PharmNotes

Monthly Communications

June 2025

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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 adds warning about serious risk of heat-related complications with antinausea patch Transderm Scōp (scopolamine transdermal system)	6/18/2025	The U.S. Food and Drug Administration (FDA) is warning that the antinausea patch Transderm Scōp (scopolamine transdermal system) can increase body temperature and cause heat-related complications, resulting in hospitalization or even death in some cases. Most cases occurred in children 17 years and younger and in adults 60 years and older, who may be sensitive to body temperature control disturbances. As a result, the FDA required that the Transderm Scōp prescribing information be revised to include a warning and other information about this risk.
FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis Following Vaccination	6/25/2025	The FDA has required and approved updates to the Prescribing Information for Comirnaty (COVID-19 Vaccine, mRNA) manufactured by Pfizer Inc. and Spikevax (COVID-19 Vaccine, mRNA) manufactured ModernaTX, Inc. to include new safety information about the risks of myocarditis and pericarditis following

		administration of mRNA COVID-19 vaccines. Specifically, the FDA has required each manufacturer to update the warning about the risks of myocarditis and pericarditis to include information about (1) the estimated unadjusted incidence of myocarditis and/or pericarditis following administration of the 2023-2024 Formula of mRNA COVID-19 vaccines and (2) the results of a study that collected information on cardiac magnetic resonance imaging (cardiac MRI) in people who developed myocarditis after receiving an mRNA COVID-19 vaccine. The FDA also required each manufacturer to describe the new safety information in the Adverse Reactions section of the Prescribing Information and in the Information for Recipients and Caregivers.
FDA requires expanded labeling about weight loss risk in patients younger than 6 years taking extended-release stimulants for ADHD	6/30/2025	The FDA is revising the labeling of all extended-release stimulants indicated to treat attention-deficit/hyperactivity disorder (ADHD) - including certain formulations of amphetamine and methylphenidate - to warn about the risk of weight loss and other adverse reactions (side effects) in patients younger than 6 years taking these medications.

New FDA-Approved Drug Products

New Molecular Entity

Enflonsia™ (clesrovimab-cfor) injection for intramuscular use

FDA-Approved Indication

For the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season.

Dosage & Administration

105 mg administered as a single intramuscular injection.

Dosage Forms & Strengths

Injection: 105 mg/0.7 mL in a single-dose prefilled syringe.

Contraindications

In infants with a history of serious hypersensitivity reactions, including anaphylaxis, to any component of Enflonsia.

Common Adverse Reactions

Injection-site erythema, injection-site swelling and rash.

Warnings & Precautions

- Hypersensitivity Including Anaphylaxis

Use in Specific Populations

- The safety and effectiveness of Enflonsia have not been established in children older than 12 months of age.

Clinical Studies

The approval came from Trial 004, a randomized, double-blind, placebo-controlled study in early and moderate preterm infants and late preterm and full-term infants. The primary endpoint was the incidence of RSV-associated Medically Attended Lower Respiratory Infection (MALRI) characterized as cough or difficulty breathing and requiring ≥ 1 indicator of LRI (wheezing, rales/crackles) or severity (chest wall indrawing/retractions, hypoxemia, tachypnea, dehydration due to respiratory symptoms) through 150 days after dosing. RSV-associated hospitalization through 150 days after dosing was evaluated as a key secondary endpoint. The incidence rate of MALRI was 0.026 and 0.065 with Enflonsia and placebo, respectively (efficacy 60.5%; $p < 0.001$). The incidence rate of hospitalization was 0.004 and 0.024 with Enflonsia and placebo, respectively (efficacy 84.3%; $p < 0.001$).

Place in Therapy

On June 26, 2025 the CDC's ACIP voted to recommend Enflonsia for all children <8 months of age born during or entering their first RSV season. This is the same recommendation that applies to Beyfortus for RSV prevention in the first season. Either Enflonsia or Beyfortus should only be used in babies whose mothers did not receive Abrysvo at 32 to 36 weeks gestation.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Ibtrozi™ (taletrectinib) capsules 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).

