PharmNotes

Monthly Communications

July 2025

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Drug Safety Alert Notification

The Drug Safety Communications are provided by the U.S. Food and Drug Administration and are intended to offer important information to patients and health care providers about new safety issues regarding certain medications. This helps prescribers and health care professionals be informed so that decisions regarding the treatment of patients are made accordingly.

Safety Alert	Date	Additional Information
FDA is requiring opioid pain medicine manufacturers to update prescribing information regarding long-term use	7/31/2025	In May 2025, the U.S. Food and Drug Administration (FDA) convened a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee to discuss two recently completed observational studies examining the risks of misuse, abuse, addiction, and fatal and non-fatal overdose in patients on long-term opioid analgesic (also referred to as opioid pain medicine) therapy. These studies (postmarketing requirements [PMR] 3033-1 and 3033-2) provided new, quantitative data on risks of these serious adverse outcomes in patients prescribed opioid pain medicines long term. After reviewing the study findings and the medical literature, as well as considering the committees' and public input, FDA has determined that this new information should be included in drug labeling to help health care professionals and patients better understand the benefit-risk profile of opioid pain medicines when prescribed long term and to make more informed decisions. Separately, a prospective, randomized, controlled clinical trial will address a different PMR to examine the risks relative to the efficacy of long-term opioid use.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Lynozyfic™ (linvoseltamab-gcpt) injection for intravenous use

FDA-Approved Indication

For the treatment of adult patients with relapsed or refractory multiple myeloma (R/R MM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti CD38 monoclonal antibody.

Dosage & Administration

Intravenous infusion with a step-up dosing regimen of 5 mg, then 25 mg; treatment doses of 200 mg weekly are then administered until transition to 200 mg every 2 weeks.

Dosage Forms & Strengths

Injection:

- 5 mg/2.5 mL (2 mg/mL) single-dose vial
- 200 mg/10 mL (20 mg/mL) single-dose vial

Contraindications

None

Common Adverse Reactions

Musculoskeletal pain, cytokine release syndrome, cough, upper respiratory tract infection, diarrhea, fatigue, pneumonia, nausea, headache, dyspnea, decreased lymphocyte count, decreased neutrophil count, decreased hemoglobin, and decreased white blood cell count

Warnings & Precautions

- ***BBW:*** Cytokine Release Syndrome and Neurologic Toxicity, Including Immune Effector Cell-Associated Neurotoxicity Syndrome
- Infections
- Neutropenia
- Hepatotoxicity
- Embryo-Fetal Toxicity

Use in Specific Populations

- Lactation: Advise not to breastfeed.

Clinical Studies

The accelerated approval was based on results of the phase 1/phase 2 multicohort LINKER-MM1 trial, which included 80 patients in the efficacy population who had previously received at least four prior therapies. The endpoints were objective response rate and duration of response. Results showed an objective response rate was 70%, with 45% achieving a complete response or better. At median follow-up of 11.3 months, median duration of response had not been reached. The estimated DOR rate was 89% at 9 months and 72% at 12 months.

Place in Therapy

In addition to Lynozyfic, other products for R/R MM include Tecvayli (teclistamab-cqyv), Talvey (talquetamab-tgvs), and Elrexfio (elranatamab-bcmm), all of which are similar bispecific antibody therapies and are available in subcutaneous formulations. An advantage of Lynozyfic is the potential to be dosed every 4 weeks in patients who achieve a very good partial response (VGPR) or better. The NCCN Guidelines recommends the use of Lynozyfic as therapy for previously treated multiple myeloma for relapsed/refractory disease in patients who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent (preferred) (category 2A).

New FDA-Approved Drug Products

New Molecular Entity

Specialty

Zegfrovy™ (sunvozertinib) tablets for oral use

FDA-Approved Indication

For the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Dosage & Administration

200 mg orally once daily taken with food.

Dosage Forms & Strengths

Tablets: 150 mg and 200 mg

Contraindications

None

Common Adverse Reactions

Diarrhea, rash, decreased appetite, stomatitis, fatigue, nausea, paronychia, vomiting, constipation, musculoskeletal pain, pruritus, dry skin, urinary tract infection, abdominal pain and decreased weight.

