PharmNotes

Monthly Communications

November 2024

ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2025

Table of Contents

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 November.

New FDA-Approved Drug Products

New Molecular Entity

Revuforj™ (revumenib) tablets, for oral use

Specialty | Orphan Drug

FDA-Approved Indication

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.

Dosage & Administration

The recommended dosage is based on patient body weight and concomitant CYP3A4 inhibitors. Please refer to package insert for further information.

Dosage Forms & Strengths

Tablets: 25 mg, 110 mg, 160 mg

Contraindications

None

Common Adverse Reactions

Hemorrhage, nausea, phosphate increased, musculoskeletal pain, infection, aspartate aminotransferase increased, febrile neutropenia, alanine aminotransferase increased, parathyroid hormone intact increased, bacterial infection, diarrhea, differentiation syndrome, electrocardiogram QT prolonged, phosphate decreased, triglycerides increased, potassium decreased, decreased appetite, constipation, edema, viral infection, fatigue, and alkaline phosphatase increased.

Warnings & Precautions

- ***BBW:*** Differentiation Syndrome
- QTc Interval Prolongation
- Embryo-Fetal Toxicity

Use in Specific Populations

Lactation: Advise not to breastfeed.

Drug interactions

- Strong CYP3A4 Inhibitors
- Strong or moderate CYP3A4 Inducers
- QTc Prolonging Drugs

Clinical Studies

The effectiveness of Revumenib was assessed in a single-arm group within an open-label, multicenter study (SNDX-5613-0700, NCT04065399; AUGMENT-101) involving 104 patients, including both adults and children diagnosed with relapsed or refractory (R/R) acute leukemia with a KMT2A translocation. The primary efficacy endpoints included the rate of complete remission (CR) plus complete remission with partial hematologic recovery (CRh), the duration of CR+CRh, and the transition from transfusion dependence to independence. The CR+CRh rate was 21.2% (95% CI: 13.8, 30.3), and the median duration of CR+CRh was 6.4 months (95% CI: 2.7, not estimable). Among the 22 patients who achieved CR or CRh, the median time to reach these outcomes was 1.9 months (range: 0.9, 5.6 months).

Place in Therapy

Before Revuforj was approved, treatment for relapsed or refractory (R/R) acute leukemias with KMT2A gene translocation typically involved conventional chemotherapy or regimens based on Venclexta (venetoclax), often followed by consolidative allogenic stem cell transplantation, as no targeted therapies were available. The approval of Revuforj now offers the first-ever targeted therapy option for this condition, specifically for R/R acute leukemias with KMT2A gene translocation.

New FDA-Approved Drug Products

New Molecular Entity

Kebilidi™ (elasocagene exuparvovec-tneq) suspension, for intraputaminal use

Specialty | Orphan Drug

FDA-Approved Indication

A one-time gene therapy administered into the putamen (a region in the brain) for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.

Dosage & Administration

A total dose of 1.8×10^{11} vector genomes (0.32 mL total volume) delivered as four 0.08 mL infusions (two sites per putamen-anterior and posterior) at a rate of 0.003 mL/minute for a total of 30 minutes per site, administered in a single stereotactic surgery using a cannula that is FDA-authorized for intraparenchymal infusion.

Dosage Forms & Strengths

Suspension for intraputaminal administration with a 35 nominal concentration of 5.6×10^{11} vg/mL. Supplied in a single-dose vial that contains 2.8×10^{11} vg of eladocagene exuparvovec-tneq in an extractable volume of 0.5 mL of suspension.

Contraindications

Patients who have not achieved skull maturity assessed by neuroimaging.

Common Adverse Reactions

Dyskinesia, pyrexia, hypotension, anemia, salivary hypersecretion, hypokalemia, hypophosphatemia, insomnia, hypomagnesemia, and procedural complications

Warnings & Precautions

- Procedural Complications
- Dyskinesia

Clinical Studies

The safety and effectiveness of Kebilidi were evaluated in an open-label, single-arm clinical trial involving 13 pediatric patients diagnosed with AADC deficiency. At the beginning of the study, all participants exhibited no gross motor function (the most severe form of AADC deficiency) and low AADC activity in their plasma. Patients who received Kebilidi treatment were compared to those who did not receive treatment (natural history group). Motor milestone assessments were performed on 12 out of the 13 patients at 48 weeks following treatment. The efficacy of Kebilidi was demonstrated by an improvement in gross motor function in 8 of the 12 treated patients, a result not observed in untreated patients with the severe form of AADC deficiency.