Dosage & Administration

600 mg orally once daily on an empty stomach.

Dosage Forms & Strengths

Capsules: 200 mg

Contraindications

None

Common Adverse Reactions

Diarrhea, nausea, vomiting, dizziness, rash, constipation, fatigue, increased ALT, increased AST, decreased neutrophils and increased creatinine phosphokinase.

Warnings & Precautions

- Hepatotoxicity
- Interstitial Lung Disease (ILD)/ Pneumonitis
- QTc Interval Prolongations
- Hyperuricemia
- Myalgia with Creatinine Phosphokinase (CPK) Elevation
- Skeletal Fractures
- Embryo-Fetal Toxicity

Drug Interactions

- Strong and Moderate CYP3A Inhibitors
- Strong and Moderate CYP3A Inducers
- Gastric Acid Reducing Agents
- Drugs that Prolong the QTc interval

Use in Specific Populations

- Lactation: Advise not to breastfeed.

Clinical Studies

The approval came from two single-arm, open-label studies (TRUST-I and TRUSTII) in patients with ROS1-positive locally advanced or metastatic NSCLC. The efficacy populations included 157 patients naïve to treatment with a ROS1 tyrosine kinase inhibitor (TKI) and 113 patients who received one prior ROS1 TKI. The major efficacy measures were confirmed overall response rate (ORR) and duration of response (DOR). In TKI-naïve patients, the ORR was 90% and 85% in TRUST-I and TRUST-II, respectively. The median DOR was not reached. In TKI-pretreated patients, the ORR was 52% and 62% in TRUST-I and TRUST-II, respectively. The median DOR was 13.2 months in TRUST-I and was not included in TRUST-II given the shorter duration of follow-up.

Place in Therapy

The NCCN Guidelines for Non-Small Cell Lung Cancer recommends the use of taletrectinib as a single agent therapy for recurrent, advanced, or metastatic disease in those with ROS1 rearrangement positive tumors (category 2A).

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Andembry™ (garadacimab-gxii) injection, for subcutaneous use

FDA-Approved Indication

For prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients aged 12 years of age and older.

Dosage & Administration

Initial loading dose of 400 mg (two 200 mg injections) administered subcutaneously followed by maintenance dosage of 200 mg once monthly.

Dosage Forms & Strengths

200 mg/1.2 mL solution in single-dose prefilled autoinjector or prefilled syringe.

Contraindications

None

Common Adverse Reactions

Nasopharyngitis and abdominal pain.

Warnings & Precautions

None

Drug Interactions

- Drug Interference with Laboratory Test: Andembry can prolong activated partial thromboplastin time (aPTT) due to an interaction of garadacimab-gxii with the aPTT assay.

Clinical Studies

The approval came from VANGUARD, a randomized, double-blind, placebo-controlled study in 64 adult and pediatric patients 12 years of age and older with HAE. Patients were randomized to Andembry or placebo. The primary endpoint was the monthly HAE attack rate at 6 months. The least squares mean rate of monthly HAE attacks was 0.22 with Andembry and 2.07 for placebo (percent reduction relative to placebo: 89.2 %; $p < 0.001$).

Place in Therapy

Andembry is the only treatment targeting factor XIIa for prophylactic use to prevent attacks of hereditary angioedema (HAE). It joins the market with other treatments approved for prophylaxis such as Cinryze, Haegarda, Takhyzro, and Orladeyo.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Xifyrm™ (meloxicam) injection for intravenous use

FDA-Approved Indication

For use in adults for the management of moderate to severe pain, alone or in combination with non-NSAIDs analgesics.

Dosage & Administration

30 mg once daily, administered by intravenous bolus injection over 15 seconds.

Dosage Forms & Strengths

- Single-dose vial containing 30 mg/mL per vial.

Contraindications

- Known hypersensitivity to meloxicam or any components of the drug product.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.
- Moderate to severe renal insufficiency patients who are at risk for renal failure due to volume depletion.

