PharmNotes

Monthly Communications

March 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.

No Drug Safety Alert Notification was released during March.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Encelto™ (revakinagene taroretcel-lwey) implant for intravitreal use

FDA-Approved Indication

For the treatment of adults with idiopathic macular telangiectasia (MacTel) type 2.

Dosage & Administration

One Encelto implant per affected eye containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotropic factor (rhCNTF).

Dosage Forms & Strengths

One single-dose implant containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF.

Contraindications

- Ocular or periocular infections
- Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)

Common Adverse Reactions

Conjunctival hemorrhage delayed dark adaptation, foreign body sensation, eye pain, suture related complications, miosis, conjunctival hyperemia, eye pruritus, ocular discomfort, vitreous hemorrhage, blurred vision, headache, dry eye, eye irritation, cataract progression or formation, vitreous floaters, severe vision loss, eye discharge, anterior chamber cell, iridocyclitis.

Warnings & Precautions

- Vitreous Hemorrhage
- Severe vision loss, infectious endophthalmitis, retinal tears and/or detachment, implant extrusion, cataract formation, and delayed dark adaptation.

Clinical Studies

The approval of Encelto was based on results from two Phase 3, randomized, multicenter studies with 228 patients (NTMT-03-A and NTMT-03-B). The results demonstrated a statistically significant reduction in the rate of change in ellipsoid zone area loss over 24 months compared with that of patients who received treatment

Place in Therapy

Encelto is the first and only FDA-approved treatment available for MacTel. MacTel is a neurodegenerative disease of the retina in adults that causes progressive and irreversible vision loss, significantly impacting patients' quality of life. Encelto uses an encapsulated cell therapy technology designed to continually deliver therapeutic doses of ciliary neurotrophic factor (CNTF) to the retina to assist in slowing the progression of the disease.

New FDA-Approved Drug Products

New Molecular Entity

Blujepa™ (gepotidacin mesylate) tablets, for oral use

FDA-Approved Indication

For the treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms with uncomplicated urinary tract infections caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii* complex, *Staphylococcus saprophyticus,* and *Enterococcus faecalis*.

Dosage & Administration

1,500 mg (two 750 mg tablets) taken orally, twice daily (approximately 12 hours apart), for 5 days.

Dosage Forms & Strengths

Tablets: 750 mg of gepotidacin

Contraindications

A history of severe hypersensitivity to Blujepa

Common Adverse Reactions

Diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candidiasis.

Warnings & Precautions

- QTc Prolongation
- Acetylcholinesterase inhibition
- Hypersensitivity Reactions
- *Clostridioides difficile* Infection (CDI)

Drug Interactions

- CYP3A4 Inhibitors
- CYP3A4 Inducers
- CYP3A4 Substrates
- Digoxin

Use in Specific Populations

- Renal Impairment: Avoid use in patients with severe renal impairment with eGFR <30 mL/min, including those receiving dialysis.
- Hepatic Impairment: Avoid use in patients with severe hepatic impairment (Child-Pugh Class C).

Clinical Studies

The approval was based on results of the Phase 3 EAGLE-2 and EAGLE-3 trials in which gepotidacin proved to be non-inferior to nitrofurantoin in patients with uUTI due to a pathogen susceptible to nitrofurantoin. In EAGLE-3, gepotidacin was statistically superior to nitrofurantoin, with successful treatment in 58.5% of patients compared to 43.6% for nitrofurantoin. In EAGLE-2, gepotidacin successfully treated 50.6% of participants compared to 47.0% for nitrofurantoin.

Place in Therapy

Nitrofurantoin or trimethoprim are often regarded as first-line choices for uUTI. Pivmecillinam and fosfomycin are usually used as second-line choices if symptoms do not improve on a first-line antibiotic after 48 hours or when first-choice antibiotics are not appropriate. Blujepa, a first-in-class oral antibiotic, provides another treatment option to patients, especially when considering rising rates of resistance to existing treatment options.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Vykat™ (diazoxide choline) tablets, for oral use

FDA-Approved Indication

Indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).