Place in Therapy

AADC deficiency is extremely rare; globally, 300 individuals have been identified by the company. There is no cure and no currently approved therapies in the U.S. Kebilidi is the first-ever gene therapy approved in the United States that is directly administered to the brain.

New FDA-Approved Drug Products

New Molecular Entity

Aucatzyl™ (obecabtagene autoleucel) cell suspension, for intravenous use

Specialty | Orphan Drug

FDA-Approved Indication

For the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia. Aucatzyl is a CD19-directed chimeric antigen receptor T-cell (CAR-T) therapy.

Dosage & Administration

The total recommended dose is 410 × 10^6 CD19 chimeric antigen receptor (CAR)- positive viable T cells. The treatment regimen consists of a split dose infusion to be administered on Day 1 and Day 10 (± 2 days).

Dosage Forms & Strengths

Cell suspension for infusion that contains a total recommended dose of 410 x 10^6 CD19 CAR-positive viable T cells supplied in 3 to 5 infusion bags.

Contraindications

None

Common Adverse Reactions

CRS, infections, musculoskeletal pain, viral infections, fever, nausea, bacterial infectious disorders, diarrhea, febrile neutropenia, ICANS, hypotension, pain, fatigue, headache, encephalopathy, and hemorrhage

Warnings & Precautions

- ***BBW:*** Cytokine Release Syndrome, Neurologic Toxicities, and Secondary Hematological Malignancies
- Prolonged Cytopenias
- Infections
- Hypogammaglobulinemia
- Hemophagocytic
- Hypersensitivity Reactions
- Hemophagocytic Lymphohistiocytosis/ Macrophage Activation Syndrome
- Secondary Malignancies
- Effects on Ability to Drive and Use Machines

Clinical Studies

The approval of Aucatzyl was based on results from the open-label, multicenter, single-arm Phase 3 FELIX trial (NCT04404660), which assessed Aucatzyl in adults with relapsed or refractory (R/R) B-cell acute lymphoblastic leukemia (ALL). Among the 65 patients evaluable for efficacy, 42% achieved the primary efficacy endpoint of complete remission (CR) within 3 months, with a median duration of CR of 14.1 months. The overall response rate (ORR), defined as the percentage of patients achieving CR or complete remission with incomplete hematologic recovery (CRi) at any point, was 63%.

Place in Therapy

Aucatzyl is the second treatment approved for acute lymphoblastic leukemia (ALL) after Tecartus (brexucabtagene autoleucel), with which it will directly compete. Aucatzyl was developed with a fast antigen off-rate CD19 binding domain, which may reduce excessive activation of the engineered T cells, potentially enhancing safety compared to Tecartus. Consistent with this design, Aucatzyl seems to be linked to lower incidences of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) compared to Tecartus.

New FDA-Approved Drug Products

New Molecular Entity

Ziihera™ (zanidatamab-hrii) lyophilized powder, for intravenous use

Specialty | Orphan Drug

FDA-Approved Indication

For the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer.

Dosage & Administration

The recommended dosage is 20 mg/kg given as an intravenous infusion once every 2 weeks. Patients have to be premedicated with acetaminophen, an antihistamine, and a corticosteroid.

Dosage Forms & Strengths

For injection: 300 mg lyophilized powder in a single-dose vial.

Contraindications

None.

Common Adverse Reactions

Diarrhea, infusion-related reaction, abdominal pain, and fatigue.

Warnings & Precautions

- ***BBW***: Embryo-Fetal Toxicity
- Left Ventricular Dysfunction
- Infusion-Related Reactions (IRRs)
- Diarrhea

Use in Specific Populations

Females and Males of Reproductive Potential: Verify the pregnancy status of females prior to initiation of Ziihera.