Common Adverse Reactions

Constipation, GGT increased, and anemia

Warnings & Precautions

- ***BBW:*** Risk of Serious Cardiovascular and Gastrointestinal Events
- Hepatotoxicity
- Hypertension
- Heart Failure and Edema
- Renal Toxicity
- Anaphylactic Reactions
- Exacerbation of Asthma Related to Aspirin Sensitivity
- Serious Skin Reactions
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
- Hematologic Toxicity
- Fetal Toxicity

Drug Interactions

- Drugs that Interfere with Hemostasis (e.g., warfarin, aspirin, SSRIs/SNRIs)
- ACE Inhibitors, Angiotensin Receptor Blockers (ARBs), or Beta-Blockers
- ACE Inhibitors and ARBs
- Diuretics

Use in Specific Populations

- Infertility: NSAIDs are associated with reversible infertility.

Place in Therapy

The approval of Xifyrm was conducted via the 505(b)(2) pathway, using another intravenous formulation of meloxicam, Anjeso (meloxicam injection), as the reference drug. Anjeso was discontinued in the United States in 2022. Injectable ketorolac is often used as a first-line option when intravenous NSAIDs are needed. Caldolor, which is an injectable ibuprofen, is another brand of an injectable NSAID option available in the market.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Widaplik (telmisartan, amlodipine and indapamide) tablets, for oral use

FDA-Approved Indication

For the treatment of hypertension, including as initial treatment, to lower blood pressure.

Dosage & Administration

Start with Widaplik (10 mg/1.25 mg/0.625 mg) or Widaplik (20 mg/2.5 mg/1.25 mg) orally once daily. Titrate up to a maximum dose of Widaplik (40 mg/5 mg/2.5 mg) orally once daily.

Dosage Forms & Strengths

Tablets: (telmisartan/amlodipine/indapamide) 10 mg/1.25 mg/0.625 mg, 20 mg/2.5 mg/1.25 mg, 40 mg/5 mg/2.5 mg.

Contraindications

- Known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan, amlodipine, indapamide, or to other sulfonamide derived drugs, or to any other component of this product
- Do not co-administer aliskiren with Widaplik in patients with diabetes
- Anuria

Common Adverse Reactions

Symptomatic hypotension, low sodium, and low potassium.

Warnings & Precautions

- ***BBW***: Fetal Toxicity
- Hypotension
- Electrolyte and Glucose Imbalances
- Impaired Renal Function
- Acute Angle Closure Glaucoma
- Hyperuricemia

Drug Interactions

- NSAIDs
- Simvastatin
- Aliskiren

Use In Specific Populations

- Lactation: Advise not to breastfeed
- Geriatric Patients: Severe cases of hyponatremia have been reported.
- Hepatic Impairment: Start treatment at lower doses

Clinical Studies

The approval came from Study 1, a 4-week, randomized, double-blind, placebo-controlled study in 295 adults with systolic hypertension who were taking 0 to 1 antihypertensive medication at screening. Patients were randomized to receive Widaplik (10 mg/1.25 mg/0.625 mg), Widaplik (20 mg/2.5 mg/1.25 mg), or placebo. The least squares mean (LSM) change in home systolic blood pressure at week 4 was -2.2 mmHg with placebo, -9.6 mmHg with Widaplik 10 mg/1.25 mg/0.625 mg and -10.4 mmHg with Widaplik 20 mg/2.5 mg/1.25 mg. The difference vs. placebo was -7.3 with Widaplik 10 mg/1.25 mg/0.625 mg and -8.2 with Widaplik 20 mg/2.5 mg/1.25 mg. Efficacy was also evaluated in another trial known as Study 2, a 12-week, randomized, double-blind study comparing Widaplik up to 40 mg/5 mg/2.5 mg vs. each of its two-drug combinations at the same doses. The LSM change in home systolic blood pressure was -4.0 mmHg with Widaplik vs. -1.5 mmHg with telmisartan/indapamide vs. 1.4 mmHg with telmisartan/amlodipine vs. 0.5 mmHg with amlodipine/indapamide.

