PharmNotes

Monthly Communications

June 2024

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 June.

New FDA-Approved Drug Products

New Molecular Entity

Rytelo™ (imetelstat) Injection

Specialty | Orphan Drug

FDA-Approved Indication

For the treatment of adult patients with low -to intenermediate-1 myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units to or are ineligible for erythropoiesis-stimulating agents (ESA).

Dosage & Administration

- 7.1 mg/kg administered as an intravenous infusion over 2 hours every 4 weeks
- Premedicate prior to dosing with diphenhydramine and hydrocortisone.

Dosage Forms & Strengths

For injection:

- 47 mg powder in a single-dose vial for reconstitution
- 188 mg powder in a single-dose vial for reconstitution.

Contraindications

None

Common Adverse Reactions

Decreased platelets, decreased white blood cells, decreased neutrophils, increased AST, increased alkaline phosphatase, increased ALT, fatigue, prolonged partial thromboplastin time, arthralgia/myalgia, COVID-19 infections, and headache.

Warnings & Precautions

- Thrombocytopenia
- Neutropenia
- Infusion-Related Reactions
- Embryo-Fetal Toxicity

Use in Specific Populations

- Lactation: Advise not to breastfeed

Clinical Studies

The FDA approval is based on results from the IMerge Phase 2/3 clinical trial. The IMerge trial met its primary and key secondary endpoints, with Rytelo demonstrating significantly higher rates of red blood cell transfusion independence (RBC-TI) versus placebo for at least eight consecutive weeks (Rytelo 39.8% vs. placebo 15.0%; $p<0.001$) and for at least 24 weeks (Rytelo 28.0% vs. placebo 3.3%; $p<0.001$). RBC-TI was durable and sustained in the Rytelo treated population, with a median RBC-TI duration for 8-week responders and 24-week responders of approximately 1 year and 1.5 years, respectively.

Place in Therapy

Myelodysplastic syndromes (MDS) are a heterogeneous group of hematopoietic cell disorders described by abnormal differentiation, morphology, and maturation of myeloid cells. Anemia is a systemic manifestation that tends to occur in patients with MDS. Patients often become blood transfusion dependent, which impacts quality of life and shortens survival. Rytelo is the first oligonucleotide human telomerase inhibitor to be approved by the FDA. Rytelo could compete with Reblozyl (luspatercept); both products are used to treat MDS in patients that fail ESAs.

New FDA-Approved Drug Products

New Molecular Entity

Iqirvo™ (elafibranor) Tablets

Specialty | Orphan Drug

FDA-Approved Indication

For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

Dosage & Administration

80 mg orally once daily with or without food.

Dosage Forms & Strengths

Tablets: 80 mg

Contraindications

None

Common Adverse Reactions

Weight gain, diarrhea, abdominal pain, nausea, vomiting, arthralgia, constipation, muscle injury, fracture, gastroesophageal reflux disease, dry mouth, weight loss, and rash.

Warnings & Precautions

- Myalgia, Myopathy and Rhabdomyolisis
- Fractures
- Adverse effects on Fetal and Newborn Development
- Drug-Induced Liver Injury
- Hypersensitivity Reactions
- Biliary Obstruction

Clinical Studies

The approval of Iqirvo is based on data from the Phase III ELATIVE trial. The ELATIVE trial demonstrated that 13 times more patients achieved the composite primary endpoint of biochemical response when treated with Iqirvo plus UDCA versus placebo plus UDCA (Iqirvo 51% versus placebo 4%, for a 47% treatment difference). ALP is a biochemical marker and is used as a surrogate endpoint in PBC trials. Secondary endpoints showed normalization in ALP levels in only Iqirvo-treated patients (15% for Iqirvo plus UDCA versus 0% for placebo plus UDCA).

Place in Therapy

Iqirvo is a first-in-class oral, once-daily peroxisome proliferator-activated receptor (PPAR) agonist. PBC is a rare, autoimmune, progressive liver disease that leads to fibrosis and inflammation of the small bile ducts and is characterized by fatigue, pruritus, and jaundice. Ursodiol (ursodeoxycholic acid [UDCA]) is FDA-approved for the treatment of PBC. Iqirvo will be used in a second line setting for PBC.

New FDA-Approved Drug Products

New Molecular Entity

Yimmugo™ (immune globulin intravenous, human-dira)

Specialty

FDA-Approved Indication

For the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age or older.