Clinical Studies

Efficacy was assessed in the HERIZON-BTC-01 trial (NCT04466891), an open-label, multicenter, single-arm study involving 62 patients with unresectable or metastatic HER2-positive (IHC3+) biliary tract cancer (BTC). Patients were required to have received at least one prior gemcitabine-based treatment regimen for advanced disease. The primary efficacy endpoints were the objective response rate (ORR) and the duration of response (DOR), as determined by an independent central review using RECIST v1.1 criteria. The ORR was 52% (95% CI: 39, 65), and the median DOR was 14.9 months (95% CI: 7.4, not estimable).

Place in Therapy

Ziihera is the first FDA-approved dual HER2-targeted therapy designed specifically for biliary tract cancer (BTC) and provides a chemotherapy-free treatment option for patients who have experienced progression after first-line therapies. NCCN Guidelines for BTC recommends the use of zanidatamab-hrii as subsequent treatment as a single agent for progression on or after systemic treatment for unresectable or resected gross residual (R2) disease or metastatic disease that is HER2-positive (IHC3+) (useful in certain circumstances) (category 2A).

New FDA-Approved Drug Products

New Molecular Entity

Attruby™ (acordamis) tablets, for oral use

Specialty | Orphan Drug

FDA-Approved Indication

For the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular related hospitalization.

Dosage & Administration

The recommended dosage is 712 mg orally twice daily.

Dosage Forms & Strengths

Tablets: 356 mg

Contraindications

None.

Clinical Studies

The efficacy and safety of Attruby were assessed in a multicenter, international, randomized, double-blind, placebo-controlled trial involving 611 adult patients with wild-type or hereditary (variant) ATTR-CM (NCT03860935). The primary endpoints of the study included overall mortality and the cumulative incidence of cardiovascular-related hospitalizations (CVH) over a 30-month period. After 30 months, a higher percentage of patients receiving Attruby were alive compared to those on placebo (81% vs. 74%), and patients on Attruby had fewer CVH events compared to those on placebo (an average of 0.3 vs. 0.6 per year).

Place in Therapy

ATTR-CM is a rare and severe condition that impacts the heart muscle. In individuals with ATTR-CM, abnormal protein deposits accumulate in the heart, leading to stiffening of the heart walls. This prevents the left ventricle from relaxing and properly filling with blood. Attruby will directly compete with Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis), both of which were approved for the treatment of ATTR-CM. All three medications have the same mechanism of action as selective stabilizers of transthyretin (TTR). In the future, Attruby may also face competition from Amvuttra (vutrisiran) and Wainua (eplontersen), both of which are under evaluation for ATTR-CM and are expected to seek approval in the upcoming years.

New FDA-Approved Drug Products

New Molecular Entity

Rapiblyk ™ (landilol) lyophilized powder, for intravenous use

FDA-Approved Indication

Indicated for the short – term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter.

Dosage & Administration

Administered as an intravenous infusion in a monitored setting. If normal cardiac function, start at 9 mcg/kg/min; adjust dose in 10-minute intervals as needed in increments of 9 mcg/kg/min to a maximum of 36 mcg/kg/min. If impaired cardiac function, start at 1 mcg/kg/min; adjust dose in 15- minute intervals as needed in increments of 1 mcg/kg/min to a maximum of 36 mcg/kg/min.

Dosage Forms & Strengths

For injection: 280 mg of landiolol (equivalent to 300 mg of landiolol HCl) as a lyophilized powder in a single-dose vial.

Contraindications

- Severe Sinus Bradycardia
- Sick Sinus Syndrome
- Heart Block Greater Than First Degree
- Decompensated Heart Failure
- Cardiogenic Shock
- Pulmonary Hypertension
- Known Hypersensitivity to Landilol

Common Adverse Reactions

Hypotension

Warnings and Precautions

- Risk of hypotension, bradycardia, and cardiac failure
- Risk of exacerbating reactive airway disease
- Diabetes mellitus
- Monitor for signs of myocardial ischemia when abruptly discontinuing in patients with coronary artery disease

Drug Interactions

- Negative Inotropes and Chronotropes
- Sympathomimetics, Positive Inotropes and Vasoconstrictors
- Catecholamine Depleting Drugs

Clinical Studies

The approval was based on data from five randomized, double-blind, placebo-controlled trials. A total of 317 adults with supraventricular tachycardia were treated with landiolol. Within approximately 10 minutes, the heart rate decreased in 40-90% of patients receiving landiolol, compared to 0-11% of those given a placebo. A decrease in heart rate was defined as a reduction of more than 20%, a heart rate of less than 100 bpm, or at least intermittent cessation of arrhythmia.

