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PharmNotes

Monthly Communications

July 2026

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Pharmacy Benefit
Management
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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 was released during the month of July.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Trutakna (atacicept-vymj) injection, for subcutaneous use

FDA-Approved Indication

To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

Dosage & Administration

150 mg once weekly by subcutaneous injection.

Dosage Forms & Strengths

Injection: 150 mg/mL in a single-dose pre-filled autoinjector.

Contraindications

Serious hypersensitivity to any of the ingredients in Trutakna.

Common Adverse Reactions

Upper respiratory tract infection, injection site reaction and injection site erythema.

Warnings & Precautions

- Immunosuppression and Increased Risk of Infections
- Immunosuppression and Immunization Risks

Clinical Studies

The approval came from ORIGIN 3, a Phase 3, randomized, double-blind, placebo-controlled study that evaluated Trutakna in adults with IgAN receiving a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy, with or without a stable dose of a sodium-glucose cotransporter 2 inhibitor (SGLT2i) and/or a mineralocorticoid receptor antagonist (MRA). Patients were randomized to receive either Trutakna or placebo. The primary endpoint was the percent change from baseline in urine protein-to-creatinine ratio (UPCR), measured using a 24-hour urine collection at Week 36. Treatment with Trutakna resulted in a 46% reduction in UPCR from baseline, compared with a 7% reduction with placebo, demonstrating a statistically significant improvement in proteinuria reduction (difference vs placebo: 42%; 95% CI, 29%-52%; $p < 0.0001$).

Place in Therapy

Trutakna is the first FDA-approved therapy that targets both B-cell activating factor (BAFF) and A Proliferation-Inducing Ligand (APRIL), two key cytokines involved in the pathogenesis of IgAN. Its approval further expands the treatment landscape for IgAN, which has evolved in recent years from primarily supportive care to the use of targeted and disease-modifying therapies. Other FDA-approved treatments include Tarpeyo (budesonide), Fabhalta (iptacopan), Voyxact (sibeprenlimab), Filspari (sparsentan), and Vanrafia (atrasentan), each targeting different aspects of disease progression. As the sixth approved therapy for IgAN, Trutakna provides an additional treatment option for patients.

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Revtorpyk (gedatolisib) for Injection, for intravenous infusion

FDA-Approved Indication

In combination with fulvestrant, with or without palbociclib, for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

Dosage & Administration

180 mg intravenously as a 30-minute infusion once weekly on Days 1, 8, and 15 of a 28-day cycle.

Dosage Forms & Strengths

For Injection: 180 mg gedatolisib in a lyophilized powder in a single-dose vial.

Contraindications

None.

Common Adverse Reactions

Decreased white blood cells, decreased neutrophils, decreased hemoglobin, decreased lymphocytes, stomatitis, nausea, decreased platelets, increased fasting glucose, fatigue, vomiting, rash, constipation, diarrhea, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), musculoskeletal pain, decreased sodium, and increased eosinophils.

Warnings & Precautions

- Stomatitis
- Dermatologic Adverse Reactions
- Hyperglycemia
- Embryo-Fetal Toxicity

Use in Specific Populations

- Lactation: Advise not to breastfeed.

Clinical Studies

The approval came from VIKTORIA-1, a randomized, open-label study that enrolled 392 adults with locally advanced or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer without a detectable PIK3CA mutation. Patients were randomized to receive Revtorpyk in combination with fulvestrant and palbociclib, Revtorpyk in combination with fulvestrant, or fulvestrant alone. Median PFS was 9.3 months with Revtorpyk plus fulvestrant/palbociclib and 7.4 months with Revtorpyk plus fulvestrant, compared with 2.0 months for fulvestrant alone (both $p < 0.0001$). Objective response rates were 32%, 28%, and 1%, respectively, while median duration of response was 17.5 months and 12.0 months in the Revtorpyk-containing arms; it was not estimable in the fulvestrant arm. At the time of the PFS analysis, overall survival data were not yet mature, with 25% of deaths having occurred in the overall study population.

Place in Therapy

Breast cancer treatment is guided by factors such as HR status, HER2 expression, disease stage, comorbidities, and patient characteristics, with multiple therapeutic options available across treatment classes. Revtorpyk is the first PI3K/mTOR pathway inhibitor approved for patients with PIK3CA wild-type, HR positive, HER2 negative advanced breast cancer, providing a targeted treatment option for a population that previously lacked an approved PI3K-directed therapy. Its approval expands the range of available therapies and offers an additional option for patients whose disease has progressed on prior endocrine-based treatment.