Dosage & Administration

The recommended starting dosage and titration schedule is based on patient's body weight – *Please refer to package insert*. The maximum recommended dosage is 5.8 mg/kg/day or 525 mg per day.

Dosage Forms & Strengths

Extended-release tablets: 25 mg, 75 mg, and 150 mg of diazoxide choline.

Contraindications

Known hypersensitivity to diazoxide, other components of Vykat XR, or to thiazides.

Common Adverse Reactions

Hypertrichosis, edema, hyperglycemia, and rash.

Warnings & Precautions

- Hyperglycemia
- Risk of Fluid Overload

Drug Interactions

- Strong CYP1A2 Inhibitors
- CYP1A2 Substrates

Use in Specific Populations

Renal Impairment or Hepatic Impairment: Use is not recommended.

Clinical Studies

The approval came from data of a 16-week, phase 3, double-blind, placebo-controlled, randomized withdrawal study, following an open-label study period of diazoxide choline extended-release. Participants were randomly assigned to receive diazoxide choline extended-release or placebo. The primary endpoint was the change from baseline to week 16 in hyperphagia using the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) total score. Results showed a statistically significant worsening of hyperphagia in patients who received placebo compared with those who received diazoxide choline extended-release (HQ-CT total score, least square mean difference: -5.0 [-8.1, -1.8]). Prior to participating in this study, patients had received diazoxide choline extended-release for about 3.3 years.

Place in Therapy

Hyperphagia is often the most restraining aspect of PWS. Although there are growth hormone products approved to treat related symptoms in PWS, Vykat is the first FDA-approved treatment to directly address the hyperphagia associated with PWS.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Qfitlia™ (fitusiran) injection, for subcutaneous use

FDA-Approved Indication

Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.

Dosage & Administration

The starting dose is 50 mg SQ once every 2 months. Dose is modified based on antithrombin activity levels.

Dosage Forms & Strengths

Injection:

- 50 mg/0.5 mL (100 mg/mL) in a single-dose prefilled pen
- 20 mg/0.2 mL (100 mg/mL) in a single-dose vial

Contraindications

None

Common Adverse Reactions

Viral infection, nasopharyngitis, and bacterial infection.

Warnings & Precautions

- ***BBW:*** Thrombotic Events and Acute and Recurrent Gallbladder Disease
- Hepatotoxicity

Use in Specific Populations

Hepatic Impairment: Avoid use in patients with established hepatic impairment (Child-Pugh Class A, B and C).

Clinical Studies

The approval was based on results of two phase 3 trials: ATLAS-A/B and ATLAS-INH. The ATLAS-A/B study included males aged 12 years and older with severe hemophilia A or B without inhibitors, while the ATLAS-INH trial included male patients with severe hemophilia A or B with inhibitors who were receiving on-demand treatment with bypassing agents (BPA). The primary endpoint was the estimated annualized bleeding rate (ABR) of treated bleeds. In participants with inhibitors who received Qfitlia, there was a 73% decrease in estimated ABR compared with those who received on-demand treatment with bypassing agents. In participants without inhibitors who received Qfitlia, there was a 71% decrease in estimated ABR compared with those who received on-demand treatment with clotting factor concentrates.

Place in Therapy

Qfitlia is the first small interfering RNA treatment option, and the first antithrombin-lowering therapy approved for the treatment of hemophilia. Qfitlia can be administered subcutaneously as infrequently as once every 2 months, unlike the other treatment options currently available. For hemophilia A, Hemlibra (emicizumab-kxwh), Hympavzi (marstacimab-hncq), and Alhemo (concizumab-mtci) are therapeutic options available. For hemophilia B, Hympavzi and Alhemo are FDA-approved therapies.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Omlyclo™ (omalizumab-igec) injection, for subcutaneous use

FDA-Approved Indication

For the treatment of [1] Asthma; [2] Chronic rhinosinusitis with nasal polyps; [3] IgE mediated food allergy; [4] Chronic spontaneous urticaria.

Dosage & Administration

Consists of SQ administrations every 2 or 4 weeks. *Refer to package insert for more information*.

Dosage Forms & Strengths

Injection: 75 mg/0.5 mL and 150 mg/mL, solution in a single-dose prefilled syringe

Contraindications

Severe hypersensitivity reaction to Omlyclo or any ingredient of Omlyclo.