Place in Therapy

Widaplik is the first and only triple combination therapy approved by the FDA for use as an initial therapy in patients who will likely need multiple medications to achieve blood pressure goals.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Zusduri™ (mitomycin) for intravesical solution

Specialty

FDA-Approved Indication

For the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)

Dosage & Administration

75 mg (56 mL) instilled once weekly for six weeks.

Dosage Forms & Strengths

Intravesical solution (kit contain):

- Two 40 mg (each) single-dose vials of mitomycin for intravesical solution
- One vial of 60 mL sterile hydrogel for reconstitution

Contraindications

- Perforation of the bladder
- Prior hypersensitivity reaction to mitomycin or any component of the product

Common Adverse Reactions

Increased creatinine, increased potassium, dysuria, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, increased eosinophils, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria.

Warnings & Precautions

- Risk in Patients with Perforated Bladder
- Embryo-Fetal Toxicity

Use In Specific Populations

Lactation: Advise not to breastfeed.

Clinical Studies

The FDA approval came from ENVISION trial, a single-arm study in 240 adults with recurrent LG-IR-NMIBC, of whom 223 were evaluable for response. The major outcome measures were complete response rate (CR) at 3 months (defined as no detectable disease in the bladder by cystoscopy, biopsy [if indicated], and urine cytology) and duration of response (DOR). The CR rate was 78%. The DOR range was 0.0 to 25.0+ months and 79% had a DOR ≥ 12 months.

Place in Therapy

Zusduri is an intravesical formulation of mitomycin and is the first and only FDA-approved nonsurgical, intravesical treatment for adult patients with recurrent LG-IR-NMIBC.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Arynta™ (lisdexamfetamine dimesylate) oral solution, CII

FDA-Approved Indication

[1] Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older; [2] Moderate to severe binge eating disorder (BED) in adults.

Dosage & Administration

- ADHD: 30mg to 70 mg per day
- BED: 50mg to 70mg per day

Dosage Forms & Strengths

- Oral Solution: 10mg/mL.

Contraindications

- Known hypersensitivity to amphetamine products or other ingredients in Arynta.
- Use with monoamine oxidase (MAO) inhibitor, or within 14 days of the last MAO inhibitor dose.

Common Adverse Reactions

Anorexia, anxiety, decreased appetite, decreased weight, diarrhea, dizziness, dry mouth, irritability, insomnia, nausea, upper abdominal pain, vomiting, increased heart rate, constipation and feeling jittery.

Warnings & Precautions

- ***BBW:*** 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
- Peripheral Vasculopathy, including Raynaud's Phenomenon
- Serotonin Syndrome
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome

Drug Interactions

- Acidifying and Alkalinizing Agents

Use in Specific Populations

- Pregnancy: May cause fetal harm.
- Lactation: Breastfeeding not recommended.

Clinical Studies

The efficacy of Arynta has been established based on adequate and well-controlled studies of oral lisdexamfetamine dimesylate in the treatment of adults and pediatric patients 6 years and older with ADHD and adults with moderate to severe binge eating disorder (BED).

Place in Therapy

Arynta is now the first oral solution formulation of lisdexamfetamine. Lisdexamfetamine is also available as an oral capsule and chewable tablet (brand Vyvanse and generics).

Other notable new approvals include:

Harliku™ (nitisinone) tablets, for oral use

Indicated for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU). Nitisinone tablets are also approved under the brand name Nityr, made by the same manufacturer (Cycle Pharmaceuticals) for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 in combination with dietary restriction of tyrosine and phenylalanine. The recommended dosage is 2 mg administered orally, once daily.

Brukinsa™ (zanubrutinib) tablets, for oral use

Brukinsa tablets are a new formulation of zanubrutinib. Previously, Brukinsa was only available as an 80 mg oral capsule. The tablet formulation will be available as a 160 mg strength.

Yeztugo™ (lenacapavir) injection for subcutaneous use; tablets for oral use

Yeztugo has been approved for HIV pre-exposure prophylaxis in adults and adolescents weighing at least 35 kg who are at risk of HIV acquisition. Lenacapavir was approved as brand name Sunlenca in 2022 for use in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced (HTE) adults with multidrug-resistant (MDR) HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

Gammagard Liquid ERC™ (immune globulin infusion (human)) Solution

This is the only ready-to-use liquid immune globulin therapy for use in the treatment of primary humoral immunodeficiency, multifocal motor neuropathy, and chronic inflammatory demyelinating polyneuropathy.

