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PharmNotes

Monthly Communications

August 2026

Table of Contents

Drug Safety Alert Notification 2

New FDA-Approved Drug Products 3

- New Molecular Entity 3
  - Orzeyful (oveporexton) tablets, for oral use 3
  - Zenbexus (iberdomide) capsules, for oral use 4
  - Pasatru (garetosmab-grts) injection, for intravenous use 5
  - Rasonque (daraxonrasib) tablets, for oral use 6
  - Mimrylo (rusfertide) for injection, for subcutaneous use 7
  - Lisraya (brepocitinib) tablets, for oral use 8
- New Formulations, Combinations, and Line Extensions 9
  - Bixlenvo (bictegravir and lenacapavir) tablets, for oral use 9

Other Notable New Approvals 10

New First-Time Generic Approvals 11

New FDA-Approved Indications for Existing Drugs 12

Pipeline 14

Pipeline Generics 15

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 was released during the month of August.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Orzeyful (oveporexton) tablets, for oral use

FDA-Approved Indication

For the treatment of narcolepsy type 1 (narcolepsy with cataplexy) in adult patients.

Dosage & Administration

1 mg or 2 mg upon awakening and repeat the same dose 3 to 5 hours later, up to a maximum of 4 mg per day.

Dosage Forms & Strengths

Tablets: 0.5 mg, 1 mg, and 2 mg.

Contraindications

- In patients taking strong CYP3A inhibitors.

Common Adverse Reactions

Insomnia, pollakiuria, micturition urgency, and salivary hypersecretion.

Warnings & Precautions

- Insomnia
- Urinary Frequency and Urgency
- Creatine Phosphokinase Elevations

Drug Interactions

- Strong CYP3A Inhibitors
- Moderate CYP3A Inhibitors
- Strong and Moderate CYP3A Inducers

Use in Specific Populations

- Severe Hepatic Impairment: Avoid use in patients with severe hepatic impairment.
- Severe Renal Impairment on Dialysis: Avoid use in patients with severe renal impairment on dialysis.

Clinical Studies

The approval came from the Phase 3 FirstLight and RadiantLight randomized, double-blind, placebo-controlled studies. The primary endpoint was the change from baseline to Week 12 in wakefulness as measured by the Maintenance of Wakefulness Test (MWT), with Orzeyful improving mean sleep latency by 12.5 to 19.1 minutes versus declines of 1.3 and 1.0 minutes with placebo.

Place in Therapy

Orzeyful joins the treatment landscape alongside Xyrem, Xywav, Lumryz, Wakix, generic modafinil/armodafinil, generic stimulants, and off-label antidepressants for narcolepsy type 1. As the first-in-class orexin receptor 2 (OX2R) agonist, it targets the underlying orexin deficiency and offers a novel treatment approach with demonstrated efficacy and low abuse potential.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Zenbexus (iberdomide) capsules, for oral use

FDA-Approved Indication

In combination with daratumumab and hyaluronidase-fihj and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulatory agent.

Dosage & Administration

1 mg orally once daily on Days 1 to 21 of repeated 28-day cycle.

Dosage Forms & Strengths

Capsules: 0.75 and 1 mg.

Contraindications

- Pregnancy.

Common Adverse Reactions

Upper respiratory tract infection, fatigue, musculoskeletal pain, pneumonia, diarrhea, motor dysfunction, rash, sleep disorder, hypogammaglobulinemia, constipation, COVID 19, neutrophil count decreased, white blood cell count decreased, and lymphocyte count decreased.

Warnings & Precautions

- ***BBW***: Embryo-Fetal Toxicity (REMS) and Serious Venous and Arterial Thromboembolism
- Neutropenia
- Infections
- Second Primary Malignancies

Drug Interactions

- Strong or moderate CYP3A inhibitors
- Strong or moderate CYP3A inducers

Use in Specific Populations

- Lactation: Advise not to breastfeed.
- Renal impairment: Reduce dose in patients with eGFR less than 30 mL/min/1.73 m^2 not on dialysis.

