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PharmNotes

Monthly Communications

March 2026

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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 Warning about Vitamin B6 Deficiency and Associated Seizures for Drug Products	3/20/2026	The U.S. Food and Drug Administration has notified application holders for all drug products containing carbidopa/levodopa that the Agency is requiring the addition of a warning, and corresponding revisions, to the prescribing information to state that these medications, approved to treat symptoms of Parkinson's disease, can cause vitamin B6 deficiency and vitamin B6 deficiency-associated seizures. The warning directs health care professionals to evaluate baseline vitamin B6 levels prior to starting patients on treatment with carbidopa/levodopa therapies and periodically while on treatment and to supplement with vitamin B6 as necessary.
FDA Identifies Cases of Serious Liver Injury in Patients Taking Tavneos (avacopan) for Severe Active Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated Vasculitis	3/31/2026	The U.S. Food and Drug Administration is alerting patients and health care professionals about serious postmarketing cases, including fatal cases, of drug-induced liver injury (DILI) associated with Tavneos (avacopan). Some cases involved vanishing bile duct syndrome (VBDS), which is characterized by progressive destruction and disappearance of the bile ducts in the liver. This condition can slow or stop the flow of bile and may lead to permanent liver damage. VBDS is often accompanied by the yellowing of skin or eyes (jaundice), itchiness, and tiredness.

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Icotyde (icotrokinra) tablets, for oral use

FDA-Approved Indication

For the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.

Dosage & Administration

200 mg orally once daily.

Dosage Forms & Strengths

Tablets: 200 mg.

Contraindications

- None

Common Adverse Reactions

Headache, nausea, cough, fungal infection, and fatigue.

Warnings & Precautions

- Infections
- Tuberculosis
- Avoid Live Vaccines

Use in Specific Populations

- Renal Impairment: Monitor for potential adverse reactions in patients with eGFR <60 mL/min.

Clinical Studies

The approval came from multiple Phase 3 trials (ICONIC program) evaluating Icotyde in patients with moderate-to-severe plaque psoriasis, which consistently met the primary efficacy endpoints and demonstrated a favorable safety profile. Across studies, significantly higher proportions of patients achieved clear or almost clear skin (Investigator's Global Assessment [IGA] 0/1) compared with placebo (e.g., ~57–65% vs ~6–8% at Week 16), with improvements maintained through longer-term follow-up. Additionally, robust responses were seen across difficult-to-treat areas (e.g., scalp and genital psoriasis).

Place in Therapy

Icotyde is an oral IL-23 receptor inhibitor for moderate-to-severe plaque psoriasis, offering a non-injectable alternative to biologics. It joins a highly competitive space with established biologics, including IL-23 inhibitors (e.g., guselkumab, risankizumab), IL-17 inhibitors (e.g., secukinumab, ixekizumab), and oral TYK2 inhibitor deucravacitinib.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Lynavoy (linerixibat) tablets, for oral use

FDA-Approved Indication

For the treatment of cholestatic pruritus associated with primary biliary cholangitis in adult patients.

Dosage & Administration

40 mg taken orally twice daily.

Dosage Forms & Strengths

Tablets: 40 mg.

Contraindications

- None

Common Adverse Reactions

Diarrhea, abdominal pain, nausea, increased ALT, hemorrhage, increased AST, headache, dyspepsia, gastroesophageal reflux disease, abdominal distension, dizziness, and arthralgia.

Warnings & Precautions

- Liver Test Elevations
- Fat-Soluble Vitamin (FSV) Deficiency
- Diarrhea

Drug Interactions

- Bile Acid Binding Resins

Clinical Studies

The approval came from the Phase 3 GLISTEN trial in patients with cholestatic pruritus due to primary biliary cholangitis, where Lynavoy demonstrated a statistically significant reduction in itch severity compared with placebo. Patients treated with Lynavoy achieved a mean reduction in Worst Itch Numeric Rating Scale (WI-NRS) score of approximately −3.2 points versus −1.7 points with placebo at Week 24, with a ≥4-point improvement (clinically meaningful response) observed in ~56% of patients compared to ~28% with placebo. Improvements were seen as early as Week 2 and sustained throughout the study.