Common Adverse Reactions

Arthralgia, pain (general), leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, headache, otitis media, earache, among others.

Warnings & Precautions

- ***BBW:*** Anaphylaxis
- Malignancy
- Acute Asthma Symptoms
- Corticosteroid Reduction
- Eosinophilic Conditions
- Fever, Arthralgia and Rash
- Potential Medication Error Related to Emergency Treatment of Anaphylaxis

Clinical Studies

The FDA's decision is based on a comprehensive data package and the totality of evidence, including the results from a phase III study demonstrating biosimilarity between Omlyclo and reference Xolair.

Place in Therapy

Omlyclo (omalizumab-igec) is the first U.S. Food and Drug Administration (FDA)-approved anti-IgE antibody biosimilar referencing Xolair.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Bomyntra™ (denosumab-bnht) injection, for subcutaneous use

FDA-Approved Indication

[1] Multiple myeloma and bone metastasis from solid tumors; [2] Giant cell tumor of bone; [3] Hypercalcemia of malignancy.

Dosage & Administration

Dosing varies by indication. *Refer to package insert for more information*.

Dosage Forms & Strengths

Injection: 120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial and in a single-dose prefilled syringe.

Contraindications

- Hypocalcemia
- Known clinically significant hypersensitivity to denosumab products

Common Adverse Reactions

Fatigue/asthenia, hypophosphatemia, nausea diarrhea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, headache, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, and constipation.

Warnings & Precautions

- Patients receiving Bomyntra should not
- receive other denosumab products concomitantly
- Hypersensitivity reactions including anaphylaxis
- Hypocalcemia
- Osteonecrosis of the jaw
- Atypical femoral fracture
- Hypercalcemia following treatment discontinuation in patients with giant cell tumor of bone and in patients with growing skeletons
- Multiple vertebral fractures following treatment discontinuation
- Embryo-fetal toxicity

Use in Specific Populations

- Pediatric patients: Recommended only for treatment of skeletally mature adolescents with giant cell tumor of bone
- Renal impairment: Patients with creatinine clearance less than 30 mL/min or receiving dialysis are at risk for hypocalcemia.

Clinical Studies

The FDA's decision is based on a comprehensive data package and the totality of evidence, including the results from a phase III study demonstrating biosimilarity between Bomyntra and reference Xgeva.

Place in Therapy

Bomyntra is the fourth FDA-approved biosimilar to Xgeva. Other biosimilars approved by the FDA include Wyost (denosumab-bbdz), Xbryk (denosumab-dssb), and Osenvelt (denosumab-bmwo).

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Conexxence™ (denosumab-bnht) injection, for subcutaneous use

FDA-Approved Indication

[1] Postmenopausal women with osteoporosis at high risk for fracture; [2] To increase bone mass in men with osteoporosis at high risk for fracture; [3] Glucocorticoid-induced osteoporosis in men and women at high risk for fracture; [4] To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; [5] To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Dosage & Administration

60 mg every 6 months as a subcutaneous injection administered by a healthcare provider.

Dosage Forms & Strengths

Injection: 60 mg/mL solution in single-dose prefilled syringe.

Contraindications

- Hypocalcemia
- Pregnancy
- Know hypersensitivity to denosumab products

Warnings & Precautions

- ***BBW:*** Severe hypocalcemia in patients with chronic kidney disease
- Patients receiving Conexxence should not receive other denosumab products concomitantly
- Hypersensitivity including anaphylactic reactions may occur
- Osteonecrosis of the jaw
- Atypical femoral fractures
- Multiple vertebral fractures have been reported following treatment discontinuation
- Serious infections including skin infections
- Dermatological reactions
- Severe bone, joint, muscle pain may occur
- Suppression of bone turnover

Common Adverse Reactions

Back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, cystitis, arthralgia, nasopharyngitis, hypertension, bronchitis, and headache.

Use in Specific Populations

- Pregnant women and females of reproductive potential: May cause fetal harm.
- Pediatric patients: Conexxence is not approved for use in pediatric patients.
- Renal impairment: No dose adjustment is necessary in patients with renal impairment.