Clinical Studies

The approval came from the EXCALIBER-RRMM randomized, open-label study in adults with relapsed or refractory multiple myeloma who had received one or two prior lines of therapy. The primary endpoint was measurable residual disease (MRD)-negative complete response rate, which was achieved in 41% of patients treated with Zenbexus plus daratumumab and dexamethasone compared with 21% of patients receiving daratumumab, bortezomib, and dexamethasone ($p<0.0001$).

Place in Therapy

Zenbexus joins the treatment landscape alongside CAR-T therapies, Tecvayli-based regimens, Sarclisa-based regimens, and other triplet combination therapies for relapsed or refractory multiple myeloma. As the first approved CELMoD agent, Zenbexus introduces a novel mechanism of action and expands treatment options in the second-line setting.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Pasatru (garetosmab-grts) injection, for intravenous use

FDA-Approved Indication

To reduce formation of new heterotopic ossification lesions and clinician-assessed flare-ups in adults with fibrodysplasia ossificans progressiva.

Dosage & Administration

10 mg/kg intravenous infusion over 60 minutes once every 4 weeks.

Dosage Forms & Strengths

Injection: 300 mg/5 mL (60 mg/mL) solution in a single-dose vial.

Contraindications

- Pregnancy.

Common Adverse Reactions

Abscess, acne, increased hair growth, madarosis, oral ulcers, and epistaxis.

Warnings & Precautions

- Embryo-Fetal Toxicity
- Skin and Soft Tissue Infections
- Epistaxis

Use in Specific Populations

- Lactation: Breastfeeding is not recommended.

Clinical Studies

The approval came from a randomized, double-blind, placebo-controlled study in adults with fibrodysplasia ossificans progressiva. The primary endpoint was the number of new heterotopic ossification lesions at Week 56, with Pasatru reducing new lesion formation by 90% and 94% at the 10 mg/kg and 3 mg/kg doses, respectively, compared with placebo ($p<0.05$ for both comparisons).

Place in Therapy

Pasatru joins the treatment landscape alongside Sohonos, the first FDA-approved therapy for fibrodysplasia ossificans progressiva. Prior to Sohonos, treatment focused primarily on symptom relief and pain management. Pasatru introduces a distinct mechanism of action by inhibiting activin A signaling, a key driver of heterotopic ossification, whereas Sohonos acts through the retinoic acid receptor gamma (RARγ) pathway.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Rasonque (daraxonrasib) tablets, for oral use

FDA-Approved Indication

For the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy.

Dosage & Administration

300 mg orally once daily.

Dosage Forms & Strengths

Tablets: 100 mg; 150 mg.

Contraindications

None.

Common Adverse Reactions

Rash, diarrhea, stomatitis, nausea, fatigue, vomiting, abdominal pain, edema, decreased appetite, hemorrhage, decreased albumin, decreased calcium, decreased hemoglobin, increased aspartate aminotransferase, decreased lymphocytes, decreased platelets, increased alanine aminotransferase, decreased sodium, decreased white blood cells, decreased magnesium, increased alkaline phosphatase, increased creatinine, and decreased potassium.

Warnings & Precautions

- Dermatologic and Soft Tissue Toxicity
- Stomatitis and Oral Disorders
- Diarrhea
- Gastrointestinal Perforation
- Interstitial Lung Disease (ILD)/Pneumonitis
- Embryo-Fetal Toxicity

Drug Interactions

- Strong CYP3A Inhibitors with P-gp Inhibition
- Strong CYP3A Inhibitors without P-gp Inhibition
- Moderate CYP3A Inhibitors with or without P-gp Inhibition
- P-gp Inhibitors
- Cyclosporine A
- Strong CYP3A Inducers
- Moderate CYP3A Inducers
- P-gp Substrate

Use in Specific Populations

- Lactation: Advise women not to breastfeed.