Warnings & Precautions

- Interstitial Lung Disease (ILD)/Pneumonitis
- Gastrointestinal Adverse Reactions
- Dermatologic Adverse Reactions
- Ocular Toxicity
- Embryo-Fetal Toxicity

Drug Interactions

- Strong CYP3A Inhibitors
- Strong and Moderate CYP3A Inducers
- P-gp or BCRP Substrates
- Hormonal Contraceptives

Use in Specific Populations

- Lactation: Advise not to breastfeed.

Clinical Studies

The accelerated approval was based on results from the phase 1/2 WU-KONG1B trial, a multinational, open-label, dose randomization trial involving 85 previously treated patients. Patients were randomly assigned 1:1 to receive Zegfrovy at 200 mg daily or 300 mg daily. The primary endpoint was overall response rate (ORR). The ORR was 46%, and the median duration of response was 11.1 months.

Place in Therapy

Rybrevant, another treatment option, is approved as a second-line option in EGFR exon 20 mutated NSCLC and as a first-line option in combination with chemotherapy in EGFR exon 20 mutated NSCLC. Rybrevant requires IV administration, while Zegfrovy is given orally. The NCCN Guidelines recommends the use of Zegfrovy as subsequent therapy (if not received previously) as a single agent for EGFR exon 20 insertion mutation positive recurrent, advanced, or metastatic disease (category 2A).

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Ekterly® (sebetralstat) tablets for oral use

FDA-Approved Indication

For the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.

Dosage & Administration

One dose of 600 mg (2 tablets) taken orally at the earliest recognition of an HAE attack. A second dose of 600 mg (2 tablets) may be taken 3 hours after the first dose if response is inadequate, or if symptoms worsen or recur. Maximum recommended dosage is 1,200 mg in any 24-hour period.

Dosage Forms & Strengths

Tablets: 300 mg

Contraindications

None

Common Adverse Reactions

Headaches

Drug Interactions

- Strong and Moderate CYP3A4 Inhibitors
- CYP3A4 Inducers

Use in Specific Populations

- Hepatic Impairment: Avoid use of Ekterly in patients with severe hepatic impairment (Child-Pugh Class C). In patients with moderate hepatic impairment (Child-Pugh Class B) dose modification is required.

Clinical Studies

The approval was based on results from the Phase 3 KONFIDENT clinical trial. In the trial, patients ≥12 years of age with type 1 or type 2 HAE who received Ekterly experienced significantly faster symptom relief, reduced attack severity, and quicker attack resolution compared with placebo (1.61 hours with Ekterly 300 mg, 1.79 hours with Ekterly 600 mg, and 6.72 hours with placebo). In KONFIDENT-S, the open-label extension trial, patients were able to treat HAE attacks early, with a median time from attack onset to treatment of 10 minutes, and a median time to onset of symptom relief for laryngeal attacks of 1.3 hours.

Place in Therapy

Ekterly is the first and only oral on-demand treatment for HAE. Other therapeutic options include intravenously and subcutaneously administered therapies such as Firazyr (icatibant), Kalbitor (ecallantide), Berinert (C1 esterase inhibitor [human]), and Ruconest (C1 esterase inhibitor [recombinant]).

New FDA-Approved Drug Products

New Molecular Entity

Specialty

Anzupgo® (delgocitinib) cream for topical use

FDA-Approved Indication

For the topical treatment of moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom topical corticosteroids (TCSs) are not advisable

Dosage & Administration

Applied twice daily to skin of the affected areas only on the hands and wrists. No more than 30 grams per 2 weeks or 60 grams per month should be used.

Dosage Forms & Strengths

Cream: Each gram of Anzupgo cream contains 20 mg of delgocitinib.

Contraindications

None

Common Adverse Reactions

Application site pain, paresthesia, pruritus, erythema, and bacterial skin infections including finger cellulitis, paronychia, other skin infections, leukopenia, and neutropenia.