Clinical Studies

The FDA's decision is based on a comprehensive data package and the totality of evidence, including the results from a phase III study demonstrating biosimilarity between Conexxence and reference Prolia.

Place in Therapy

Conexxence is the fourth FDA-approved biosimilar to Prolia. Other biosimilars approved by the FDA include Jubbonti (denosumab-bbdz), Ospomyv (denosumab-dssb) and Stoboclo (denosumab-bmwo).

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Arbli™ (losartan potassium) suspension for oral use

FDA-Approved Indication

[1] Hypertension; [2] Hypertensive Patients with Left Ventricular Hypertrophy; [3] Nephropathy in Type 2 Diabetic Patients.

Dosage & Administration

Usual dose is 50 mg orally once daily. Varies in pediatric patients. *Please refer to package insert for more information*.

Dosage Forms & Strengths

Oral Suspension: 10 mg/mL

Contraindications

- Hypersensitivity to any component
- Co-administration with aliskiren in patients with diabetes

Common Adverse Reactions

Dizziness, upper respiratory infection, nasal congestion, and back pain.

Warnings & Precautions

- ***BBW:*** Fetal Toxicity
- Hypotension
- Monitor renal function and potassium in susceptible patients

Drug Interactions

- Agents Increasing Serum Potassium
- Lithium
- NSAIDs
- Dual Inhibition of the Renin-Angiotensin System

Use in Specific Populations

- Lactation: Advise not to breastfeed during treatment with Arbli and for 2 days after the last dose.
- Hepatic Impairment: Recommended starting dose 25 mg once daily.
- Pediatric Patients: Arbli is not recommended in pediatric patients less than 2 years of age or in pediatric patients with glomerular filtration rate less than 30 mL/min/1.73 m^2.

Drug Interactions

- Agents Increasing Serum Potassium
- Lithium
- NSAIDs
- Dual Inhibition of the Renin-Angiotensin System

Clinical Studies

The effectiveness was established based on adequate and well-controlled studies of losartan solid dosage form.

Place in Therapy

Losartan is an angiotensin II receptor blocker (ARB) that is also currently available generically as an oral tablet. Arbli provides a treatment option for patients who need or prefer an oral liquid formulation of losartan.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Hemiclor™ (chlorthalidone) tablets for oral use

FDA-Approved Indication

For the treatment of hypertension in adults, to lower blood pressure.

Dosage & Administration

12.5 mg or 25 mg orally once daily. Dose may be doubled after 2 to 4 weeks as needed based on individual response, up to a maximal dose of 100 mg once daily.

Dosage Forms & Strengths

Tablets: 12.5 mg

Contraindications

- Anuria
- Hypersensitivity to chlorthalidone or other sulfonamide-derived drugs

Common Adverse Reactions

Electrolyte abnormalities and metabolic disturbances.

Warnings & Precautions

- Acute Kidney Injury
- Electrolyte Abnormalities
- Metabolic Disturbances
- Systemic Lupus Erythematosus

Drug Interactions

- Insulin requirements and oral hypoglycemic agent dosages may require adjustments.
- Possible increased responsiveness to tubocurarine.
- Possible decreased arterial responsiveness to norepinephrine.
- Lithium renal clearance is reduced by chlorthalidone, increasing the risk of lithium toxicity.

Use in Specific Populations

- Pregnancy: May cause fetal harm.
- Lactation: Breastfeeding is not recommended.
- Geriatric Use: No overall difference in responses versus younger patients, but care should be taken in dose selection in patients with impaired renal function.
- Hepatic Impairment: Alterations on fluid and electrolyte balance should be monitored in patients with hepatic impairment.

Clinical Studies

The efficacy of a once daily dose of chlorthalidone 12.5 mg for the treatment of hypertension in adults is derived from a published randomized, double-blind, multinational, study along with other supportive studies from published literature.

Place in Therapy

Chlorthalidone is used alone or together with other medicines for the treatment of hypertension.

