ProCare Rx

Insights on the Drugs Pipeline

EXPLORING THE CHANGES IN THE DRUGS MARKET.

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Insights on the Drugs Pipeline JULY 2025

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01

Overview

ProCare 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 pharma- cists, 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

02 Hot Topic

GLP-1s for Obesity: Expanding Uses, But Real-World Challenges Remain

Glucagon-like peptide-1 receptor agonists (GLP-1s) have quickly become one of the most influential classes of medications in contemporary clinical practice. Though originally intended to improve blood sugar levels in patients with type 2 diabetes, formulations like semaglutide (Wegovy) and liraglutide (Saxenda) are now officially approved for long-term weight control in people with obesity. Their growing adoption has been fueled by research demonstrating steady reductions in body weight, better cardiometabolic markers, and fewer major cardiovascular events over time.

In 2024, the U.S. Food and Drug Administration granted Wegovy a label specifically stating that it lowers the risk of major adverse cardiovascular events in adults with obesity or overweight who have existing cardiovascular disease, marking it as the first obesity drug with such a cardiovascular indication. That same year, tirzepatide (Zepbound) received approval to treat obstructive sleep apnea in patients with obesity, further expanding the reach of GLP-1 receptor therapy. Researchers are now studying these agents in other conditions, including heart failure with preserved ejection fraction (HFpEF), chronic kidney disease, and metabolic dysfunction-associated steatohepatitis (MASH).

A decision on semaglutide for MASH was approved on 8/15/2025, based on results from the phase 3 ESSENCE trial.

Even with rising enthusiasm, real-world evidence reveals a growing disconnect between the success of these medications in clinical trials and how consistently they're used in daily life. In a claims-based review of more than 4,000 obese adults without diabetes, just 32.3% were still taking a GLP-1 therapy one year after starting it (Gleason et al., 2024). Persistence was highest for semaglutide (Ozempic) at 47.1%, and lowest for liraglutide (Saxenda) at just 19.2%. Overall adherence, meaning the medication was taken at least 80% of the time, stood at only 27.2%. Common obstacles like nausea, restrictive coverage policies, high out-of-pocket costs, and ongoing product shortages likely contributed to early discontinuation.

02 Hot Topic (cont'd)

Taken together, these findings raise important questions. The level of weight loss observed in tightly controlled trial environments may never be fully replicated in real-world settings if patients discontinue treatment during the first three to six months. Additionally, weight regain after stopping GLP-1 therapy is now well documented. In the STEP 1 trial extension, most participants who discontinued semaglutide regained roughly two-thirds of their lost weight within a single year (Wilding et al., 2022).

Meanwhile, the therapeutic horizon for GLP-1 receptor agonists continues to widen. Semaglutide is currently under review for indications in HFpEF and MASH, while two oral formulations, 25 mg semaglutide and orforglipron, are also seeking approval for long-term weight management. Additional trials are tracking semaglutide's effects on cognitive decline in Alzheimer's disease, exploring possible anti-inflammatory benefits in the brain.

With each new indication, however, come persistent concerns about treatment adherence, cost sustainability, and access equity. While GLP-1s have reshaped the treatment landscape for obesity and related conditions, their benefits in everyday clinical practice will ultimately depend on how well patients are supported throughout long-term therapy.

References:

Gleason P et al. Real-world persistence and adherence to GLP-1 receptor agonists among obese adults without diabetes. JMCP. 2024;30(8):860-867.

Wilding JP et al. Weight regain after withdrawal of semaglutide: STEP 1 trial extension. Diabetes Obes Metab. 2022;24(8):1553–64.

Lincoff AM et al. Semaglutide and cardiovascular outcomes in obesity without diabetes. N Engl J Med. 2023;389(24):2221–32.

IPD Analytics. Latest Updates for GLP-1s. Podcast transcript. June 26, 2025.

03 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?
Aficamten (Cytokinetics)	NDA Filed	12/26/2025	Cardiac myosin inhibitor for the treatment of obstructive Hypertrophic cardiomyopathy (HCM); oral
Brensocatib (Insmed)	NDA Filed	8/12/2025	Dipeptidyl peptidase 1 (DPP1) inhibitor for the treatment of Non-Cystic Fibrosis Bronchiectasis; oral
Depemokimab (GSK)	BLA Filed	12/16/2025	Long acting IL-5 monoclonal antibody for the treatment of severe eosinophilic asthma and chronic rhinosinusitis with nasal polyps; Subcutaneous (SC every 6 months)
Deramiocel (Capricor Therapeutics)	BLA Filed	8/31/2025	Allogenic stem cell therapy for the treatment of Duchenne muscular dystrophy cardiomyopathy; IV infusion
Donidalorsen (Ionis Pharmaceuticals)	NDA Filed	8/21/2025	Antisense medicine designed to reduce the production of prekallikrein (PKK) for the prevention of hereditary angioedema (HAE) attacks in adult and pediatric patients 12 years of age and older; SC injection
Garadacimab (CSL Behring)	BLA Filed	6/17/2025	Fully human recombinant FXIIa antagonist monoclonal antibody for the prevention of hereditary angioedema (HAE); SC
Linovoseltamab (Regeneron Pharmaceuticals)	BLA Filed	7/10/2025	BCMAxCD3 bispecific antibody for the treatment of multiple myeloma; IV