Warnings & Precautions

- Serious Infections
- Non-melanoma Skin Cancers
- Immunizations
- Potential Risk Related to JAK Inhibition

Clinical Studies

The approval was based on results from two Phase 3 studies, DELTA1 and DELTA 2. These randomized, double-blind, vehicle-controlled studies enrolled a total of 960 adult patients with CHE to assess the cream's safety and efficacy over 16 weeks. The primary endpoints were met, with Anzupgo outperforming placebo vehicle in the achievement of Investigator's Global Assessment for CHE (IGA-CHE) score of 0 (clear) or 1 (almost clear) with a ≥2-step improvement from baseline at Week 16. In DELTA 1 and DELTA 2, 20% and 29% of patients, respectively, achieved IGA-CHE TS versus 10% and 7% with placebo.

Place in Therapy

Anzupgo is the first drug approved to specifically treat CHE. Anzupgo is reserved for second-line use after TCSs. There are several topical products available that are used off label for CHE such as Eucrisa (crisaborole), Opzelura (ruxolitinib), Vtama (tapinarof), and Zoryve (roflumilast).

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Sephience (sepiapterin) oral powder

FDA-Approved Indication

For the treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU).

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

Oral Powder: 250mg and 1,000mg

Contraindications

None

Common Adverse Reactions

Diarrhea, headache, abdominal pain, hypophenylalaninemia, feces discoloration, and oropharyngeal pain.

Warnings & Precautions

- Increased Bleeding
- Hypophenylalaninemia
- Interaction with Levodopa

Drug Interactions

- Dihydrofolate Reductase (DHFR) Inhibitors
- Sepiapterin Reductase (SR) Inhibitors
- Drugs Affecting Nitric Oxide-Mediated Vasorelaxation
- Levodopa

Clinical Studies

The approval was based on results from the 2-part phase 3 APHENITY trial which evaluated the efficacy of sepiapterin in adult and pediatric patients aged 1 to 61 years with a diagnosis of PKU and hyperphenylalaninemia with at least 2 blood Phe measurements of at least 600µmol/L. In Part 1, 157 study participants received daily open-label treatment with sepiapterin. Findings showed 66% of participants had at least a 30% reduction in Phe level. Following that initial treatment period to identify Sephience responders, followed by a washout period (Part 2), the trial met its primary endpoint, with a −64.2% difference in the adjusted mean change from baseline to Weeks 5 and 6 in blood Phe levels for Sephience versus placebo (P <0.0001).

Place in Therapy

Dietary therapy is the mainstay of therapy for patients with PKU. Sephience will join the treatment landscape alongside Kuvan (sapropterin dihydrochloride), which is available generically. Palynziq (pegvaliase-pqpz) injection, a Phe-metabolizing enzyme, is approved for patients who are not controlled on existing management.

New FDA-Approved Drug Products

New Molecular Entity

Vizz (aceclidine ophthalmic solution) 1.44%, for topical ophthalmic use

FDA-Approved Indication

For the treatment of presbyopia in adults.

Dosage & Administration

Instill one drop in each eye, wait 2 minutes and instill a second drop in each eye once daily

Dosage Forms & Strengths

Ophthalmic solution: aceclidine 1.44% in a single-dose vial.

Contraindications

None

Common Adverse Reactions

Instillation site irritation, dim vision, and headache

Warnings & Precautions

- Blurred Vision
- Risk of Retinal Tear/Detachment
- Iritis

Clinical Studies

The approval was based on results from two randomized, double-masked, controlled Phase 3 studies which evaluated the efficacy of aceclidine in 466 adults with a refractive range from -4.00 to +1.00 D sphere, astigmatism up to 2.00 D, and aspherical equivalent no more myopic than -4.00 D. The primary endpoint was the proportion of participants gaining 3 lines or more in distance corrected, near visual acuity at 40cm, without loss of 1 line or more (≥5 letters) of distance corrected, distance visual acuity at 4 meters at day 1, hour 3. Results showed that 65% of patients treated with aceclidine met the primary endpoint compared with 12% of those on brimonidine in CLARITY-1. Similar results were seen in CLARITY-2, with 71% of the aceclidine group achieving the primary endpoint vs 8% of the vehicle group.

Place in Therapy

Presbyopia is commonly treated with the use of glasses. Surgery is sometimes also an option.
Vuity was the first product FDA approved for presbyopia, followed by Qlosi.

