PharmNotes

Monthly Communications

April 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 April.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Vanrafia™ (atrasentan) tablets for oral use

FDA-Approved Indication

To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.

Dosage & Administration

0.75 mg orally once daily with or without food.

Dosage Forms & Strengths

Tablets: 0.75 mg

Contraindications

- Pregnancy
- Hypersensitivity

Common Adverse Reactions

Peripheral edema and anemia

Warnings & Precautions

- ***BBW***: Embryo-Fetal toxicity
- Hepatotoxicity
- Fluid Retention
- Decreased Sperm Counts

Drug Interactions

- Strong or moderate CYP3A inducers
- OATP1B1/1B3 inhibitors

Use in Specific Population

- Lactation: Advise not to breastfeed.

Clinical Studies

The approval came from a prespecified interim analysis of the Phase 3 ALIGN study, a randomized, double-blind, placebo-controlled, multicenter, multicenter study in adults with biopsy-proven primary IgAN, an eGFR ≥30 mL/min/1.73 m^2, and urine protein ≥1 g/day on a stable dose of maximally tolerated renin-angiotensin system inhibitor. Results showed that Vanrafia reduced proteinuria by 36.1% compared to placebo. Among the 29 patients taking SGLT2 inhibitors, Vanrafia demonstrated a 37.4% reduction in proteinuria compared with placebo.

Place in Therapy

The Kidney Disease: Improving Global Outcomes (KDIGO) 2021 Clinical Practice Guidelines recommend as initial therapy an ACE inhibitor or ARB for patients with proteinuria >0.5 g per day. Newer therapies have emerged such as Tarpeyo (budesonide), Filspari (sparsentan) and, recently, Fabhalta (iptacopan).

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Penpulimab-kcqx injection for intravenous use

FDA-Approved Indication

[1] In combination with either cisplatin or carboplatin and gemcitabine for the first-line treatment of adults with recurrent or metastatic nonkeratinizing nasopharyngeal carcinoma (NPC); [2] As a single agent for the treatment of adults with metastatic nonkeratinizing NPC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.

Dosage & Administration

- In combination with either cisplatin or carboplatin and gemcitabine 200 mg intravenously over 60 minutes every 3 weeks until disease progression or a maximum of 24 months.
- Single agent: 200 mg intravenously over 60 minutes every 2 weeks until disease progression or a maximum of 24 months.

Dosage Forms & Strengths

Injection: 100 mg/10 mL (10 mg/mL) solution in a single-dose vial.

Contraindications

None

Common Adverse Reactions

- Penpulimab-kcqx as a single agent: Anemia and hypothyroidism.
- Penpulimab-kcqx in combination with either cisplatin or carboplatin and gemcitabine: Nausea, vomiting, hypothyroidism, constipation, decreased appetite, decreased weight, cough, COVID-19 infection, fatigue, rash, and pyrexia.

Warnings & Precautions

- Immune-Mediated Adverse Reactions
- Infusion-Related Reactions
- Complications of Allogeneic HSCT*C*
- Embryo-Fetal Toxicity

Use in Specific Populations

Lactation: Advise not to breastfeed.

Clinical Studies

The FDA approval is based on two pivotal clinical trials. The Phase 3 Study AK105-304 compared penpulimab-kcqx plus chemotherapy versus placebo plus chemotherapy in first-line recurrent or metastatic non-keratinizing NPC. The median progression-free survival (PFS) was 9.6 months for the penpulimab-kcqx arm versus 7.0 months for placebo. The 12-month PFS rate was 31% versus 11%, respectively. The Phase 2 Study AK105-202 evaluated single-agent penpulimab-kcqx in patients with disease progression after platinum-based chemotherapy and one additional prior systemic therapy. The overall response rate (ORR) was 28%.

Place in Therapy

Penpulimab-kcqx will compete most directly with Loqtorzi, which is also approved for the first-line treatment of NPC. NCCN Head and Neck Cancers Guidelines – Recommended Systemic Therapies for NPC: Recurrent, Unresectable, Oligometastatic, or Metastatic Disease (With No Surgery or RT Option) state as a first-line preferred option the use of cisplatin/gemcitabine + Loqtorzi (category 1).