Place in Therapy

Lynavoy joins the treatment landscape alongside therapeutic alternatives for pruritus include bile acid sequestrants (e.g., cholestyramine), antibiotics such as rifampin, opioid antagonists (e.g., naltrexone), and SSRIs (e.g., sertraline). Additionally, another IBAT inhibitor, odevixibat, is approved in other cholestatic conditions and represents mechanistic competition.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Avlayah (tividenofusp alfa-eknm) for injection, for intravenous use

FDA-Approved Indication

For the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment.

Dosage & Administration

Recommended maintenance dosage is 15 mg/kg administered once weekly as an intravenous infusion over approximately 4 hours.

Dosage Forms & Strengths

For injection: 150 mg of tividenofusp alfa-eknm as a lyophilized powder in a single-dose vial for reconstitution and further dilution.

Contraindications

- None

Common Adverse Reactions

IAR, upper respiratory tract infection, ear infection, pyrexia, anemia, cough, vomiting, diarrhea, rash, COVID-19, rhinorrhea, nasal congestion, fall, headache, skin abrasion, and urticaria.

Warnings & Precautions

- ***BBW***: *Hypersensitivity Reactions Including Anaphylaxis*
- Membranous Nephropathy
- Anemia
- Infusion-Associated Reactions

Clinical Studies

The approval came from a Phase 1/2 open-label study in patients with Hunter syndrome (MPS II), where treatment resulted in substantial reductions in cerebrospinal fluid (CSF) heparan sulfate levels, with mean decreases of approximately 60–70% from baseline over 24–52 weeks. Plasma heparan sulfate levels were also markedly reduced. Although clinical endpoints were exploratory, some patients demonstrated stabilization or modest improvements in neurodevelopmental measures.

Place in Therapy

Avlayah is a CNS-penetrant enzyme replacement therapy for Hunter syndrome (MPS II), addressing neurologic manifestations not impacted by existing therapies. Current standard treatment includes intravenous enzyme replacement therapies such as idursulfase, which improves somatic symptoms but does not cross the blood–brain barrier. Hematopoietic stem cell transplantation may be considered in select cases but has variable neurologic benefits.

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Lifyorli (relacorilant) capsules, for oral use

FDA-Approved Indication

In combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab.

Dosage & Administration

150 mg orally once on the day before, the day of, and the day after each nab-paclitaxel infusion.

Dosage Forms & Strengths

Capsules: 25 mg, 100 mg.

Contraindications

- Concurrent systemic glucocorticoid therapy for a lifesaving indication.

Common Adverse Reactions

Decreased hemoglobin, decreased neutrophils, fatigue, nausea, diarrhea, decreased platelets, rash, and decreased appetite.

Warnings & Precautions

- Neutropenia and Severe Infections
- Adrenal insufficiency
- Exacerbation of Conditions Treated with Glucocorticoids
- Embryo-Fetal Toxicity

Drug Interactions

- Strong CYP3A Inducers
- CYP2C8 Inducers and Moderate CYP3A Inducers
- CYP2C8 Inhibitors
- CYP3A Substrates
- Certain CYP2C8 Substrates

Use in Specific Populations

- Lactation: Advise not to breastfeed.
- Hepatic Impairment: Avoid use in patients with moderate or severe hepatic impairment.

Clinical Studies

The approval came from a Phase 3 randomized trial in patients with platinum-resistant ovarian cancer, where Lifyorli in combination with nab-paclitaxel significantly improved progression-free survival (PFS) compared to nab-paclitaxel alone. Median PFS was 6.5 months in the combination arm versus 5.5 months with chemotherapy alone (hazard ratio [HR] ~0.70). Overall survival showed a favorable trend, with median OS of approximately 15.5 months versus 12.5 months (HR ~0.75). Objective response rates were also higher with the combination (~29% vs ~18%).

Place in Therapy

Lyfiorli is indicated for platinum-resistant ovarian cancer and is best positioned as a later-line treatment option. It competes with multiple established regimens, including single-agent chemotherapies (e.g., pegylated liposomal doxorubicin, topotecan, paclitaxel), anti-angiogenic therapy (e.g., bevacizumab), and biomarker-driven options such as PARP inhibitors (e.g., olaparib) in select populations.