New FDA-Approved Drug Products

New Biosimilar Product

Kirsty™ (insulin aspart-xjhz) injection, for subcutaneous use

FDA-Approved Indication

Indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

Injection: 100 units/mL (U-100) of insulin aspart-xjhz available as:

- 3 mL single-patient-use prefilled pen
- 10 mL multiple-dose vial

Contraindications

- During episodes of hypoglycemia
- Hypersensitivity to insulin aspart products or any of the excipients in Kirsty

Common Adverse Reactions

Hypoglycemia, allergic reactions, local injection site reactions, lipodystrophy, rash, and pruritus.

Warnings & Precautions

- Never share a Kirsty prefilled pen, needles or syringes between patients, even if the needle is changed
- Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen
- Hypoglycemia
- Medication Errors
- Hypersensitivity Reactions
- Hypokalemia
- Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs)
- Hyperglycemia and Ketoacidosis Due to Insulin Pump Device Malfunction

Drug Interactions

- Drugs that may increase the risk of hypoglycemia
- Drugs that may decrease the blood glucose lowering effect
- Drugs that may increase or decrease the blood glucose lowering effect
- Drugs that may blunt the signs and symptoms of hypoglycemia

Clinical Studies

The approval for Kirsty was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that Kirsty is highly similar to NovoLog. The data demonstrated that there were no clinically meaningful differences between Kirsty and NovoLog in terms of safety, efficacy, purity and potency.

Place in Therapy

Kirsty is the first rapid-acting interchangeable biosimilar to NovoLog (insulin aspart). Kirsty is the second insulin aspart biosimilar to receive FDA approval. It follows Merilog (insulin aspart-szjj), which was approved in February 2025.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Vostally (ramipril) solution for oral use

FDA-Approved Indication

For the treatment of: [1] for the treatment of hypertension in adults, to lower blood pressure; [2] In patients 55 years or older at high risk of developing a major cardiovascular event, Vostally is indicated to reduce the risk of myocardial infarction, stroke, or death from cardiovascular causes; [3] In adult patients with post-myocardial infarction heart failure to reduce the risk of cardiovascular death and hospitalization for heart failure.

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

Oral Solution: 1 mg/mL

Contraindications

- Angioedema or hypersensitivity related to previous treatment with an ACE inhibitor, or a history of hereditary or idiopathic angioedema.
- Contraindicated in combination with a neprilysin inhibitor (e.g., sacubitril).
- Do not co-administer aliskiren with Vostally in patients with diabetes.

Common Adverse Reactions

Cough and hypotension.

Warnings & Precautions

- ***BBW***: Fetal Toxicity
- Edema, increased risk in patients with a prior history
- Hypotension
- Rare cholestatic jaundice and hepatic failure
- Renal impairment: monitor renal function during therapy
- Hyperkalemia

Drug Interactions

- Diuretics
- Potassium-sparing diuretics/potassium supplements
- Dual inhibition of the renin-angiotensin system
- Lithium
- Gold
- NSAID
- mTOR inhibitor or neprilysin inhibitor

Use In Specific Populations

Lactation: Advise not to breastfeed

Clinical Studies

The efficacy of Vostally was established based on previously reported drug data to support the use of this new formulation.

Place in Therapy

This is the first liquid formulation of the ACE inhibitor ramipril, addressing a significant treatment gap for hypertensive patients who struggle with swallowing traditional tablets.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Sdamlo (amlodipine) for oral solution

FDA-Approved Indication

For the treatment of hypertension and coronary artery disease in adults.

Dosage & Administration

- Adults recommended starting dose: 5 mg orally once daily with maximum dose of 10 mg orally once daily.
- Pediatric starting dose: 2.5 mg to 5 mg orally once daily.

Dosage Forms & Strengths

For oral solution: 2.5 mg, 5 mg, and 10 mg.

Contraindications

Known sensitivity to amlodipine.

Common Adverse Reactions

Fatigue, nausea, abdominal pain, and somnolence

Warnings & Precautions

- Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis.
- Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of Sdamlo, particularly in patients with severe obstructive coronary artery disease.
- Titrate slowly in patients with severe hepatic impairment.

Drug Interactions

- Do not exceed doses greater than 20 mg daily of simvastatin

Use in Specific Populations

- Pediatric: Effect on patients less than 6 years old is not known.
- Geriatric: Start dosing at the low end of the dose range.