03 Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Marnetegragene autotemcel (Kresladi - Rocker Pharmaceuticals)	Complete Response	2025	Gene modified cell therapy for Leukocyte Adhesion Deficiency-I (LAD-I); IV infusion (one time)
Ordronextamab (Regeneron)	BLA Filed	2025	CD20xCD3 bispecific antibody for the treatment of relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (B-NHL); IV infusion
Plozasiran (Arrowhead Pharmaceuticals)	NDA Filed	11/18/2025	RNAi therapy for treating patients with Familial Chylomicronemia Syndrome; SC
Rebisufligene Etisparvovec (Ultragenyx)	BLA Filed	8/18/2025	adeno-associated viral-9 (AAV-9)-based gene therapy, expressing human sulfoglucosamine sulfohydrolase, for the treatment of Sanfilippo syndrome type A (mucopolysaccharidosis IIIA); IV injection
Rilzabrutinib (Sanofi)	NDA Filed	8/29/2025	Bruton's tyrosine kinase inhibitor for the treatment of immune thrombocytopenia; oral
Sebetraslat (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
Sonprietigene isteparvovec (Nanoscope Therapeutics)	Phase 2	2026	A gene therapy-based treatment involved an adeno associate virus carried multi characteristic opsin for the treatment of retinitis pigmentosa (RP) a type of Stargardt disease; intravitreal injection.

03 Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Sunvozertinib (Dizal Pharmaceuticals)	NDA Filed	7/7/2025	irreversible EGFR inhibitor for the first-line treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) exon 20 insertion (Exon20ins) mutations; oral
Taletrectinib (Nuvation Bio)	NDA Filed	6/23/2025	ROS1 tyrosine kinase inhibitor (TKI) for the treatment of patients with advanced ROS1 positive (ROS1+) non-small cell lung cancer (NSCLC); oral
Tolebrutinib (Sanofi)	NDA Filed	9/29/2025	Bruton's tyrosine kinase (BTK) inhibitor to reduced disease activity associated with multiple sclerosis (MS); oral
Vusolimogene oderparepvec (Replimune)	BLA Filed	7/22/2025	Oncolytic immunotherapy in combination with nivolumab for the treatment of adults who have advanced melanoma who have previously received an anti-PD1 containing regimen; intra-tumoral
Zopapogene imadenovec (Precigen)	BLA Filed	8/27/2025	Off-the-shelf AdenoVerse gene therapy designed to elicit immune responses directed against cells infected with human papillomavirus (HPV) 6 or HPV 11 for the treatment of recurrent respiratory papillomatosis (RRP); SC

04 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 (insulinaspart)	H2:2024	Pending FDA Approval
insulin aspart biosimilar	Amphastar	Novolog (insulinaspart)	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 (insulinlispro)	H2:2024	Pending FDA Approval

04 Biosimilar Pipeline (cont'd)

Product Name / Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
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

05 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 empirictreatment 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. Journalof 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) **Guidelines:** 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 inhibitorindicated 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 Academyof 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 cutaneousT-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 CancerNetwork (NCCN) (Version 1.2025)

05 New Drug Entities (cont'd)

New Drug Entities	Details
Aflibercept-abzv	**Dosage form:** Injection: 2 mg (0.05mL of 40 mg/mL) solutionin 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 patientswith: Neovascular (Wet) Age-Related MacularDegeneration (AMD). **Comparables:** Eyleaand biosimilars **Guidelines:** Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related MacularDegeneration Preferred Practice Pattern®. Ophthalmology. 2019;127(1):P1-P65. doi:10.1016/j. ophtha.2019.09.024
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 solutionin 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 indicatedfor 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 severelyactive Crohn's disease(CD). • moderately to severelyactive 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

05 New Drug Entities (cont'd)

New Drug Entities	Details
Marstacimab-hncq (HYMPAVZI)	**Dosage form: I**njection: 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 preventor reduce the frequency of bleeding episodesin 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 BleedingDisorders 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 sulopenemetzadroxil 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 FocusedUpdate Guidelines on Management of Clostridioides difficile Infection in Adults. Clin Infect Dis. 2021;73(5):e1029-e1044. doi:10.1093/cid/ciab549