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Immavy™ (nipocalimab) injection, for intrevanous use

FDA-Approved Indication

For the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Dosage & Administration

Initial dosage of 30 mg/kg once via intravenous infusion over at least 30 minutes. Two weeks after the initial dosage, administer a maintenance dosage of 15 mg/kg via intravenous infusion over at least 15 minutes, and continue every two weeks thereafter.

Dosage Forms & Strengths

- Injection: 300 mg/1.62 mL (185 mg/mL) in a single-dose vial.
- Injection: 1,200 mg/6.5 mL (185 mg/mL) in a single-dose vial.

Contraindications

In patients with a history of serious hypersensitivity reaction to nipocalimab or to any of the excipients in Imaavy.

Common Adverse Reactions

Respiratory tract infections, peripheral edema, and muscle spasms.

Warnings & Precautions

- Infections
- Hypersensitivity
- Infusion-Related Reactions

Drug Interactions

- Closely monitor for reduced effectiveness of medications that bind to the human neonatal Fc receptor.

Clinical Studies

The approval of Imaavy came from the results of the ongoing Phase 3 Vivacity-MG3 study, which enrolled 199 adults with gMG, 153 of whom were antibody positive. The efficacy of Imaavy was measured using the Myasthenia Gravis-Activities of Daily Living (MG-ADL) scale. Patients who received Imaavy plus standard-of-care therapy demonstrated a statistically significant improvement in MG-ADL scores versus patients who received standard-of-care plus placebo at 24 weeks. Patients who received Imaavy also experienced a reduction in autoantibody levels of up to 75% from the first dose through 24 weeks.

Place in Therapy

Medications such as pyridostigmine, corticosteroids, immunosuppressants, and rituximab (off-label) are available for the treatment of this disease. Immavy will compete directly with several FcRn blockers approved to treat gMG in adults such as Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo vial and prefilled syringe (efgartigimod alfa and hyaluronidase-qvfc), and Rystiggo (rozanolixizumab-noli). In pediatric patients 12 years of age and older, there are no direct competitors that are FcRn blockers; however, Imaavy may compete with complement inhibitors in pediatric patients who are anti-AChR antibody positive.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Zevaskyn™ (prademagene zamikeracel) gene-modified cellular sheets, for topical use

FDA-Approved Indication

For the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

Dosage & Administration

Based on the surface area of the wound(s). One sheet of Zevasky covers an area of 41.25 cm^2.

Dosage Forms & Strengths

Supplied as a single-dose of up to twelve cellular sheets, each measuring 41.25 cm^2 and consisting of patient's own, viable, gene-modified cells that contain functional copies of the COL7A1 gene, which express collagen 7 (C7) protein.

Contraindications

None

Common Adverse Reactions

Procedural pain and pruritus.

Warnings & Precautions

- Hypersensitivity reactions to vancomycin, amikacin, or product excipients may occur with Zevaskyn application.
- Retroviral vector (RVV)-mediated insertional oncogenesis may potentially occur after treatment with Zevaskyn.
- Transmission of infectious agents may occur because Zevaskyn is manufactured using human- and bovine-derived reagents.

Clinical Studies

The approval came from a randomized, intrapatient-controlled study known as VIITAL. The study compared the application of Zevaskyn to the standard of care treatment in patients with wounds associated with RDEB. A total of 86 wounds in 11 patients were enrolled and treated with Zevaskyn or standard of care. The co-primary efficacy outcome measures were proportion of randomized wound pairs with at least 50% healing at month 6 with confirmation of wound healing two weeks later, and pain reduction as assessed by the mean differences in patient-reported pain scores using the Wong-Baker FACES scale between randomized wound pairs at month 6. The proportion of randomized wound pairs that healed ≥ 50% from baseline was 81% with Zevaskyn and 16% with control ($p < 0.0001$). The mean pain reduction from baseline was -3.07 with Zevaskyn and -0.90 with control ($p = 0.0002$).

