New Generics

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Baricitinib Tablets	Aurobindo Pharma USA, Inc.	Olumiant	7/22/2024	For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies
Tazarotene Cream	Padagis Israel Pharmaceuticals Ltd	Tazorac	7/15/2024	For the treatment as an adjunctive agent for use in the mitigation (palliation) of facial fine wrinkling, facial mottled hyper- and hypo-pigmentation, and benign facial lentigines in patients who use comprehensive skin care and sunlight avoidance programs
Nimodipine Oral Solution	Annora Pharma Private Limited	Nymalize	7/9/2024	For the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage
L-Glutamine Oral Powder	Novitium Pharma LLC	Endari	7/8/2024	For the reduction of the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older
Indium In-111 Pentetreotide Kit for Injection	Sun Pharmaceutical Industries, Inc.	Octreoscan	7/2/2024	For the treatment of the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors

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Recall Notifications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Date	Drug Name	Reason for Recall	Company name
11/21/2024	Umary Hyaluronic acid tablets	Undeclared Drug Ingredients: Diclofenac and Omeprazole	MXBBB
11/19/2024	Clonazepam Orally Disintegrating Tablets, USP (C-IV)	Mislabeled with the incorrect strength on the carton	Endo, Inc.
10/16/2024	Ascorbic Acid Solution for Injection	Device & Drug Safety - Presence of glass particulates	STASKA Pharmaceuticals Inc.
9/23/2024	Veklury (remdesivir) for Injection	Due to Presence of Glass Particle	Gilead Sciences, Inc.
9/18/2024	Atovaquone Oral Suspension, 750 mg/ mL	Product found to be contaminated with Cohnella bacteria	Bionpharma Inc.
8/8/2024	0.9% Sodium Chloride for Injection USP 1000 mL in E3 containers	Potential for particulate matter and fluid leakage of the containers	B. Braun Medical Inc.
8/6/2024	Heparin Sodium in 0.9% Sodium Chloride Injection	Elevated endotoxin levels	Baxter International Inc
7/24/2024	Migraine Relief Acetaminophen 250 mg, Aspirin (NSAID) 250 mg & Caffeine 65 mg tablets	Device & Drug Safety - Mislabeling	Aurobindo Pharma USA, Inc.
7/22/2024	Umary Hyaluronic acid tablets	Undeclared Drug Ingredients: Diclofenac and Omeprazole	Main Products, Inc.
7/22/2024	Acetaminophen Injection 1,000 mg per 100 mL (10 mg/mL) 100 mL	Potential presence of Dexmedetomidine HCL Injection (400 mcg/100 mL) inside the overwrap that is labelled Acetaminophen Injection, 1000 mg/100 mL, (10 mg/mL).	Hikma Pharmaceuticals PLC

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FDA reviewed a post-marketing case of serious drug-induced liver injury that occurred in a patient who received Veozah to treat menopausal hot flashes. Before starting Veozah, the patient's liver blood test levels were normal. Within 40 days of starting it, several liver blood test values were significantly elevated: alanine transaminase, more than 10 times the normal level; alkaline phosphatase, more than four times the normal level; and total bilirubin, more than 3 times the normal level. The patient reported symptoms of liver injury, including fatigue, nausea, decreased appetite, itching of hands and feet that later spread to the entire body, jaundice, pale feces, and dark urine. The patient's prescriber found no abnormalities when checking for other causes of liver injury, using ultrasonography of the liver and blood tests for viral hepatitis. With discontinuation of Veozah, the signs and symptoms gradually resolved, and liver blood test values returned to normal. We concluded this patient had liver injury as a result of Veozah treatment.

Last Updated December 24, 2024.

Shortages (New)

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Generic name (Brand Name)	Presentation	Posting Date	Related Information
Adalimumab-adbm (Cyltezo)	40 mg/0.8 mL, injection kit	12/10/2024	None available
Lodoxamide Tromethamine (Alomide)	Alomide, Solution, 1 mg/1 mL	12/9/2024	Novartis has made a business decision to permanently discontinue ALOMIDE® (lodoxamide tromethamine) ophthalmic solution, 0.1%. Discontinuation of the product is due in part to manufacturing concerns. Short-dated material is available until January 2025.
Fentanyl Citrate	Tablet 100 mcg, 200 mcg Troche/Lozenge: 1600 mcg, 800 mcg, 400 mcg	9/24/2024	Company decision to discontinue the product
Hydrocortisone Probutate	Cream 0.1%	8/21/2024	Business decision to discontinue product manufacturing. ANI anticipates ceasing distribution of all configurations on September 30, 2024.
Hydroxocobalamin	Injection 5 g/250 mL	11/4/2024	Restrictions on supply of Cyanokit will continue until Q2 2025 (estimated). All efforts are being made to shorten the disruption period.
Lanadelumab-Flyo	Injection 300 mg/2 mL	9/4/2024	None available

Last Updated December 24, 2024.

References:

- FDA Approved Drugs. Food and Drug Administration (FDA). Retrieved from https://www.access.fda.gov/
- FDA: Drug Shortages. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages
- FDA: First Generic Drug Approvals. https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals
- FDA: Recalls, Market Withdrawals, & Safety Alerts. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

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(787) 286-6032

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