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Lipfendra (enlicitide) tablets, for oral use

FDA-Approved Indication

As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Dosage & Administration

One 20 mg tablet taken orally once daily.

Dosage Forms & Strengths

Film-Coated Tablets: 20 mg enlicitide.

Contraindications

None.

Common Adverse Reactions

Diarrhea and dizziness.

Clinical Studies

The approval came from CORALreef Lipids and CORALreef HeFH, two randomized, double-blind, placebo-controlled studies in patients with hypercholesterolemia, including those with HeFH, who required additional LDL-C lowering despite stable lipid-lowering therapy. In CORALreef Lipids, Lipfendra reduced LDL-C by 57% from baseline compared with a 3% increase with placebo at Week 24 ($p < 0.001$). In CORALreef HeFH, Lipfendra reduced LDL-C by 58% from baseline compared with a 3% increase with placebo at Week 24 ($p < 0.001$).

Place in Therapy

Lipfendra is the first FDA-approved oral PCSK9 inhibitor for LDL-C reduction. As a macrocyclic peptide, it inhibits PCSK9 by preventing its interaction with LDL receptors, offering an oral alternative to injectable PCSK9-targeted therapies. Lipfendra joins the treatment landscape alongside established agents such as Repatha (evolocumab), Praluent (alirocumab), Leqvio (inclisiran), and Lerochol (lerodalcibep).

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Jideytro (zidesamtinib) tablets, for oral use

FDA-Approved Indication

For the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received a prior ROS1 kinase inhibitor.

Dosage & Administration

100 mg orally once daily.

Dosage Forms & Strengths

Tablets: 25 mg and 100 mg.

Contraindications

None.

Common Adverse Reactions

Edema, peripheral neuropathy, constipation, fatigue, and dyspnea.

Warnings & Precautions

- Central Nervous System (CNS) Adverse Reactions
- QTc Interval Prolongation
- Interstitial Lung Disease (ILD)/pneumonitis
- Skeletal Fractures
- Myalgia with Creatine Phosphokinase (CPK) Elevation
- Pancreatic Toxicity
- Embryo-Fetal Toxicity

Use in Specific Populations

- Lactation: Advise not to breastfeed.
- Infertility: May impair fertility.

Drug Interactions

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

Clinical Studies

The approval came from ARROS-1, a global Phase I/II, single-arm, open-label, multi-cohort study evaluating Jideytro in patients with advanced ROS1-positive malignancies. The efficacy analysis included 117 patients with previously treated, locally advanced or metastatic ROS1-positive NSCLC who had received at least one prior ROS1 tyrosine kinase inhibitor, with or without prior platinum-based chemotherapy or immunotherapy. The primary efficacy endpoints were confirmed overall response rate (ORR) and duration of response (DOR). Jideytro demonstrated an ORR of 44% (95% CI, 34%-53%), with responses lasting from 1.9 months to 28.5+ months.

Place in Therapy

The treatment landscape for NSCLC has evolved substantially with the development of biomarker-driven targeted therapies and immune checkpoint inhibitors. Jideytro is a next-generation, ROS1-selective tyrosine kinase inhibitor designed to address resistance mutations and improve CNS penetration while minimizing off-target TRK inhibition.

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Simtriyo (centanafadine) extended-release capsules, for oral use

FDA-Approved Indication

For the treatment of ADHD in adults and pediatric patients 6 years of age and older weighing at least 20 kg.

Dosage & Administration

In pediatric patients, the recommended dosage of Simtriyo varies by age and body weight. In adults, the recommended dosage is 210 mg orally once daily, which may be increased to 280 mg once daily based on clinical response and tolerability.

Dosage Forms & Strengths

Extended-release capsules: 140 mg, 210 mg, and 280 mg of centanafadine.

Contraindications

- Known hypersensitivity to centanafadine or any of the excipients of Simtriyo
- Taking or within 14 days of stopping a monoamine oxidase inhibitor
- Patients with pheochromocytoma or a history of pheochromocytoma

Common Adverse Reactions

Decreased appetite, nausea, rash, headache, and abdominal pain.

