PharmNotes

Monthly Communications

October 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.

No Drug Safety Alert Notification was released during October.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Jascayd® (nerandomilast) tablets for oral use

FDA-Approved Indication

For the treatment of idiopathic pulmonary fibrosis in adults.

Dosage & Administration

18 mg orally twice daily approximately 12 hours apart with or without food.

Dosage Forms & Strengths

Tablets: 9 mg and 18 mg

Contraindications

None.

Common Adverse Reactions

Diarrhea, COVID-19, upper respiratory tract infection, depression, weight decreased, decreased appetite, nausea, fatigue, headache, vomiting, back pain, and dizziness.

Drug Interactions

- Strong CYP3A Inhibitors
- Moderate or Strong CYP3A Inducers

Clinical Studies

The approval was based on results from 2 randomized, double-blind, placebo-controlled trials (FIBRONEER-IPF and Trial 2). The primary endpoint was the absolute change from baseline in FVC at week 52. Results showed Jascayd led to a slower decline in absolute change from baseline in FVC compared with placebo. The adjusted mean decline was -106mL and -122mL in the Jascayd 18mg and 9mg arms, respectively, compared with -170mL in the placebo arm.

Place in Therapy

Jascayd is the first and only preferential inhibitor of phosphodiesterase 4B (PDE4B) to be approved in this indication. Jascayd may be used as monotherapy or in combination with Esbriet (pirfenidone) or Ofev (nintedanib).

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Blenrep™ (belantamab mafodotin-blmf) injection for intravenous use

FDA-Approved Indication

In combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

Dosage & Administration

2.5 mg/kg as an intravenous infusion over 30 minutes once every 3 weeks for 8 cycles, followed by Blenrep 2.5 mg/kg every 3 weeks as a single agent.

Dosage Forms & Strengths

For injection: 70 mg as a lyophilized powder in a single-dose vial for reconstitution and further dilution.

Contraindications

None.

Common Adverse Reactions

Reduction in best-corrected visual acuity (BCVA), corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract, COVID19, decreased platelets, decreased lymphocytes, decreased neutrophils, increased gamma-glutamyl transferase, decreased white blood cells, and decreased hemoglobin.

Warnings & Precautions

- ***BBW:*** Ocular Toxicity
- Thrombocytopenia
- Embryo-Fetal Toxicity

Use in Specific Populations

Lactation: Advise not to breastfeed.

Clinical Studies

The approval was based on results from DREAMM-7, an open-label, randomized, multicenter trial in adults with relapsed or refractory multiple myeloma who had received at least one line of prior therapy. Patients were randomized (1:1) to receive either belantamab mafodotin blmf, bortezomib, and dexamethasone (BVd) or daratumumab, bortezomib, and dexamethasone (DVd). The primary endpoints were progression-free survival (PFS) and overall survival (OS). The median PFS was 31.3 months in the BVd arm and 10.4 months in the DVd arm. The median OS was NR and 35.7 months in respective arms.

Place in Therapy

Blenrep joins the market alongside other third-line therapy options like CAR-T treatments, Sarclisa, and various combination regimens. The NCCN Guidelines for Multiple Myeloma recommends the use of Blenrep as therapy for previously treated multiple myeloma for relapsed/refractory disease in patients who have received at least three prior lines of therapy (useful in certain circumstances) (category 2A).

New FDA-Approved Drug Products

New Molecular Entity

Lynkuet® (elinzanetant) capsules for oral use

FDA-Approved Indication

For the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause.

Dosage & Administration

120 mg (two 60 mg capsules) orally once daily at bedtime with or without food.

Dosage Forms & Strengths

Capsules: 60 mg

Contraindications

Pregnancy.

Common Adverse Reactions

Headaches, fatigue, dizziness and somnolence.

Warnings and Precautions

- CNS Depressant Effect and Daytime Impairment
- Hepatic Transaminase Elevations
- Risk of Pregnancy Loss
- Risk Of Seizures in Patients with a History of Seizures

Drug Interactions

- Strong CYP3A4 Inhibitors and grapefruit (juice)
- Moderate CYP3A4 Inhibitors
- Strong and Moderate CYP3A4 Inducers

Use in Specific Populations

- End Stage Renal Disease with or without hemodialysis: Not recommended.
- Moderate to Severe Hepatic Impairment: Not recommended.

