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PharmNotes

Monthly Communications

February 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 February.

New FDA-Approved Drug Products

New Molecular Entity

Adquey (difamilast) ointment, for topical use

FDA-Approved Indication

For the topical treatment of adults and pediatric patients 2 years of age and older with mild to moderate atopic dermatitis (AD).

Dosage & Administration

Apply a thin layer twice daily to affected areas and rub in completely.

Dosage Forms & Strengths

Ointment: 1%.

Contraindications

- None

Common Adverse Reactions

Nasopharyngitis

Clinical Studies

The approval came from three randomized, double-blind, vehicle-controlled trials in a total of 612 patients with mild to moderate atopic dermatitis. The primary endpoint was the proportion of patients who achieved an Investigator's Global Assessment (IGA) success, defined as an IGA grade of clear (0) or almost clear (1) and with a 2-grade or greater improvement from baseline, at week 4. In all three trials, Adquey demonstrated a significantly higher proportion of patients achieved IGA success at Week 4 versus vehicle.

Place in Therapy

Mild to moderate AD is generally treated with topical corticosteroids and topical calcineurin inhibitors. Topical products such as Eucrisa (crisaborole) Zoryve (roflumilast), Opzelura (ruxolitinib), and now Adquey tend to be reserved for patients that fail the first-line therapies.

New FDA-Approved Drug Products

New Molecular Entity

Bysanti (milsaperidone) tablets for oral use

FDA-Approved Indication

[1] Treatment of schizophrenia in adults; [2] Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

Dosage & Administration

Taken orally twice daily with or without food. Following a titration schedule, the recommended maintenance dosage for schizophrenia is 6 to 12 mg twice daily, and for bipolar mania is 12 mg twice daily.

Dosage Forms & Strengths

Tablets: 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg.

Contraindications

- Known hypersensitivity to milsaperidone or the inactive ingredients in Bysanti.

Common Adverse Reactions

Dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, weight increased, and hepatic enzymes increased.

Drug Interactions

- Strong CYP2D6 Inhibitors
- Strong CYP3A4 Inhibitors
- Strong CYP2D6 and Strong CYP3A4 Inhibitors
- Drugs that Lower Blood Pressure

Use in Specific Populations

- Pregnancy: Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk of extrapyramidal and/or withdrawal symptoms following delivery.
- Lactation: Advise not to breastfeed during treatment and for 6 days after the last dose in CYP2D6 normal metabolizers and 8 days after the last dose in CYP2D6 poor metabolizers.
- Hepatic Impairment: Not recommended for patients with severe hepatic impairment.

Warnings & Precautions

- ***BBW***: *Increased Mortality in Elderly Patients with Dementia-Related Psychosis*
- QTc Interval Prolongation
- Neuroleptic Malignant Syndrome (NMS)
- Tardive Dyskinesia
- Metabolic Changes
- Orthostatic hypotension and Syncope
- Seizures
- Leukopenia, Neutropenia, and Agranulocytosis
- Priapism
- Potential for Cognitive and Motor Impairment
- Intraoperative Floppy Iris Syndrome (IFIS)

Clinical Studies

The approval came adequate and well-controlled studies of iloperidone tablets.

Place in Therapy

Bysanti, an atypical antipsychotic that converts to iloperidone in vivo, joins the treatment landscape alongside other oral antipsychotics such as aripiprazole, quetiapine, lurasidone, among many others.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Loargys (pegzilarginase-nbln) injection for intravenous or subcutaneous use

FDA-Approved Indication

For the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction.

Dosage & Administration

The recommended starting dosage is 0.1 mg/kg administered via intravenous infusion once weekly. Dose adjustments should be aimed at achieving a pre-dose level of plasma arginine near the upper limit of normal.

Dosage Forms & Strengths

Injection: 2 mg/0.4 mL and 5 mg/mL in a single-dose vial.

Contraindications

- None

Common Adverse Reactions

Vomiting, pyrexia, infusion associated reactions and constipation.

Warnings & Precautions

- ***BBW***: *Hypersensitivity Reactions Including Anaphylaxis*

Clinical Studies

The approval came from the PEACE trial, a randomized, double-blind, placebo-controlled phase 3 study in 32 patients. The change from baseline in plasma arginine concentration at week 24, which was the primary endpoint, was significantly lower in the Loargys-treated group compared with placebo group. The mean percent change treatment difference was -72%. Moreover, 90% of the Loargys-treated patients achieved target plasma arginine levels and normalized levels whereas 0% of patients in the placebo arm achieved this.

Place in Therapy

ARG1-D is a rare genetic disorder of the urea cycle characterized by complete or partial lack of the enzyme arginase. Because of this, hyperargininemia occurs and can lead to hyperammonemia. Children most often experience spasticity, but they can also experience seizures, short stature, and intellectual disability.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Yuviwel (navepegritide) for injection, for subcutaneous use

FDA-Approved Indication

To increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses.

Dosage & Administration

Administered once weekly by subcutaneous injection. Dosage is based on body weight.

Dosage Forms & Strengths

For injection: 1.3 mg, 2.8 mg, and 5.5 mg as a lyophilized powder in single-dose vial for reconstitution.

Contraindications

- None

Common Adverse Reactions

Vomiting, injection-site reaction, pain in extremity, and nausea.

Warnings & Precautions

- Risk of Low Blood Pressure

Use in Specific Populations

- Renal Impairment: Not recommended for patients with moderate or severe renal impairment.

Clinical Studies

The approval came from three randomized, double-blind, placebo-controlled clinical trials and up to three years of open-label extension data. 84 patients were randomized 2:1 to receive either Yuviwel or placebo for 52 weeks. Patients that received Yuviwel had a mean annualized growth velocity of 5.89 cm per year compared with an annualized growth velocity of 4.41 cm per year with placebo.