Use in Specific Populations

- Hepatic Impairment: Not recommended for use in patients with severe hepatic impairment

Drug Interactions

- Alcohol
- CYP1A2 Substrates
- CNS Stimulants

Warnings & Precautions

- **BBW**: Suicidal Ideation and Behaviors in Pediatric Patients Aged 6 Years and Older; And Abuse, Misuse and Addiction
- Risks to Patients with Serious Cardiac Disease
- Increased Blood Pressure and Heart Rate
- Psychiatric Adverse Reactions
- Long-Term Suppression of Growth in Pediatric Patients
- Hypersensitivity Reactions
- Peripheral Vasculopathy Including Raynaud's Phenomenon
- Serotonin Syndrome
- Motor and Verbal Tics and Worsening of Tourette's Syndrome

Clinical Studies

The approval came from two randomized, placebo-controlled studies in pediatric patients with ADHD and two short-term, randomized, double-blind, placebo-controlled studies of another centanafadine formulation in adults with ADHD. In pediatric patients aged 6 to 12 years and 13 to 17 years, Simtriyo demonstrated greater improvements in ADHD-RS-5 total scores at Week 6 compared with placebo, with treatment differences of -5.6 points and -4.4 points, respectively. Efficacy in adults was supported by two studies involving 859 patients, in which low- and high-dose centanafadine showed greater reductions in AISRS total scores versus placebo at Day 42.

Place in Therapy

Simtriyo is the first and only approved norepinephrine, dopamine, and serotonin reuptake inhibitor (NDSRI) for the treatment of ADHD, offering a novel mechanism of action. Its approval expands the available treatment options, although its role relative to established stimulant and non-stimulant therapies remains to be determined.

New FDA-Approved Drug Products

Specialty

New Formulations, Combinations, and Line Extensions

Lytenava (bevacizumab-vikg) injection, for intravitreal use

FDA-Approved Indication

For the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD).

Dosage & Administration

1.25 mg administered by intravitreal injection once monthly (approximately 28 days).

Dosage Forms & Strengths

Injection: 1.25 mg (0.05 mL of 25 mg/mL) in a single-dose glass vial.

Contraindications

- Ocular or periocular infections
- Active intraocular infections
- Hypersensitivity

Common Adverse Reactions

Conjunctival hemorrhage.

Warnings & Precautions

- Endophthalmitis and Retinal Detachments
- Increases in Intraocular Pressure
- Potential Risk of Arterial Thromboembolic Events

Clinical Studies

The approval came from NORSE TWO, a randomized, masked, active-controlled study that enrolled 228 patients with nAMD and compared Lytenava with ranibizumab. The primary endpoint was the proportion of patients achieving a gain of ≥15 Best Corrected Visual Acuity (BCVA) letters from baseline to Month 11, which was achieved by 41.7% of patients treated with Lytenava compared with 23.1% of patients receiving ranibizumab. Additional evidence was provided by NORSE EIGHT, a randomized, masked, controlled study in 400 adults with nAMD, which evaluated change in BCVA at Week 8. Although Lytenava demonstrated improvements in BCVA, it did not meet the prespecified non-inferiority margin versus ranibizumab for the primary endpoint in NORSE EIGHT.

Place in Therapy

Lytenava is the first FDA-approved ophthalmic bevacizumab product. Although bevacizumab has long been used off-label for the treatment of nAMD, Lytenava provides an FDA-approved formulation specifically for ophthalmic use. VEGF inhibitors remain a cornerstone of nAMD treatment, and Lytenava joins the treatment landscape alongside other anti-VEGF agents, including Eylea (aflibercept), Vabysmo (faricimab-svoa), Lucentis (ranibizumab), Susvimo (ranibizumab injection), and Beovu (brolucizumab-dbll).

New FDA-Approved Drug Products

New Biosimilar Product

Drug Name	Reference Product	Additional Information
Garzulys (insulin aspart-fsan)	NovoLog	Garzulys is the third FDA-approved biosimilar to Novolog.

Other Notable New Approvals

Sarclisa Escena (isatuximab-irfc) injection, for subcutaneous use

- Sarclisa Escena is a subcutaneous (SC) formulation of isatuximab-irfc that expands the administration options available for Sarclisa, which was previously available only as an intravenous infusion. Approved across all existing indications of IV Sarclisa in combination with standard-of-care regimens for multiple myeloma, Sarclisa Escena is the first oncology therapy to offer both on-body injector and manual SC administration, providing an alternative delivery option that may improve treatment convenience

Gwyn LO (norelgestromin and ethinyl estradiol transdermal system)

- Gwyn Lo is a new combined hormonal contraceptive patch that delivers norelgestromin 220 mcg/day and ethinyl estradiol 20 mcg/day. As a low-dose estrogen contraceptive patch, it provides an additional transdermal birth control option for individuals seeking a non-daily hormonal contraceptive method.