Place in Therapy

This product is the first and only autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). There is no cure for RDEB but Zevaskyn, being the only FDA-approved product indicated for this disorder, can be used to treat RDEB wounds with a single application.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Jobevne™ (bevacizumab-nwgd) injection, for intravenous use

FDA-Approved Indication

[1] Metastatic colorectal cancer; [2] First-line non-squamous non-small cell lung cancer; [3] Recurrent glioblastoma; [4] Metastatic renal cell carcinoma; [5] Persistent, recurrent, or metastatic cervical cancer; [6] Epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Dosage & Administration

Refer to package insert for further information.

Dosage Forms & Strengths

Injection: 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) in a single dose vial.

Contraindications

None

Common Adverse Reactions

Epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis.

Warnings & Precautions

- Gastrointestinal Perforations and Fistula
- Surgery and Wound Healing Complications
- Hemorrhage
- Arterial Thromboembolic Events (ATE)
- Venous Thromboembolic Events (VTE)
- Hypertension
- Posterior Reversible Encephalopathy Syndrome (PRES)
- Renal Injury and Proteinuria
- Infusion-Related Reactions
- Embryo-Fetal Toxicity
- Ovarian Failure
- Congestive Heart Failure (CHF)

Use in Specific Populations

Lactation: Advise not to breastfeed.

Clinical Studies

The approval for Jobevne (bevacizumab-nwgd) was based on a comprehensive package of comparative pharmacokinetic, safety, efficacy, nonclinical, structural, analytical and functional data, which confirmed that Jobevne is highly similar to Avastin (bevacizumab). The data demonstrated that there were no clinically meaningful differences between Jobevne and Avastin in terms of pharmacokinetics, safety, efficacy, and immunogenicity.

Place in Therapy

Jobevne is the sixth FDA-approved biosimilar to Avastin. Other biosimilars available include Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-adcd) and Avzivi (bevacizumab-tnjn).

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Mezofy (aripiprazole) oral film

FDA-Approved Indication

For the treatment of schizophrenia in adult and pediatric patients ages 13 years and older.

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

Oral Film: 5 mg, 10 mg, 15mg

Contraindications

Known hypersensitivity to aripiprazole.

Common Adverse Reactions

Akathisia, extrapyramidal disorder, somnolence and tremor.

Warnings & Precautions

- ***BBW:*** Increased Mortality in Elderly Patients with Dementia-Related Psychosis
- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis
- Neuroleptic Malignant Syndrome
- Tardive Dyskinesia
- Metabolic Changes
- Pathological Gambling and Other Compulsive Behaviors
- Orthostatic Hypotension
- Leukopenia, Neutropenia, and Agranulocytosis
- Seizures
- Potential for Cognitive and Motor Impairment

Use in Specific Populations

Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure.

Clinical Studies

The efficacy of Mezofy oral film has been established based on adequate and well-controlled studies of oral aripiprazole in the treatment of schizophrenia in adult and pediatric patients ages 13 to 17 years.

Place in Therapy

Aripiprazole is already available across different oral and injectable formulations for schizophrenia. This new formulation, which is easily dissolved in the mouth, can help improve the adherence of patients with schizophrenia.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Eliquis™ & Eliquis™ Sprinkle (apixaban) tablets and pellets for oral suspension

FDA-Approved Indication

[1] Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation; [2] Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery; [3] Treatment of Deep Vein Thrombosis; [4] Treatment of Pulmonary Embolism; [5] Reduction in the Risk of Recurrence of DVT and PE; [6] Treatment of VTE and Reduction in the Risk of Recurrent VTE in Pediatric Patients.

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

- Tablet For Oral Suspension: 0.5 mg
- For Oral Suspension: 0.15 mg in a yellow opaque capsule

Contraindications

- Active pathological bleeding
- Severe hypersensitivity to Eliquis

Common Adverse Reactions

Bleeding, headache, excess menstrual bleeding, and vomiting.