Clinical Studies

The approval came from the Phase 3 RASolute 302 randomized, open-label study in 500 patients with previously treated metastatic pancreatic ductal adenocarcinoma. The primary endpoint was overall survival (OS), with Rasonque reducing the risk of death by 60% versus chemotherapy (HR 0.40; $p<0.0001$) and improving median OS to 13.2 months compared with 6.7 months for standard chemotherapy. Significant improvements in progression-free survival and objective response rate were also observed.

Place in Therapy

Rasonque joins the treatment landscape alongside chemotherapy-based regimens and other targeted therapies for patients with previously treated metastatic pancreatic ductal adenocarcinoma. Although most patients enrolled had a RAS mutation, Rasonque is approved without a biomarker requirement, making it a treatment option regardless of documented RAS mutation status.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Mimrylo (rusfertide) for injection, for subcutaneous use

FDA-Approved Indication

For the treatment of erythrocytosis in adults with polycythemia vera.

Dosage & Administration

The recommended starting dose is 19 mg administered subcutaneously once weekly and may be adjusted based on efficacy or safety to a maximum dose of 108 mg weekly.

Dosage Forms & Strengths

For injection: 9.5 mg, 19 mg, 28 mg, 41 mg, and 54 mg of rusfertide as a lyophilized powder in single-dose vials for reconstitution.

Contraindications

None.

Common Adverse Reactions

Injection site reactions and anemia.

Warnings & Precautions

- New or Worsening Thrombocytosis
- Injection-Site Reactions
- Embryo-Fetal Toxicity

Use in Specific Populations

- Lactation: Breastfeeding not recommended.

Clinical Studies

The approval came from the Phase 3 VERIFY randomized, placebo-controlled study in 293 patients with polycythemia vera who had uncontrolled hematocrit despite standard-of-care therapy. The primary endpoint was the proportion of patients achieving a response during Weeks 20-32, defined as the absence of phlebotomy eligibility, and Mimrylo met the primary endpoint while also improving hematocrit control, reducing phlebotomy requirements, and improving fatigue versus placebo.

Place in Therapy

Mimrylo joins the treatment landscape alongside phlebotomy, hydroxyurea, interferons (including Besremi), and Jakafi in the management of polycythemia vera. As the first-in-class hepcidin mimetic, Mimrylo introduces a novel mechanism of action that regulates iron availability and reduces red blood cell overproduction to help control hematocrit levels. It may provide an additional option for patients who remain phlebotomy-dependent despite standard-of-care treatment, potentially reducing the need for frequent phlebotomies while improving disease-related symptoms.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Lisraya (brepocitinib) tablets, for oral use

FDA-Approved Indication

For the treatment of dermatomyositis in adult patients.

Dosage & Administration

30 mg orally once daily.

Dosage Forms & Strengths

Tablets: 30 mg.

Contraindications

- In patients with a history of hypersensitivity reactions to brepocitinib or any of the excipients in Lisraya.

Common Adverse Reactions

Upper respiratory tract infection, headache, fatigue, urinary tract infection, nausea, bronchitis, arthralgia, diarrhea, back pain, fall, influenza, and acne.

Warnings & Precautions

- ***BBW***: Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis
- Serious Infections
- Hypersensitivity Reactions
- Gastrointestinal (GI) Perforations
- Hypoglycemia in Patients with Diabetes
- Laboratory Abnormalities
- Immunizations (Live Vaccines)
- Embryofetal Toxicity

Use in Specific Populations

- Lactation: Advise not to breastfeed during treatment and for 3 days after the last dose.
- Renal impairment: Not recommended in patients with severe renal impairment.
- Hepatic impairment: Not recommended in patients with severe hepatic impairment.

Clinical Studies

The approval came from the Phase 3 VALOR randomized, double-blind, placebo-controlled study in 241 patients with dermatomyositis receiving standard background therapy. The primary endpoint was Total Improvement Score (TIS) at Week 52, with Lisraya demonstrating a significantly greater improvement than placebo (47.5 vs 33.3; difference, 14.2 [95% CI: 5.5-22.9]). Additionally, 69% of patients achieved at least a moderate response and 48% achieved a major response compared with 47% and 26%, respectively, with placebo.