New FDA-Approved Drug Products

New Molecular Entity

Awiqli (insulin icodec-abae) injection, for subcutaneous use

FDA-Approved Indication

As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosage & Administration

Injected subcutaneously once weekly on any day of the week on the same day each week. Individualize and titrate the dose of Awiqli based on the patient's metabolic needs, blood glucose monitoring results, and glycemic control goal.

Dosage Forms & Strengths

700 units/mL (U-700) solution in 3 mL, 1.5 mL, and 1 mL single-patient-use FlexTouch prefilled pens.

Contraindications

- During episodes of hypoglycemia
- Hypersensitivity to insulin icodec-abae or any of the excipients in Awiqli

Common Adverse Reactions

Hypoglycemia, hypersensitivity reactions (e.g., urticaria, swelling face and lips), injection site reactions, lipodystrophy, pruritus, rash, edema, and weight gain.

Warnings & Precautions

- Hypoglycemia Due to Medication Errors and Accidental Overdose
- Hypoglycemia
- Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen
- Hypersensitivity Reactions
- Hypokalemia
- Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones

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 came from results of the ONWARDS clinical trial program, which included multiple large, active-controlled, treat-to-target studies evaluating once-weekly Awiqli in adults with type 2 diabetes. Across these trails, Awiqli demonstrated comparable or slightly greater reductions in HbA1c versus once-daily basal insulins, with reductions ranging from -1.16% to -1.68% in both insulin-naïve patients and those on combination regimens. In some studies, Awiqli showed modest superiority, while in others it achieved noninferiority.

Place in Therapy

Up until the approval of Awiqli, the basal insulin landscape was composed of once-daily options such as insulin glargine and insulin degludec. Awiqli is the first once-weekly long-acting basal insulin, offering an improvement in patient adherence and a reduction in treatment burden.

New FDA-Approved Drug Products

New Biosimilar Product

Drug Name	Reference Product	Designations	Additional Information
Ponlimsi (denosumab-adet)	Prolia	Biosimilar	Ponlimsi is the tenth FDA-approved biosimilar to Prolia.

Other Notable New Approvals

Atoncy (atomoxetine) oral solution

- A selective norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of ADHD in adults and pediatric patients 6 years of age and older.

Wegovy HD (semaglutide)

- A new 7.2-milligram strength of semaglutide indicated to reduce excess body weight and maintain weight reduction long-term in adults with obesity, or overweight with at least one weight-related condition. The approval of a new higher dose will provide adult patients with an additional therapeutic option offering the potential for greater weight loss.

Kresladi (marnetegragene autotemcel) suspension for intravenous infusion Gene/Cell Therapy

- An autologous hematopoietic stem cell-based gene therapy indicated for the treatment of pediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in ITGB2 without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant.

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*
Rifaximin Tablets 550 mg	Actavis Laboratories, Inc.	Xifaxan	Travelers' Diarrhea; Hepatic Encephalopathy; IBS-D	1/1/2028
Ferric Citrate Tablets 210 mg (ferric iron)	Teva Pharmaceuticals USA, Inc.	Auryxia	Hyperphosphatemia of Renal Failure; Iron Deficiency Anemia	3/11/2026
Fluticasone Propionate Metered Inhalation Aerosol 0.044 mg/inh	Glenmark Specialty S.A	Flovent HFA	Asthma	Mid-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
Tecvayli (teclistamab-cqyv) From: Janssen Biotech, Inc.	For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody	Plus Darzalex Faspro (daratumumab and hyaluronidase-fihj) for the treatment of adults with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent
Sotyktu (deucravacitinib) From: Bristol Myers Squibb	The treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	The treatment of active psoriatic arthritis in adults
Cosentyx (secukinumab) From: Novartis	Adults with moderate to severe hidradenitis suppurativa	Patients 12 years and older with moderate to severe hidradenitis suppurativa
Arexvy (respiratory syncytial virus vaccine, adjuvanted) From: GSK	For active immunization for the prevention of lower respiratory tract disease caused by respiratory syncytial virus in individuals 60 years of age and older; individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV	Adults aged 18 to 49 years at increased risk for lower respiratory tract disease caused by RSV
Wellcovorin (leucovorin) From: GSK	To reduce the toxicity of: methotrexate in adult patients with impaired methotrexate elimination, and; folic acid antagonists or dihydrofolate reductase inhibitors following an overdose in adult patients	For the treatment of cerebral folate transport deficiency in adult and pediatric patients who have a confirmed variant in the folate receptor 1 gene
Imcivree (setmelanotide acetate) From: Rythm	To reduce excess body weight and maintain weight reduction long term in adults and pediatric patients 2 years of age and older with syndromic or monogenic obesity due to [1] Bardet-Biedl syndrome ; [2] Pro-opiomelanocortin, proprotein convertase subtilisin/kexin type 1, or leptin receptor deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance	4 years and older with acquired hypothalamic obesity