Clinical Studies

The approval was based on results from OASIS 1 and OASIS 2 clinical trials, which included 796 menopausal women who had at least 50 moderate to severe hot flashes per week. The primary endpoint was the mean change in frequency and severity of moderate to severe VMS from baseline to weeks 4 and 12, including day and night hot flashes measured using the Hot Flash Daily Diary (HFDD). Results showed treatment with Lynkuet led to a statistically significant reduction (≥2 hot flashes over 24 hours) in the frequency and severity of moderate to severe VMS compared with placebo.

Place in Therapy

Hormone therapy is the most effective treatment for vasomotor symptoms and has been shown to prevent bone loss and fracture. Lynkuet joins the treatment landscape alongside Veozah. Lynkuet offers a slight benefit since its label does not carry a boxed warning for hepatoxicity but does recommend baseline hepatic monitoring.

New FDA-Approved Drug Products

New Biosimilar Product

Eydenzelt® (aflibercept-boav) injection, for intravitreal use

FDA-Approved Indication

[1] Neovascular (Wet) Age-Related Macular Degeneration (AMD); [2] Macular Edema Following Retinal Vein Occlusion (RVO); [3] Diabetic Macular Edema (DME); [4] Diabetic Retinopathy (DR).

Dosage & Administration

Refer to package insert for dosage and administration instructions.

Dosage Forms & Strengths

Injection: 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose pre-filled syringe or vial.

Contraindications

- Ocular or periocular infection
- Active intraocular inflammation
- Hypersensitivity

Common Adverse Reactions

Conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Warnings and Precautions

- Endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion
- Increases in intraocular pressure
- Potential risk of arterial thromboembolic events

Clinical Studies

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

Place in Therapy

Eydenzelt is the sixth FDA-approved Eylea biosimilar.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Contepo™ (fosfomycin) injection for intravenous use

FDA-Approved Indication

For the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI), including acute pyelonephritis, caused by susceptible isolates of *Escherichia coli* and *Klebsiella pneumoniae*.

Dosage & Administration

6 grams every 8 hours by intravenous (IV) infusion over 1 hour for up to 14 days, in patients 18 years of age or older with an estimated creatinine clearance greater than 50 mL/min.

Dosage Forms & Strengths

Injection contains 6 grams of fosfomycin as a sterile powder in single dose vials for reconstitution and further dilution.

Contraindications

In patients with known serious hypersensitivity to fosfomycin, or any of the excipients.

Common Adverse Reactions

Transaminase elevations, hypokalemia, neutropenia, nausea, vomiting, diarrhea, hypocalcemia, hypernatremia, headache, and hypophosphatemia.

Warnings & Precautions

- Serum Electrolyte Abnormalities
- QT Prolongation
- Increased Transaminase Levels
- Hypersensitivity Reactions
- Neutropenia Including Agranulocytosis
- *Clostridioides difficile-Associated Diarrhea* (CDAD)

Drug Interactions

- Avoid co-administration with drugs known to prolong the QT interval.

Use in Specific Populations

- Lactation: Breastfeeding not recommended during treatment and 24 hours after the last dose.

Clinical Studies

The approval was based on results from the phase 2/3 ZEUS (ZTI-01) trial which found that IV fosfomycin was noninferior to piperacillin/tazobactam in terms of the primary end point of overall success (defined as clinical cure and microbiological eradication) in the microbiological intent-to-treat population.

Place in Therapy

Fosfomycin is also available as a 3 gm packet of granules for oral solution for the treatment of uncomplicated UTI in women. Contepo represents a new treatment option for cUTIs treated in the hospital setting.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Javadin™ (clonidine hydrochloride) solution for oral use

FDA-Approved Indication

For the treatment of hypertension in adult patients to lower blood pressure.

Dosage & Administration

Initial dosage is 0.1 mg orally twice daily with or without food (morning and bedtime). Titrate in increments of 0.1 mg per day at weekly intervals, until the desired response is achieved. The maximum daily dose recommended is 2.4 mg.

Dosage Forms & Strengths

Oral Solution: 0.02 mg/mL

Contraindications

In patients with known hypersensitivity to clonidine.

Common Adverse Reactions

Dry mouth, drowsiness, dizziness, constipation and sedation.