Clinical Studies

The efficacy of Sdamlo was established based on previously reported drug data to support the use of this new formulation.

Place in Therapy

This new formulation of amlodipine provides an alternative dosage form for patients that struggle with swallowing traditional tablets.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Orphan Drug | Specialty

Doptelet® Sprinkle (avatrombopag) oral granules

FDA-Approved Indication

Treatment of thrombocytopenia in pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP).

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

Oral Granules: 10 mg

Contraindications

None

Common Adverse Reactions

- In adult patients: pyrexia, abdominal pain, nausea, headache, fatigue, edema peripheral, contusion, epistaxis, upper respiratory tract infections, arthralgia, gingival bleeding, petechiae and nasopharyngitis.
- In pediatric patients: viral infection, nasopharyngitis, cough, pyrexia, and oropharyngeal pain.

Warnings & Precautions

- Thrombotic/Thromboembolic Complications

Drug Interactions

- Moderate or Strong Dual CYP2C9 and CYP3A4 Inducers or Inhibitors

Use in Specific Populations

- Pregnancy: May cause fetal harm
- Lactation: Advise not to breastfeed

Clinical Studies

The pediatric approval is based on results from AVA-PED-301, a global, randomized, phase 3 study evaluating the efficacy, safety, and pharmacokinetics of Doptelet in the treatment of pediatric subjects with ITP. The study showed that 27.8% of Doptelet patients achieved the primary endpoint of durable platelet response (defined as a platelet count ≥50,000/uL for six of the last eight weeks in the 12-week trial) versus 0% of placebo patients in the absence of rescue medication. Also, 81.5% of Doptelet patients achieved the alternative primary endpoint of platelet response versus no patients in the placebo group.

Place in Therapy

Doptelet has several competitors such as Promacta (eltrombopag) and Nplate (romiplostim), both of which are approved for second-line ITP treatment in patients 1 year of age and older. Off-label rituximab can also be used. First-line treatment of ITP in children includes corticosteroids and immunoglobulins.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Vyscoxa™ (celecoxib) oral suspension

FDA-Approved Indication

For the treatment of: [1] Osteoarthritis (OA); [2] Rheumatoid arthritis (RA); [3] Ankylosing Spondylitis; [4] Juvenile rheumatoid arthritis (JRA)

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

Oral suspension: 10 mg/mL

Contraindications

- Known hypersensitivity to celecoxib, or any components of the drug product or sulfonamides.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of CABG surgery

Common Adverse Reactions

Abdominal pain, diarrhea, dyspepsia, flatulence, peripheral edema, accidental injury, dizziness, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, rash.

Warnings & Precautions

- ***BBW:*** Risk of Serious Cardiovascular and Gastrointestinal Events
- Hepatotoxicity
- Hypertension
- Heart Failure and Edema
- Renal Toxicity
- Anaphylactic Reactions
- Exacerbation of Asthma Related to Aspirin Sensitivity
- Serious Skin Reactions
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
- Fetal Toxicity
- Hematologic Toxicity

Drug Interactions

- Drugs that Interfere with Hemostasis (e.g., warfarin, aspirin, selective serotonin reuptake inhibitors [SSRIs]/serotonin norepinephrine reuptake inhibitors [SNRIs])
- Angiotensin Converting Enzyme (ACE) Inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers
- ACE Inhibitors and ARBs
- Diuretics
- Digoxin

Use in Specific Populations

Infertility: NSAIDs are associated with reversible infertility.

Clinical Studies

The effectiveness of Vyscoxa has been established based on adequate and well-controlled studies of another formulation of celecoxib.

Place in Therapy

This new formulation of celecoxib provides an alternative dosage form for patients that struggle with swallowing traditional solid forms.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Atmeksi (methocarbamol) oral suspension

FDA-Approved Indication

A muscle relaxant indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions in patients 16 and older.

Dosage & Administration

Initial dosage of 1,500 mg (10 mL) 4 times daily. Maintenance dosage of 750 mg (5 mL) every 4 hours or 1,500 mg (10 mL) 3 times daily.