Opdivo (nivolumab) From: Bristol Myers Squibb	Several including melanoma, non-small cell lung cancer, esophageal cancer, and hepatocellular carcinoma	Adult and pediatric (12 years and older) patients with previously untreated, stage III or IV classical Hodgkin lymphoma in combination with doxorubicin, vinblastine, and dacarbazine

Pipeline

PDUFA Date: December 2026

Lorundrostat

Overview

Lorundrostat is an investigational, oral aldosterone synthase inhibitor being developed for the treatment of uncontrolled or resistant hypertension. By selectively inhibiting aldosterone production, it targets a key hormonal driver of persistent hypertension, particularly in patients already receiving multiple antihypertensive therapies. This represents a novel upstream approach compared to currently available mineralocorticoid receptor antagonists (MRAs).

Clinical Studies

The clinical development program for lorundrostat includes Phase 2 and Phase 3 studies in patients with uncontrolled or resistant hypertension. In the pivotal Phase 3 Launch-HTN trial (n=1,083), lorundrostat demonstrated a statistically significant reduction in systolic blood pressure, with a least-squares mean change of −16.9 mmHg vs −7.9 mmHg with placebo at Week 6 (difference: −9.1 mmHg). Earlier Phase 2 data (e.g., Target-HTN) demonstrated consistent and dose-dependent reductions in blood pressure, with ~−13 to −14 mmHg reductions from baseline and placebo-adjusted differences of approximately −7.8 to −9.6 mmHg, supporting robust antihypertensive activity across studies. Additionally, the Phase 2 EXPLORE-OSA trial evaluated lorundrostat in patients with obstructive sleep apnea (OSA) and hypertension. While the study did not meet its primary endpoint (no significant reduction in apnea-hypopnea index), it demonstrated clinically meaningful reductions in blood pressure, including approximately −11.1 mmHg vs −1.0 mmHg with placebo over 4 weeks. Across the clinical program, placebo-adjusted reductions in systolic blood pressure were generally in the range of ~7–10 mmHg, consistent with effects observed with fourth-line antihypertensive agents. The safety profile was generally manageable, with hyperkalemia, hyponatremia, and renal function changes observed more frequently than placebo, though most events were mild to moderate.

Place in Therapy

Lorundrostat is expected to be positioned as an add-on therapy for patients with uncontrolled or resistant hypertension, particularly those receiving ≥2–3 antihypertensive agents. Current standard of care includes ACE inhibitors/ARBs, calcium channel blockers, thiazide-like diuretics, and mineralocorticoid receptor antagonists (MRAs) such as spironolactone and eplerenone, which are recommended as preferred fourth-line agents. Lorundrostat offers a novel mechanism (aldosterone synthase inhibition) compared to MRAs (receptor blockade), which may provide benefit in patients with persistent aldosterone-driven hypertension or intolerance to MRAs. However, given similar safety considerations (e.g., hyperkalemia), lack of head-to-head comparisons with MRAs, and absence of long-term cardiovascular outcomes data, it will likely be positioned as a later-line or alternative to MRAs rather than a replacement. While exploratory data suggests potential utility in patients with comorbid conditions such as OSA, its role remains limited to blood pressure reduction, as no benefit was demonstrated on OSA disease parameters.

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
Sitagliptin Phosphate	Januvia	Merck
Metformin Hydrochloride; Sitagliptin Phosphate	Janumet	Merck