Qlonilik (clonidine hydrochloride) oral solution

- A central alpha-2 adrenergic agonist indicated for the treatment of hypertension, to lower blood pressure in adults.

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*
Iloprost Inhalation Solution 10 mcg/mL and 20mcg/mL	Beloteca, Inc.	Ventavis	Pulmonary Arterial Hypertension	2026 (Q3-Q4)
Afatinib Dimaleate Tablets 20mg (base), 30 mg (base) and 40 mg (base)	Apotex Inc.; Hetero Labs Limited	Gilotrif	Non-small cell lung cancer	2027-2028
Pitolisant Hydrochloride Tablets 4.45mg (base) and 17.8mg (base)	Novitium Pharma LLC	Wakix	Narcolepsy	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
Rezzayo (rezafungin acetate) From: Mundipharma	In patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis	In adults and pediatric patients 12 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis
Pluvicto (lutetium lu-177 vipivotide tetraxetan) From: Novartis	For the treatment of adult patients with prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor pathway inhibitor therapy, and are considered appropriate to delay taxane-based chemotherapy, or have received prior taxane-based chemotherapy	In combination with androgen receptor pathway inhibitor therapy for adults with prostate-specific membrane antigen-positive metastatic androgen pathway modulation-naïve or-sensitive prostate cancer (previously referred to as metastatic hormone-sensitive prostate cancer)
Skyrizi(risankizumab-rzaa) From: Abbvie	[1] Moderate-to-severe plaque psoriasis; [2] Psoriatic arthritis in adults; [3] Crohn's disease; [4] Ulcerative colitis	Active psoriatic arthritis in adults and pediatric patients 6 years of age and older
Keytruda (pembrolizumab) From: Merck	Several including head and neck squamous cell cancer, triple-negative breast cancer, cutaneous squamous cell carcinoma, among others	In combination with enfortumab vedotin-ejfv as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, for the treatment of adult patients with muscle invasive bladder cancer
Ryaltris (mometasone furoate; olopatadine hydrochloride) From: Glenmark	For the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older	For the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 6 years of age and older

Pipeline

PDUFA Date: Possibly 2028

Frexalimab

Overview

Frexalimab is an investigational anti-CD40 ligand (CD40L) monoclonal antibody being developed for the treatment of relapsing multiple sclerosis (RMS) and non-relapsing secondary progressive multiple sclerosis (nrSPMS). By blocking the CD40/CD40L pathway, frexalimab modulates both adaptive and innate immune responses, reducing activation of immune cells and limiting the production of disease-driving autoantibodies without broadly depleting B- or T-cell populations. This represents a novel immunomodulatory approach compared with currently available MS therapies and may offer a differentiated treatment option as a potential first therapy specifically developed for patients with nrSPMS. Frexalimab is being investigated as a chronic maintenance therapy administered as an intravenous infusion every 4 weeks, with a subcutaneous formulation dosed every 2 weeks also in development.

Clinical Studies

The clinical development program for frexalimab includes Phase 2 and ongoing Phase 3 studies in patients with relapsing multiple sclerosis and non-relapsing secondary progressive multiple sclerosis. The study met its primary endpoint, demonstrating significant reductions in new gadolinium-enhancing T1-weighted lesions at Week 12. The adjusted mean number of new lesions was 0.2 with IV frexalimab and 0.3 with SC frexalimab, compared with 1.4 in the placebo group, corresponding to rate ratios of 0.11 and 0.21, respectively, versus placebo. Secondary MRI outcomes, including new or enlarging T2 lesions, were generally consistent with the primary findings and supported a marked reduction in inflammatory disease activity. Longer-term follow-up demonstrated sustained efficacy, with 96% of patients receiving high-dose frexalimab remaining free of new gadolinium-enhancing T1 lesions at Week 24 and an annualized relapse rate as low as 0.04 at Week 48. The safety profile was generally manageable, with the most commonly reported adverse events including COVID-19 infection (9.8%) and headache (up to 5.8%).

Place in Therapy

Frexalimab is a potential high-efficacy disease-modifying therapy that would primarily compete with established anti-CD20 agents, such as Ocrevus, Kesimpta, and Briumvi, in the treatment of RMS. While its novel anti-CD40L mechanism offers a differentiated approach, its every-4-week IV administration may be less convenient than competing therapies with less frequent dosing schedules or self-administered formulations. However, frexalimab may have a more favorable opportunity in nrSPMS, where treatment options are limited and it could potentially become the first therapy specifically indicated for this patient population if ongoing Phase 3 studies confirm its efficacy and safety.