Place in Therapy

Lisraya joins the treatment landscape alongside corticosteroids and other supportive therapies for the treatment of dermatomyositis. As the first FDA-approved oral therapy and the first targeted TYK2/JAK1 inhibitor for this condition, Lisraya offers a novel treatment option that has demonstrated improvements in skin disease, muscle strength, physical function, and overall disease burden, while also supporting corticosteroid dose reduction.

New FDA-Approved Drug Products

Specialty

New Formulations, Combinations, and Line Extensions

Bixlenvo (bictegravir and lenacapavir) tablets, for oral use

FDA-Approved Indication

For the treatment of HIV-1 in adults 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 resistance to the individual components of Bixlenvo.

Dosage & Administration

Treatment is initiated with a 2-day regimen of Bixlenvo plus oral Sunlenca, followed by maintenance therapy with Bixlenvo administered once daily starting on Day 3.

Dosage Forms & Strengths

Tablets: 75 mg BIC and 50 mg LEN.

Contraindications

- Concomitant administration with dofetilide, and strong CYP3A inducers.

Common Adverse Reactions

Headache, nausea, and diarrhea.

Drug Interactions

- Coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.

Clinical Studies

The approval came from the Phase 3 ARTISTRY-1 and ARTISTRY-2 randomized switch studies in virologically suppressed adults with HIV-1. The primary endpoint was the proportion of participants with HIV-1 RNA ≥50 copies/mL at Week 48, which was 1% in both the Bixlenvo and comparator arms, demonstrating maintenance of viral suppression after switching therapy.

Place in Therapy

Bixlenvo joins the treatment landscape alongside other single-tablet regimens (STRs) and multi-tablet antiretroviral therapies for adults with HIV-1. As a once-daily STR, Bixlenvo may be particularly beneficial for virologically suppressed patients who were previously managed on more complex multi-tablet regimens, offering a simplified treatment option while maintaining viral suppression.

Other Notable New Approvals

Tudriqev (vusolimogene oderparepvec-wtpg) suspension Gene/Cell Therapy

- In combination with nivolumab for the treatment of adult patients with unresectable advanced cutaneous melanoma who experienced disease progression with a programmed death receptor-1 (PD-1)-blocking antibody-based regimen.

Genglycos (pariglasgene brecaparvovec-opnr) suspension Gene/Cell Therapy

- To reduce daily cornstarch intake as an adjunct to nutritional management in adult and pediatric patients 8 years of age and older with glycogen storage disease type Ia.

MFlusiva (Influenza Vaccine, mRNA) injectable suspension, for intramuscular use

- For active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine. MFlusiva is approved for use in persons 50 years of age and older. This is the first mRNA-based influenza vaccine FDA-approved.

Vobrig (leuprolide acetate) injection for subcutaneous use

- For the treatment of central precocious puberty in pediatric patients.

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	Indication(s)	Estimated Availability Date*
Lisinopril Oral Solution 1 mg/mL	Annora Pharma Private Limited	Qbrelis	Hypertension, Heart Failure, Myocardial Infarction	End of 2026
Cabozantinib (S)-malate Tablets 20 mg (base), 40 mg (base) and 60 mg (base)	MSN Laboratories	Cabometyx	Renal Cell Carcinoma, Hepatocellular Carcinoma, Thyroid Cancer, Pancreatic Neuroendocrine Tumors	2031
Sodium Zirconium Cyclosilicate Powder for Oral Suspension 5 gm/packet and 10 gm/packet	Lupin Limited	Lokelma	Hyperkalemia	2034