Place in Therapy

Landiolol enters the market of injectable supraventricular tachycardia (SVT) treatment. Other treatment options for SVT include: nondihydropyridine calcium channel blockers (such as diltiazem and verapamil), β-adrenergic blockers (including esmolol, metoprolol, and propranolol), and other medications like amiodarone and digoxin.

New FDA-Approved Drug Products

New Biosimilar Product

Yesintek™ (ustekinumab-kfce) injection for intravenous or subcutaneous use

Specialty

FDA-Approved Indication

[1] For the treatment of adult and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis; [2] For the treatment of adult and pediatric patients 6 years of age and older with active psoriatic arthritis; [3] For the treatment of adult patients with moderately to severely active Crohn's disease; [4] For the treatment of adult patients with moderately to severely active ulcerative colitis.

Dosage & Administration

Recommended dose is based on patient body weight. Please refer to package insert for details.

Dosage Forms & Strengths

- Subcutaneous injection: 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe; 45 mg/0.5 mL solution in a single-dose vial.
- Intravenous Infusion: 130 mg/26 mL (5 mg/mL) solution in a single-dose vial.

Contraindications

Clinically significant hypersensitivity to ustekinumab products or to any of the excipients in Yesintek.

Common Adverse Reactions

Nasopharyngitis, upper respiratory tract infections, headache, fatigue, vomiting, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, sinusitis, abdominal pain, influenza, fever, diarrhea and nausea.

Warnings & Precautions

- Infections
- Theoretical Risk for Particular Infections
- Tuberculosis (TB)
- Malignancies'
- Hypersensitivity Reactions
- Posterior Reversible Encephalopathy Syndrome (PRES)
- Avoid Live Vaccines
- Noninfectious Pneumonia

Clinical Studies

The approval was supported by a comprehensive review of scientific evidence that the product was highly similar to Stelara. This included data from the phase 3 STELLAR-2 trial which compared the efficacy and safety of ustekinumab-kfce with Stelara in patients with moderate to severe chronic plaque psoriasis.

Place in Therapy

Yesinktek is the sixth ustekinumab biosimilar approved by the FDA, behind Wezlana (ustekinumab-auub), Selarsdi (ustekinumab-aekn), Pyzchiva (ustekinumab-ttwe), Otulfi (ustekinumab-aauz), and Imuldosa (ustekinumab-srlf).

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Emrosi™ (minocycline) capsules, for oral use

FDA-Approved Indication

For the treatment of inflammatory lesions of rosacea in adults.

Dosage & Administration

The recommended dosage is 40mg orally, once daily.

Dosage Forms & Strengths

Extended-release capsules: 40 mg

Contraindications

Known hypersensitivity to any of the tetracyclines.

Warnings & Precautions

- Serious Skin/Hypersensitivity Reactions
- Tooth Discoloration and Enamel Hypoplasia
- Inhibition of Bone Growth
- *Clostridioides difficile*-Associated Diarrhea (Antibiotic-Associated Colitis)
- Hepatotoxicity
- Central Nervous System Effects
- Idiopathic Intracranial Hypertension
- Autoimmune Syndromes
- Metabolic Effects

Common Adverse Reactions

Dyspepsia

Use in Specific Population

Lactation: Breastfeeding is not recommended

Drug Interactions

- Anticoagulants

Clinical Studies

The approval of Emrosi is backed by data from two Phase 3 clinical trials, MVOR-1 (NCT05296629) and MVOR-2 (NCT05343455), which achieved all co-primary and secondary endpoints. Emrosi showed superiority over both Oracea (doxycycline delayed-release) 40 mg capsules and placebo in terms of Investigator's Global Assessment treatment success and the reduction in total inflammatory lesion count in both studies. In the MVOR-1 trial, IGA treatment success was observed in 65.0%, 46.1%, and 31.2% of patients in the Emrosi, Oracea, and placebo groups, respectively. The average reduction in lesion count was 21.3, 15.9, and 12.2 lesions in the Emrosi, Oracea, and placebo groups, respectively. Similar results were obtained in the MVOR-2 trial.