Dosage Forms & Strengths

Oral suspension: 750 mg/5mL

Contraindications

Hypersensitivity to Atmeksi or any component in the product

Common Adverse Reactions

Anaphylactic reaction, angioneurotic edema, fever, headache, bradycardia, flushing, hypotension, syncope, thrombophlebitis, dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting, blurred vision, conjunctivitis, nasal congestion, metallic taste, pruritus, rash and urticaria, amnesia, confusion, diplopia, dizziness or lightheadedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, sedation, seizures (including grand mal), vertigo.

Warnings & Precautions

- May potentiate the effects of CNS (central nervous system) depressants and alcohol
- May impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle

Drug Interactions

- Pyridostigmine bromide
- Laboratory test interference

Use in Specific Populations

Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Atmeksi.

Place in Therapy

Classified as a skeletal muscle relaxant, methocarbamol is a helpful medication used to manage acute musculoskeletal pain.

Other notable new approvals include:

Shingrix (zoster vaccine recombinant, adjuvanted) pre-filled syringe

A prefilled syringe presentation of Shingrix (Recombinant Zoster Vaccine) for the prevention of shingles (herpes zoster). The new prefilled syringe removes the need to reconstitute separate vials prior to administration, simplifying the vaccine administration process for healthcare professionals. The existing vaccine presentation consists of two vials, a lyophilized (powder) antigen and a liquid adjuvant, which healthcare professionals combine prior to administering.

New First-Time Generic Approvals

First-Time Generics are the first generic forms of brand name drugs. The generic version is formulated to work in the same way as the brand-name product and provides the same clinical benefit.

Product	Manufacturer	Generic For	Therapeutic Class	Indication(s)	Market Release Date
Perampanel Oral Suspension 0.5mg/mL	MSN Laboratories	Fycompa Oral Suspension	Anticonvulsants	Seizures	2025
Tazarotene Topical Lotion 0.045%	Padagis Pharmaceuticals Ltd	Arazlo	Dermatologicals	Acne Vulgaris	2029 - 2030

*Note: Various legal factors may come into play, affecting the estimated availability date.

New FDA-Approved Indications for Existing Drugs

The following table contains drugs that have gained FDA approval for the treatment of additional diseases or conditions.

Drug Name and Manufacturer	Previous Indication(s)	New Indication
Kerendia™ (finerenone) From: Bayer Healthcare	To reduce the risk of sustained EGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).	To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.
Skytrofa™ (lonapegsomatropin-tcgd) From: Ascendis	For the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).	For the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD).
Doptelet® (avatrombopag) From: Akarkx Inc	[1] Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure; [2] Thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.	Thrombocytopenia in pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.
Empaveli™ (pegcetacoplan) From: Apellis Pharms	For the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).	For the treatment of adult and pediatric patients aged 12 years and older with C3 glomerulopathy (CG3) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria.
Biktarvy™ (bictegravir, emtricitabine and tenofovir alafenamide) From: Gilead Sciences Inc	As a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg: [1] who have no antiretroviral treatment history or [2] to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.	[3] With an antiretroviral treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir

Leqvio™ (inclisiran) *From: Novartis*	As an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia, to reduce low density lipoprotein cholesterol (LDL-C).	As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia.
Alhemo™ (concizumab-mtci) *From: Novo Nordisk Inc*	For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: [1] Hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors; [2] Hemophilia B (congenital factor IX deficiency) with FIX inhibitors.	For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: [1] Hemophilia A (congenital factor VIII deficiency) with or without FVIII inhibitors; [2] Hemophilia B (congenital factor IX deficiency) with or without FIX inhibitors.

Pipeline

The goals of the NDA (or BLA) are to provide enough information to permit FDA approval of a new pharmaceutical for sale and marketing in the U.S.

Drug Name and Manufacturer	Indication(s)	Additional Information	Impact
Reproxalap From: Aldeyra Therapeutics, Inc	Dry Eye Disease	NDA accepted	Low

Pipeline Generics

This section describes generics that may possibly be available on the market in the next month. Various legal factors may come into play, affecting the date.

Generic Name	Brand Name	Brand Manufacturer
Stiripentol (powder and capsule)	Diacomit	Biocodex
Carbidopa; Levodopa	Rytary	Amneal