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)	Market Release Date
Sitagliptin Phosphate and Metformin Hydrochloride Extended Release Tablets 50mg (base)/500mg, 50mg (base)/1000mg and 100mg (base)/1000mg	Endo Pharmaceuticals	Janumet XR	Antidiabetics	Type 2 Diabetes	July 2026
Rivaroxaban for Oral Suspension 1mg/mL	Alkem Laboratories	Xarelto for Oral Suspension	Anticoagulants	Treatment and Prevention of Blood Clots	Mid-End 2025

*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
Nubeqa (darolutamide) From: Bayer Healthcare	[1] Non-metastatic castration-resistant prostate cancer (nmCRPC); [2] Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.	For the treatment of metastatic castration-sensitive prostate cancer (mCSPC).
Mavyret (glecaprevir and pibrentasvir) From: Abbvie	[1] For the treatment of adult and pediatric patients 3 years and older with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A); [2] For the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.	For the treatment of adult and pediatric patients 3 years and older with acute HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis.
mResvia™ (respiratory syncytial virus vaccine) From: Moderna	For active immunization of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.	For active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older, or individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.
Keytruda™ (pembrolizumab) From: Merck Sharp Dohme	Several including head and neck squamous cell cancer (HNSCC) [1] In combination with platinum and FU for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC; [2] As a single agent for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [combined positive score (CPS) ≥1] as determined by an FDA-approved test; [3] As a single agent for the treatment of patients with recurrent or	For the treatment of adult patients with resectable locally advanced HNSCC whose tumors express PD-L1 [combined positive score (CPS) ≥1] as determined by an FDA-approved test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent.

	metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.	
Monjuvi™ (tafasitamab-cxix) From: Morphosys US Inc.	In combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).	In combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).
Dupixent™ (dupilumab) From: Regeneron Pharmaceuticals	[1] Atopic dermatitis; [2] Asthma; [3] Chronic Rhinosinusitis with Nasal Polyps; [4] Eosinophilic Esophagitis; [5] Prurigo Nodularis; [6] Chronic Obstructive Pulmonary Disease; [7] Chronic Spontaneous Urticaria.	For the treatment of adult patients with bullous pemphigoid (BP).
Datroway™ (datopotamab deruxtecan-dlnk) From: Daiichi Sankyo Inc.	For the treatment of adult patients with unresectable or metastatic, hormone receptor (HR) – positive, human epidermal growth factor receptor 2 (HER2) – negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.	For the treatment of adult patients with locally advanced or metastatic EGFR-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy.
Gamifant™ (emapalumab-lzsg) From: Novimmune S.A.	Adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.	Adult and pediatric (newborn and older) patients with HLH/Macrophage Activation Syndrome (MAS) in known or suspected Still's disease, including systemic juvenile idiopathic arthritis with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

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
Ziftomenib From: Kura Oncology, Inc. and Kyowa Kirin Co., Ltd	Acute Myeloid Leukemia	NDA accepted	Moderate
Linerixibat From: GSK	Primary Biliary Cholangitis	NDA accepted	High
Brimochol PF (brimonidine tartrate and carbachol) Ophthalmic Solution From: Tenpoint Therapeutics, Ltd	Presbyopia	NDA accepted	Low
Reproxalap From: Aldeyra Therapeutics, Inc	Dry Eye Disease	NDA resubmitted	Moderate
Cytisinicline From: Achieve Life Sciences, Inc	Smoking Cessation	NDA submitted	Moderate

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
Gabapentin enacarbil	Horizant	Azurity Pharmaceuticals, Inc.
Glycerol phenylbutyrate	Ravicti	Horizon Therapeutics USA, Inc.
Sacubitril; Valsartan	Entresto (tablet)	Novartis Pharmaceutical
Carbidopa; Levodopa	Rytary	Amneal Pharmaceuticals LLC