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*
Rivaroxaban Tablets 2.5mg	Lupin Pharmaceuticals, Inc.; Taro Pharmaceutical Industries Ltd	Xarelto 2.5 mg	Anticoagulants	Treatment and Prevention of Blood Clots	3/7/2025
Eluxadoline Tablets 75 mg and 100 mg	Zydus Pharmaceuticals (USA) Inc.	Viberzi	Gastrointestinal Agents	Irritable Bowel Syndrome with Diarrhea (IBS-D)	2029
Apalutamide Tablets 60 mg	Zydus Pharmaceuticals (USA) Inc.	Erleada 60 mg	Antineoplastics and Adjunctive Therapies	Prostate Cancer	Possibly 2035
Bimatoprost Ophthalmic Solution 0.01%	Mankind Pharma Limited	Lumigan	Ophthalmic Agents	Glaucoma	Possibly 2027
Lidocaine Topical Patch 1.8%	Aveva Drug Delivery Systems Inc	ZTlido	Dermatologicals	Post-Herpetic Neuralgia	Possibly 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
Tevimbra (tislelizumab-jsgr) From: Beigene	[1] As a single agent in adult with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-L1 inhibitor; [2] In combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first line treatment of unresectable or metastatic HER-2 negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1.	In combination with platinum-containing chemotherapy, for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
Neffy (epinephrine) From: ARS Pharmaceuticals, Inc	For the treatment of type I allergic reactions in pediatric patients.	For the emergency treatment of type I allergic reactions, including anaphylaxis, in adults and pediatric patients who weigh 30kg or greater.
Furoscix (furosemide) From: Scpharmaceuticals	For the treatment of edema in adult patients with chronic heart failure or chronic kidney disease.	For the treatment of congestion due to fluid overload in chronic heart failure.
Iluvien (fluocinolone acetonide) From: Ani Pharmaceuticals	For the treatment of diabetic macular edema.	For the treatment of chronic non-infectious uveitis.
Tremfya (guselkumab) From: Janssen Biotech	[1] Moderate to severe plaque psoriasis; [2] Active psoriatic arthritis; [3] Moderate to severe ulcerative colitis.	For the treatment of moderate to severe Crohn's disease.
Fabhalta (iptacopan) From: Novartis	[1] Paroxysmal Nocturnal Hemoglobinuria; [2] Immunoglobulin A Nephropathy.	For the treatment of adults with complement 3 glomerulopathy to reduce proteinuria.
Amvuttra (vutrisiran) From: Alnylam Pharms Inc	For the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.	For the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalization and urgent heart failure visits.

Cabometyx (cabozantinib) From: Exelixis Inc	For the treatment of: [1] Patients with advanced renal cell carcinoma (RCC); [2] Patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab; [3] Patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib; [4] Adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.	For the treatment of adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well differentiated extra-pancreatic and pancreatic neuroendocrine tumors.
Imfinzi (durvalumab) From: AstraZeneca	[1] For the treatment of adult patients with unresectable, stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; [2] Indicated in combination with tremelimumab-actl and platinum-based chemotherapy, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; [3] In combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC); [4] In combination with gemcitabine and cisplatin, as treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC); [5] In combination with tremelimumab - actl, for the treatment of adult patients with unresectable hepatocellular carcinoma (UHCC); [6] Indicated in combination with carboplatin and paclitaxel	In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer.

	followed by Imfinzi as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (DMMR); [7] For the treatment of resectable non-small cell lung cancer before and after surgery ; [8] For the treatment of adult patients with limited -stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (CCRT).	
Pluvicto (lutenium lu 177 vipivotid tetraxetan) From: Novartis	For the treatment of adult patients with prostate-specific membrane antigen (PSMA)-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.	For the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy.

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
Depemokimab From: GSK	Asthma, Chronic Rhinosinusitis with Nasal Polyps	BLA accepted	Moderate
Deramiocel From: Capricor Therapeutics	Duchenne Muscular Dystrophy Cardiomyopathy	BLA accepted	High
Bysanti From: Vanda Pharmaceuticals Inc.	Bipolar Disorder, Schizophrenia	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
Ticagrelor	Brilinta	AstraZeneca
Eslicarbazepine Acetate	Aptiom	Sumitomo Pharma