Warnings & Precautions

- ***BBW:*** Premature Discontinuation of Eliquis Increases the Risk of Thrombotic Events & Spinal/Epidural Hematoma
- Not Recommended in Prosthetic Heart Valves
- Increased Risk of Thrombosis in Patients with Triple Positive Antiphospholipid Syndrome

Drug Interactions

- Combined P-gp and strong CYP3A4 inhibitors increase blood levels of apixaban
- Simultaneous use of combined P-gp and strong CYP3A4 inducers reduces blood levels of apixaban

Use in Specific Populations

- Pregnancy: Not recommended.
- Lactation: Advise not to breastfeed
- Severe Hepatic Impairment: Not recommended

Clinical Studies

The approval of Eliquis for the new pediatric indication was based on CV185325, a randomized, active-controlled, open-label study in 229 pediatric patients from birth to less than 18 years with confirmed VTE. Patients were randomized to receive either an age-appropriate formulation and body weight-adjusted dose of Eliquis or standard of care. The percentage of patients with symptomatic and asymptomatic recurrent VTE and VTE related mortality was 2.6% with Eliquis vs. 2.7% with standard of care.

Place in Therapy

Both new formulations offer patients, particularly pediatric patients weighing less than 35 kg, ease of administration.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Qamzova™ (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-NSAID analgesics.

Dosage & Administration

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

Dosage Forms & Strengths

Injection: 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 Rash 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.

Clinical Studies

The efficacy and safety of meloxicam injection in the treatment of moderate to severe pain was evaluated in two Phase 3 randomized, double-blind, placebo-controlled, multiple-dose clinical trials in patients with postoperative pain.

Place in Therapy

Meloxicam is currently available generically as an oral tablet and suspension.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Atzumi (dihydroergotamine mesylate) nasal powder

FDA-Approved Indication

For the acute treatment of migraine with or without aura in adults.

Dosage & Administration

The recommended dose is 5.2 mg, the contents of one nasal device, administered into one nostril. The dose may be repeated, if needed, a minimum of 1 hour after the first dose. The maximum dose in a 24-hour period is 10.4 mg (two doses).

Dosage Forms & Strengths

Nasal powder: 5.2 mg

Contraindications

- Concomitant use of strong CYP3A4 inhibitors
- Ischemic heart disease or coronary artery vasospasm
- Uncontrolled hypertension, peripheral arterial diseases, sepsis, following vascular surgery, or severe hepatic or renal impairment.
- Hypersensitivity to ergot alkaloids
- Concomitant use of other 5-HT1 agonists or ergotamine-containing or ergot-type medications within 24 hours
- Concomitant use of peripheral and central vasoconstrictors

Common Adverse Reactions

Rhinitis, nausea, altered sense of taste, application site reactions, dizziness, vomiting, somnolence, pharyngitis, and diarrhea.

Warnings & Precautions

- ***BBW:*** Peripheral Ischemia Following Coadministration with Strong CYP3A4 Inhibitors
- Myocardial Ischemia and/or Infarction or other Cardiac Adverse Reactions and Fatalities
- Cerebrovascular Reactions and Fatalities
- Other Vasospasm Related Adverse Reactions
- Medication Overuse Headache
- Preterm Labor
- Fibrotic Complications
- Local Irritation

Drug Interactions

- Beta Blockers/Nicotine
- Selective Serotonin Reuptake Inhibitors

Use in Specific Populations

- Pregnancy: Based on animal data, may cause fetal harm.
- Lactation: Advise not to use during breastfeeding.

Clinical Studies

The approval of Atzumi was based on data from 2 clinical trials: a phase 1 pharmacokinetics study and the phase 3 ASCEND trial, which evaluated the long-term safety and tolerability of the product. Results from the phase I study showed fast absorption with Atzumi, and rapid and sustained DHE plasma concentrations. Compared with dihydroergotamine mesylate nasal spray, DHE plasma concentrations were found to be higher with the nasal powder. Results from the ASCEND trial showed that long term, repeated, as-needed use of Atzumi was safe and beneficial, leading to rapid freedom from pain and symptoms associated with migraine.