06 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): Practiceguideline 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 prostatichyperplasia (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/orcentral nervous system depression. **Comparables:** nalmefene for injection, Opvee® (nalmefene) nasal spray. **Guidelines:** Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC ClinicalPractice Guideline for Prescribing Opioids for Pain - United States,2022. MMWR RecommRep. 2022;71(3):1-95. Published 2022 Nov 4. doi:10.15585/mmwr.rr7103a1

06 New Drug Formulations (cont'd)

New Drug Formulations	Details
Paliperidone palmitate (Erzofri)	**New Dosage form:** Extended-release injectable suspension. Extended-release injectable suspension: 39 mg/0.25 mL, 78 mg/0.5mL, 117 mg/0.75mL, 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 treatmentof schizoaffective disorderin 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): Practiceguideline for the treatment of patients with schizophrenia, 3rd edition (2020)
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 treatedwith 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 diarrheaand flushing episodesassociated with the disease. • Vasoactive Intestinal PeptideTumors (VIPomas): For the treatmentof profuse watery diarrhea associated with VIP-secreting tumors. **Comparables: Octreotide** **Guidelines: Neuroendocrine and Adrenal tumors.National Comprehensive CancerNetwork (NCCN) (Version 2.2024)**

06 New Drug Formulations (cont'd)

New Indications	Details
Docetaxel (Beizray)	**New Dosage form:** BEIZRAY (docetaxel) injection 80mg/4ml, available in 80mg and 160mg kits. **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, advancedGC, including the gastroesophageal junction (1.4) • Squamous Cell Carcinoma of the Head and Neck (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advancedSCCHN (1.5) **Comparables:** Docetaxel **Guidelines:** National Comprehensive Cancer Network (NCCN).https://www.nccn.org/guidelines/category_1

07 New Indications

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

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 growthfactor 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.

07 New Indications (cont'd)

New Indications	Details
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 patients1 through 3 years of age with a confirmed diagnosis of peanut allergy.
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 patientswith primary advanced or recurrent endometrial cancer (EC) in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent.

07 New Indications (cont'd)

New Indications	Details
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).
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.

07 New Indications (cont'd)

New Indications	Details
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.
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).
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 pediatricpatients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

07 New Indications (cont'd)

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.
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).
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)

08 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 • 94 mcg/0.98mL pen, labeled doses of 15, 18, or 21 mcg • 420 mcg/1.4mL pen, labeled doses of 24, 27, or 30 mcg. **Indication:** Is a parathyroid hormoneanalog (PTH) indicatedfor the treatmentof hypoparathyroidism in adults. **Comparables:** none **Guidelines:** SchaferAL, 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)

08 In-Market Brand (cont'd)

In-Market Brands	Details
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 unableto tolerate UDCA. **Comparables:** Iqirvo (elafibranor), Ocaliva (obeticholic acid) **Guidelines:** American Association for the Study of Liver Diseases (AASLD): Primary biliary cholangitis – Practiceguidance update (2021)
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:** none **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)

08 In-Market Brand (cont'd)

In-Market Brands	Details
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
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 Gynecologists. 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

08 In-Market Brand (cont'd)

In-Market Brands	Details
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)

08 In-Market Brand (cont'd)

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 StageII 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-L1stained ≥ 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) • n 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

08 In-Market Brand (cont'd)

In-Market Brands	Details
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)
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: I**s 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 JunctionCancers. National Comprehensive Cancer Network (NCCN) (Version 4.2024)

09 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	BBraun 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 adultswith 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 dosageescalation for palliative care
Riluzole Oral suspension	Alkem Laboratories Limited	Tiglutik	8/22/2024	Forthe 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

09 New Generics (cont'd)

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
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
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 Pharmaceuti-cals 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

09 New Generics (cont'd)

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
L-Glutamine Oral Powder	Novitium PharmaLLC	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

10 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% SodiumChloride 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 ReliefAcetaminophen 250 mg, Aspirin (NSAID) 250 mg & Caffeine 65 mg tablets	Device & Drug Safety - Mislabeling	Aurobindo Pharma USA, Inc.

10 Recall Notifications (cont'd)

Date	Drug Name	Reason for Recall	Company Name
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, 1000mg/100 mL, (10 mg/mL).	Hikma Pharmaceuticals PLC
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% SodiumChloride 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 ReliefAcetaminophen 250 mg, Aspirin (NSAID) 250 mg & Caffeine 65 mg tablets	Device & Drug Safety - Mislabeling	Aurobindo Pharma USA, Inc.

11 Safety Notifications

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

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.

12 Shortages (New)

Generic name (Brand Name)	Presentation	Posting Date	Related Information
Adalimumab-adbm (Cyltezo)	40mg/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

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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