Place in Therapy

Biphasic doxycycline monohydrate 40-mg capsules are primarily prescribed for the treatment of rosacea in adults. Since rosacea treatment typically involves prolonged use, a low "subantimicrobial" dose, such as the 40 mg dose in Oracea, is preferred. Emrosi will compete with generic oral doxycycline products (including Oracea 40 mg doxycycline and its generics), as well as generic oral minocycline and tetracycline antibiotics available in the market.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Danziten™ (nilotinib) tablets, for oral use

Specialty

FDA-Approved Indication

[1] Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase; [2] Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib.

Dosage & Administration

- Newly diagnosed Ph+ CML-CP: 142 mg orally twice daily.
- Resistant or intolerant Ph+ CML-CP and CML-AP: 190 mg orally twice daily.

Dosage Forms & Strengths

Tablets: 71 mg and 95 mg

Contraindications

In patients with hypokalemia, hypomagnesemia or QT syndrome.

Warnings & Precautions

- ***BBW:*** QT Prolongation and Sudden Deaths
- Substitution with Other Nilotinib Products and Risk of Medication Errors
- Myelosuppression
- Cardiac and Arterial Vascular Occlusive Events
- Pancreatitis and Elevated Serum Lipase
- Hepatotoxicity
- Electrolyte Abnormalities
- Tumor Lysis Syndrome
- Hemorrhage
- Fluid Retention
- Effects on Growth and Development in Pediatric Patients
- Embryo-Fetal Toxicity
- Treatment Discontinuation

Common Adverse Reactions

Nausea, rash, headache, fatigue, pruritus, vomiting, diarrhea, cough, constipation, arthralgia, nasopharyngitis, pyrexia, night sweats, thrombocytopenia, neutropenia, and anemia.

Use in Specific Population

Lactation: Advise women not to breastfeed.

Clinical Studies

The effectiveness of Danziten tablets for both indications has been established from an adequate and well-controlled study of Tasigna (nilotinib) capsules, which has a different recommended dosage than Danziten.

Place in Therapy

Tyrosine kinase inhibitors (TKIs, such as Tasigna) are the backbone of CML. Danziten is a 505(b)(2) product referencing Tasigna. Danziten is the first and only nilotinib formulation without mealtime restrictions, indicated for adult patients with newly diagnosed Ph+ CML in the chronic phase, as well as for adult patients in chronic phase (CP) or accelerated phase (AP) who are resistant or intolerant to prior therapy, including imatinib.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Imkeldi™ (imatinib) oral solution

Specialty

FDA-Approved Indication

For the treatment of: [1] Newly diagnosed Philadelphia Positive Chronic Myeloid Leukemia (Ph+ CML); [2] Ph+ CML in Blast Crisis, Accelerated Phase, or Chronic Phase after IFN therapy; [3] Adult patients with Ph+ Acute Lymphoblastic Leukemia (ALL); [4] Pediatric patients with Ph+ ALL; [5] Myelodysplastic/Myeloproliferative Diseases; [6] Aggressive Systematic Mastocytosis; [7] Hypereosinophilic Syndrome and/or Chronic Eosinophilic Leukemia; [8] Dermatofibrosarcoma Protuberans; [9] Kit+ Gastrointestinal Stromal Tumors (GIST); [10] Adjuvant treatment of GIST.

Dosage & Administration

Recommended dose may vary from 100mg/day to 800mg/day depends on patient diagnosis.

Dosage Forms & Strengths

Oral solution: 80 mg/mL of imatinib

Contraindications

None

Warnings & Precautions

- Fluid Retention and Edema
- Hematologic Toxicity
- Congestive Heart Failure and Left Ventricular Dysfunction
- Hepatotoxicity
- Hemorrhage
- Gastrointestinal Disorders
- Hypereosinophilic Cardiac Toxicity
- Dermatological Toxicities
- Hypothyroidism
- Embryo-Fetal Toxicity
- Growth Retardation in Children and Adolescents
- Tumor Lysis Syndrome
- Renal Toxicity
- Use Accurate Measuring Device

Common Adverse Reactions

Edema, nausea, vomiting, muscle cramps, musculoskeletal pain, diarrhea, rash, fatigue, and abdominal pain.