Place in Therapy

Achondroplasia is a rare genetic condition that primarily affects bone growth. Yuviwel joins the treatment landscape alongside Voxzogo, which was the first FDA-approved treatment for children with achondroplasia.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Desmoda (desmopressin acetate) oral solution

FDA-Approved Indication

For the management of central diabetes insipidus as antidiuretic replacement therapy for adults and pediatric patients.

Dosage & Administration

The recommended starting dosage is 0.05 mg twice daily. The daily dosage should be titrated as needed to obtain an adequate antidiuretic response.

Dosage Forms & Strengths

Oral solution: 0.05 mg desmopressin acetate in 1 mL (0.05 mg/mL).

Contraindications

- Hypersensitivity to desmopressin acetate or any of the inactive ingredients of Desmoda.
- Patients with moderate to severe renal impairment defined as creatinine clearance below 50 mL/min.
- Patients with hyponatremia or a history of hyponatremia.

Common Adverse Reactions

Headache, dizziness, nausea, abdominal pain, hypertension, and diarrhea.

Warnings & Precautions

- Hyponatremia
- Fluid Retention
- Hypersensitivity

Drug Interactions

- Drugs that may Increase Risk of Hyponatremia
- Other Vasoconstrictors

Use in Specific Populations

- Pediatric Use: Use requires careful fluid restriction to prevent hyponatremia with water intoxication.
- Geriatric Use: Carefully select dose and monitor renal function.
- Renal Impairment: The risk of adverse reactions may be greater in patients with renal impairment.

Clinical Studies

The approval came from dose response studies of desmopressin acetate tablets in patients with diabetes insipidus.

Place in Therapy

Desmoda provides an alternative formulation of desmopressin for patients that may have trouble swallowing the solid formulation.

Other Notable New Approvals

Avopef (etoposide) injection for intravenous use

- A topoisomerase inhibitor indicated, in combination with other chemotherapy and/or immunotherapy, for the treatment of adult patients with: [1] Refractory testicular cancer; [2] Small cell lung cancer.

Favlyxa (fluorouracil) injection for intravenous use

- A nucleoside metabolic inhibitor indicated for the treatment of patients with [1] Adenocarcinoma of the Colon and Rectum; [2] Adenocarcinoma of the Breast; [3] Gastric Adenocarcinoma; [4] Pancreatic Adenocarcinoma.

Ozempic (semaglutide) tablets

- Oral semaglutide will be renamed from the brand name Rybelsus, to now Ozempic.

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.

No notable first-time generics were approved during the month of February.

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
Hernexeos (zongertinib) From: Boehringer Ingelheim Pharmaceuticals, Inc.	For the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy	For the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations, as detected by an FDA-approved test
Dupixent (dupilumab) From: Sanofi-Aventis	[1] For the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable; [2] As an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma; [3] As an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps; [4] For the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis; [5] For the treatment of adult patients with prurigo nodularis; [6] As an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype; [7] For the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment; [8] For the treatment of adult patients with bullous pemphigoid	For the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis who have a history of sino-nasal surgery

Darzalex Faspro (daratumumab and hyaluronidase-fihj) From: Janssen Biotech, Inc.	For the treatment of [1] Multiple myeloma; [2] Light chain amyloidosis; [3] Adult patients with high risk smoldering multiple myeloma	Multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant
Leqvio (inclisiran) From: Novartis Pharmaceuticals Corporation	As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia	As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol in: [1] adults with hypercholesterolemia; [2] adults and pediatric patients aged 12 years and older with heterozygous familial hypercholesterolemia; [3] pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia
Calquence (acalabrutinib) From: AstraZeneca Pharmaceuticals LP	[1] In combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma who are ineligible for autologous hematopoietic stem cell transplantation; [2] For the treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy; [3] For the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma	In combination with venetoclax for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma
Wakix (pitolisant) From: Harmony Biosciences, LLC	[1] Treatment of excessive daytime sleepiness or cataplexy in adult patients with narcolepsy; [2] Treatment of excessive daytime sleepiness in pediatric patients 6 years of age and older with narcolepsy	For the treatment of excessive daytime sleepiness or cataplexy in patients 6 years of age and older with narcolepsy
Keytruda (pembrolizumab) From: Merck Sharp Dohme	Several including head and neck squamous cell cancer, triple-negative breast cancer, cutaneous squamous cell carcinoma, among others	In combination with paclitaxel, with or without bevacizumab, for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens

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
Adrabetadex From: Beren Therapeutics P.B.C.	Niemann-Pick disease type C	NDA accepted	High
Garetosmab From: Regeneron Pharmaceuticals, Inc.	Fibrodysplasia ossificans progressiva	BLA accepted	High
Giredestrant From: Genentech	Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated locally advanced or metastatic breast cancer	NDA accepted	Moderate
Iberdomide From: Bristol-Myers Squibb	Relapsed or refractory multiple myeloma	NDA accepted	Moderate
Tirabrutinib From: Deciphera Pharmaceuticals Inc.	Relapsed or refractory primary central nervous system lymphoma	NDA accepted	Moderate
Oveporexton From: Takeda	Narcolepsy type 1	NDA accepted	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
Milnacipran Hydrochloride	Savella	Allergan
Pomalidomide	Pomalyst	Celgene
Nintedanib Esylate	Ofev	Boehringer Ingelheim
Dapagliflozin Propanediol; Saxagliptin Hydrochloride	Qtern	AstraZeneca