**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
Imaavy (nipocalimab-aahu) From: Johnson & Johnson	Generalized myasthenia gravis in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive	Warm autoimmune hemolytic anemia in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroid
Tivicay PD (dolutegravir) From: ViiV Healthcare	In combination with other antiretroviral agents for the treatment of HIV-1 infection in in pediatric patients (treatment-naïve or -experienced but integrase strand transfer inhibitor [INSTI]-naïve) aged at least 4 weeks and weighing at least 3 kg	In combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients (treatment-naïve or -experienced but INSTI- naïve) weighing at least 2 kg
Ziihera (zanidatamab-hrii) From: Jazz Pharmaceuticals	For the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer, as detected by an FDA-approved test	[1] In combination with fluoropyrimidine- and platinum containing chemotherapy, and tislelizumab-jsgr, as first-line treatment of adult patients with HER2-positive (IHC 3+ or IHC 2+/ISH+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma, as detected by an FDA-authorized test; [2] In combination with fluoropyrimidine- and platinum-containing chemotherapy, as first-line treatment of adult patients with HER2-positive (IHC 3+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma, as detected by an FDA-authorized test
Tevimbra (tislelizumab-jsgr) From: BeOne Medicines Ltd.	[1] Esophageal Cancer; [2] Gastric Cancer	In combination with zanidatamab-hrii and fluoropyrimidine- and platinum containing chemotherapy, is indicated for the first-line treatment for adults with HER2-positive (IHC 3+ or IHC 2+/ISH+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma as detected by an FDA-authorized test
Mounjaro (tirzepatide) From: Eli Lilly and Company	As an adjunct to diet and exercise to improve glycemic control in adults and	To reduce the risk of major adverse cardiovascular (CV) events (CV death,

	pediatric patients 10 years of age and older with type 2 diabetes mellitus	non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events
Besremi (ropeginterferon alfa-2b-njft) From: PharmAEssentia	The treatment of adults with polycythemia vera	The treatment of adults with essential thrombocythemia

Pipeline

PDUFA Date: June 24, 2027

Ralinepag

Overview

Ralinepag is an investigational, once-daily oral, extended-release prostacyclin (IP) receptor agonist being developed for the treatment of pulmonary arterial hypertension (PAH). As a highly selective non-prostanoid IP receptor agonist, ralinepag exerts vasodilatory, anti-proliferative, and anti-inflammatory effects that target the prostacyclin pathway, one of the key pathways involved in PAH pathogenesis. If approved, ralinepag would be the first once-daily oral prostacyclin pathway agent for PAH and could offer a more convenient dosing option compared with currently available oral prostacyclin therapies.

Clinical Studies

The clinical development program for ralinepag includes the Phase 3 ADVANCE OUTCOMES study in patients with pulmonary arterial hypertension receiving background therapy. The primary endpoint was time to clinical worsening, and ralinepag demonstrated a statistically significant 55% reduction in the risk of clinical worsening compared with placebo. The study also met key secondary endpoints, including significant reductions in N-terminal pro-B-type natriuretic peptide (NT-proBNP) levels and improvements in exercise capacity as measured by six-minute walk distance (6MWD). In addition, ralinepag improved the odds of achieving clinical improvement by 47% (p=0.015). Treatment effects were generally consistent across patient subgroups, including disease severity, PAH etiology, baseline NT-proBNP levels, and background treatment regimens.

Place in Therapy

Ralinepag joins a crowded PAH treatment landscape that includes prostacyclin pathway agents such as Uptravi, Orenitram, Tyvaso, Remodulin, Flolan, and Veletri, as well as endothelin receptor antagonists, phosphodiesterase-5 inhibitors, soluble guanylate cyclase stimulators, and the recently approved activin signaling inhibitor Winrevair. As a highly selective oral IP receptor agonist, ralinepag is expected to compete most directly with Uptravi and Orenitram. Its potential differentiation lies in its once-daily dosing schedule, which may offer a convenience advantage over twice-daily Uptravi and could improve treatment adherence.

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
Iloprost	Ventavis	Actelion; Johnson & Johnson