Drug Interactions

- CYP3A4 inducers and inhibitors
- CYP3A4 substrates
- CYP2D6 substrates

Use in Specific Population

Lactation: Advise not to breastfeed

Clinical Studies

The approval came from studies of the reference product imatinib.

Place in Therapy

This formulation provides improved dosing accuracy and greater convenience for patients, particularly for those who may benefit from an alternative to tablet-based treatments, such as children, individuals with difficulty swallowing, or those needing customized doses. The solution is a flavored and stable formulation that does not require refrigeration.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Raldesy™ (trazodone hydrochloride) oral solution

FDA-Approved Indication

For the treatment of major depressive disorder (MDD) in adults.

Dosage & Administration

Starting dosage is 150 mg orally in divided doses daily. The maximum dosage is 400 mg per day.

Dosage Forms & Strengths

Oral solution: 10 mg/mL

Contraindications

Concomitant use of monoamine oxidase inhibitors (MAOIs) or use within 14 days of stopping MAOIs.

Warnings & Precautions

- ***BBW***: Suicidal Thoughts and Behavior
- Serotonin Syndrome
- Cardiac Arrhythmias
- Orthostatic Hypotension and Syncope
- Increased Risk of Bleeding
- Priapism
- Activation of Mania or Hypomania
- Potential for Cognitive and Motor Impairment
- Angle-Closure Glaucoma

Common Adverse Reactions

Edema, blurred vision, syncope, drowsiness, fatigue, diarrhea, nasal congestion, weight loss.

Drug Interactions

- CNS Depressants
- CYP3A4 Inhibitors and Inducers
- Digoxin or Phenytoin
- Warfarin

Use in Specific Population

Lactation: Advise not to breastfeed

Clinical Studies

The efficacy of Raldesy for the treatment of MDD in adults is based on studies of trazodone hydrochloride tablets.

Place in Therapy

Depression treatment typically involves a combination of psychotherapy and medication, either separately or together. There are numerous affordable generic medication options available, including those from the following classes: selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), and atypical antidepressants such as bupropion and mirtazapine.

Other notable new approvals include:

Iomervu™ (iomeprol) injection, for intravenous or intra-arterial use

- A radiographic contrast agent for intra-arterial and intravenous procedures.

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)
Exenatide Injection 300 mcg/1.2 mL (250mcg/mL) and 600mcg/2.4mL (250mcg/mL)	Amneal Pharmaceuticals LLC	Byetta	Incretin Mimetic Agents	Type 2 Diabetes

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
Bimzelx (bimekizumab) From: UCB Inc	[1] For the treatment of adult patients with active psoriatic arthritis; [2] For the treatment of adult patients with active non-radiographic axial spondylarthritis with objective signs of inflammation; [3] For the treatment of adult patients with active ankylosing spondylitis; [4] Moderate to severe plaque psoriasis.	For the treatment of adult patients with moderate to severe hidradenitis suppurativa.

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
Donidalorsen From: Ionis Pharmaceuticals	Hereditary Angioedema	NDA accepted	High
Oxylanthanum carbonate From: Unicycive Therapeutics, Inc	Hyperphosphatemia of renal failure	NDA accepted	Moderate
Prademagene zamikeracel From: Abeona Therapeutics, Inc.	Epidermolysis Bullosa	BLA resubmission accepted	High
Reproxalap From: Aldeyra Therapeutics, Inc.	Dry Eye Disease	NDA accepted	Moderate
Plozasiran From: Arrowhead Pharmaceuticals, Inc.	Familial Chylomicronemia Syndrome	NDA submitted	High
Sunvozertinib From: Dizal	Non-Small Cell Lung Cancer	NDA submitted	High
Datopotamab deruxtecan From: AstraZeneca and Daiichi Sankyo	Non-Small Cell Lung Cancer	BLA submitted	High