Warnings & Precautions

- Bradycardia, Cardiac Conduction Abnormalities, and Symptomatic Hypotension
- Rebound Hypertension
- Sedation and Somnolence

Drug Interactions

- Sedating Drugs
- Tricyclic Antidepressants
- Neuroleptics
- Drugs Known to Affect Sinus Node Function or AV Nodal Conduction

Use in Specific Populations

- Renal Impairment: Patients with renal impairment may require a lower initial dose and should be closely monitored.

Place in Therapy

This ready-to-use oral solution may help in the hypertension care for some patients who have difficulty swallowing capsules or tablets, eliminating the need for tablet cutting, compounding, or applying a transdermal delivery system.

Other notable new approvals include:

Lasix ONYU solution for subcutaneous infusion

The U.S. Food and Drug Administration (FDA) has approved its drug-device combination Lasix ONYU (furosemide injection) for the treatment of edema (due to fluid overload) in adult patients with chronic heart failure. Lasix ONYU was developed to enable subcutaneous infusion of furosemide outside the healthcare setting for selected patients, as prescribed by a clinician without the need for a healthcare professional to administer the drug.

Zoryve® (roflumilast) cream 0.05% for topical use

The U.S. Food and Drug Administration (FDA) has approved Zoryve (roflumilast) 0.05% cream for the treatment of mild to moderate atopic dermatitis in children aged 2 to 5 years. Zoryve cream is also available in a 0.15% strength for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

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)	Estimated Availability Date
Dalbavancin Hydrochloride Powder for Injection 500 mg (base)/vial	Teva Pharmaceuticals, Inc.	Dalvance	Anti-infective Agents – Misc.	Bacterial Skin and Skin Structure Infections	2025 - 2026

*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
Zepzelca™ (lurbinectedin) From: Jazz Pharmaceuticals	For the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.	In combination with atezolizumab (Tecentriq) or atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza) as a maintenance treatment for adults with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with atezolizumab, carboplatin and etoposide.
Simponi™ (golimumab) From: Johnson & Johnson (Janssen)	Adult patients with moderate to severe ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy.	Adult and pediatric patients weighing at least 15 kg with moderately to severely active ulcerative colitis (UC).
Libtayo™ (cemiplimab-rwlc) From: Regeneron Pharmaceuticals	For the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.	For the adjuvant treatment of adult patients with CSCC at high risk of recurrence after surgery and radiation.
Uzedy™ (risperidone) From: Teva	For the treatment of schizophrenia in adults.	For the treatment of adults with bipolar I disorder.
Rybelsus™ (semaglutide) From: Novo Nordisk	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events.
Tezspire® (tezepelumab-ekko) From: Amgen	For the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.	For the add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps in adult and pediatric patients aged 12 years and older.
Yuflima™ (adalimumab-aaty) From: Celltrion Inc.	For the treatment of adult patients with: [1] Rheumatoid arthritis (RA); [2] Psoriatic arthritis (PsA); [3] Juvenile idiopathic arthritis (JIA);[4] Ankylosing spondylitis (AS); [5]	[1] For the treatment of hidradenitis suppurativa (HS) in adolescent patients aged 12 years and older; [2] For the treatment of uveitis in

	Crohn's Disease (CD); [6] Ulcerative colitis (UC) ;[7] Plaque psoriasis (Ps); [8] Hidradenitis suppurativa (HS); [9] Uveitis (UV)	pediatric patients aged 2 years and older.
Gazyva™ (obinutuzumab) From: Genetech Inc.	[1] In combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia; [2] In combination with bendamustine followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen; [3] In combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma.	For the treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy.
Winrevair™ (sotatercept) From: Merck Sharp Dohme	For the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.	For the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1 pulmonary hypertension) to improve exercise capacity and WHO functional class (FC), and reduce the risk of clinical worsening events, including hospitalization for PAH, lung transplantation and death.
Revuforj™ (revumenib) From: Syndax	For the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older.	For the treatment of relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation in adult and pediatric patients 1 year and older who have no satisfactory alternative treatment options.

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
Vusolimogene oderparepvec (RP1) From: Replimune Group, Inc.	Melanoma	BLA Acceptance	High

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
Linagliptin; Metformin Hydrochloride	Jentadueto / Jentadueto XR	Boehringer Ingelheim; Eli Lilly
Tapentadol Hydrochloride	Nucynta (oral solution)	Depomed; Grunenthal; Collegium Pharmaceuticals; Assertio Therapeutics