Place in Therapy

DHE has been widely used as a first-line treatment option for migraine. Atzumi is the first DHE nasal powder available for the acute treatment of migraine and utilizes an innovative technology known as SMART (Simple MucoAdhesive Release Technology) which combines the powder formulation and the nasal device technology for delivery of DHE.

Other notable new approvals include:

Livmarli (maralixibat) tablets for oral use

Livmarli is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS). It is also indicated for the treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Livmarli tablets are a new formulation of maralixibat. Livmarli is also available as an oral solution (9.5 mg and 19 mg per mL).

Lopressor (metoprolol tartrate) solution for oral use

Lopressor is a beta-adrenergic blocker indicated in adult patients for the treatment of hypertension, angina pectoris, and myocardial infarction. Metoprolol tartrate is available generically as an oral tablet.

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*
Siponimod Tablets 0.25mg (base), 1mg (base), and 2mg (base)	RiconPharma LLC	Mayzent	Psychotherapeutic and Neurological Agents	Multiple Sclerosis	2033-2034
Naloxone Hydrochloride Nasal Spray 8mg per spray	Padagis Pharmaceuticals Ltd	Kloxxado	Antidotes and Specific Antagonists	Opioid Overdose	2033-2034
Pilocarpine Hydrochloride Ophthalmic Solution 1.25%	Amneal Pharmaceuticals LLC	Vuity	Ophthalmic Agents	Presbyopia	Mid 2025
Latanoprostene Bunod Ophthalmic Solution 0.024%	Gland Pharma Limited	Vyzulta	Ophthalmic Agents	Glaucoma	2028-2029

*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
Uplizna (inebilizumab-cdon) From: Amgen	For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.	For the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients.
Opdivo (nivolumab) From: Brystol Myers Squibb	[1] Melanoma; [2] Non-Small Cell Lung Cancer; [3] Malignant Pleural Mesothelioma; [4] Renal Cell Carcinoma (RCC); [5] Classical Hodgkin Lymphoma (CHL); [6] Squamous Cell Carcinoma of The Head And Neck (SCCHN); [7] Urothelial Carcinoma; [8] Colorectal Cancer; [9] Hepatocellular Carcinoma; [10] Esophageal Cancer; [11] Gastric Cancer, Gastroesophageal Junction Cancer, And Esophageal Adenocarcinoma.	[1] Plus Yervoy (ipilimumab) for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC); [2] Plus Yervoy (ipilimumab) as a first-line treatment for adult patients with unresectable or metastatic hepatocellular carcinoma.
Valtoco (diazepam) From: Neurelis, Inc	For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older.	For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 years of age and older.
Isturisa (osilodrostat) From: Recordati Rare	For the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.	For the treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom surgery is not an option or has not been curative.
Dupixent (dupilumab) From: Regeneron Pharmaceuticals	[1] Atopic Dermatitis; [2] Asthma; [3] Chronic Rhinitis with Nasal Polyps; [4] Eosinophilic Esophagitis; [5] Prurigo Nodularis; [6] Chronic Obstructive Pulmonary Disease (COPD).	For the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment.
Eliquis (apixaban) From: Bristol Myers Squibb	[1] To reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation; [2] For the prophylaxis	For the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth

	of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in adult patients who have undergone hip or knee replacement surgery; [3] For the treatment of adults with DVT; [4] For the treatment of adults with PE; [5] To reduce the risk of recurrent DVT and PE in adult patients following initial therapy.	and older after at least 5 days of initial anticoagulant treatment.
Rinvoq (upadacitinib) From: Abbvie	[1] Rheumatoid Arthritis; [2] Psoriatic Arthritis; [3] Atopic Dermatitis; [4] Ulcerative Colitis; [5] Crohn's Disease; [6] Ankylosing Spondylitis; [7] Non-Radiographic Axial Spondylarthritis; [8] Polyarticular Juvenile Idiopathic Arthritis.	For the treatment of Giant Cell Arteritis (GCA).

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.

No significant drugs were in the Pipeline during the month of April.

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
Eslicarbazepine Acetate	Aptiom	Sumitomo Pharma
Perampanel	Fycompa (tablets)	Eisai; Catalyst Pharmaceuticals