Dosage & Administration

- 1st infusion recommended dose: 300–800 mg/kg (3–8 mL/kg) every 3–4 weeks
- From the 2nd infusion and on: 300–800 mg/kg (3–8 mL/kg) every 3–4 weeks

Dosage Forms & Strengths

Solution containing 10% IgG (100 mg/mL): 5 g in 50 mL, 10 g in 100 mL, 20 g in 200 mL

Contraindications

- History of anaphylactic or severe systemic reaction to human immune globulin.
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

Common Adverse Reactions

Headache, upper respiratory tract infections, fatigue, nausea and increased blood pressure.

Warnings & Precautions

- IgA-deficient patients with antibodies to IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions to Yimmugo.
- Hemolysis, either intravascular or due to enhanced red blood cell sequestration can develop subsequent to Yimmugo treatments.
- In patients at risk of developing acute renal failure, monitor renal function, including blood urea nitrogen (BUN) and serum creatinine, and urine output.
- Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia can occur in patients receiving IGIV treatment.

Warnings & Precautions, cont.

- Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments, especially with high doses or rapid infusion
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI])
- Yimmugo is made from human blood and may contain infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease [vCJD] agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent

Clinical Studies

The approval was based on data from an open-label, prospective, phase 3 study that evaluated the efficacy and safety of Yimmugo in 60 patients with PI, who had established immune globulin intravenous therapy for at least 3 months with a constant dose, and at least one IgG trough level of at least 5g/L during the previous 3 months. The primary efficacy outcome measure was the rate of serious bacterial infections. The study demonstrated that treatment with Yimmugo resulted in less than one SBI per person-year.

Place in Therapy

Yimmugo has little clinical differentiation from other IVIG products, except for its approved maximum administration rate of 13 mg/kg/min after the first dose.

New FDA-Approved Drug Products

New Molecular Entity

Capvaxive™ (pneumococcal 21-valent conjugate) Vaccine

FDA-Approved Indication

- Active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.
- Active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.

Dosage & Administration

For intramuscular use: Administer a single 0.5 mL dose.

Dosage Forms & Strengths

Injection: A single dose is 0.5 mL.

Contraindications

Severe allergic reaction (e.g., anaphylaxis) to any component of Capvaxive or to diphtheria toxoid.

Common Adverse Reactions

Injection-site pain, fatigue, headache, myalgia, injection-site erythema, and injection-site swelling.

Clinical Studies

The STRIDE-3 and STRIDE-6 studies evaluated the safety and immunogenicity of Capvaxive in pneumococcal vaccine-naïve adults and adults 50 years of age and older who previously received a pneumococcal vaccination at least 1 year prior to study enrollment. Patients were randomly assigned to receive 1 dose of either Capvaxive or PCV20 (or PPSV23). Capvaxive prompted robust immune responses in vaccine-naïve and previously vaccinated individuals.

Place in Therapy

Pneumococcal disease is a serious bacterial infection caused by Streptococcus pneumoniae. This is the first pneumococcal vaccine that is specifically designed to protect against the serotypes that primarily infect older adults. Those serotypes are responsible for about 27% of invasive diseases caused by *S. pneumoniae*. The ACIP voted unanimously in support of recommendations for its use in [1] Adults 65 years of age or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown; [2] Adults 19-64 years of age or older with certain underlying medical conditions or other risk factors who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown; [3] Adults 19 years of age and older who have started their pneumococcal vaccine series with Prevnar 13 but have not received all recommended Pneumovax 23 doses; [4] Adults who have completed their vaccine series with Prevnar 13 and Pneumovax 23, with shared clinical decision making. The ACIP will discuss recommendations for use of Prevnar 20 and Capvaxive for adults aged 50 and over at its meeting in October 2024.

New FDA-Approved Drug Products

New Molecular Entity

Sofdra™ (sofpironium) Topical Gel

FDA-Approved Indication

For the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

Dosage & Administration

1 pump of Sofdra applied per underarm once a day at bedtime.

Dosage Forms & Strengths

Topical gel: 12.45% of sofpironium

Contraindications

Medical conditions that can be exacerbated by the anticholinergic effect of Sofdra (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjögren's syndrome).

Common Adverse Reactions

Dry mouth, vision blurred, application site pain, application site erythema, mydriasis, application site dermatitis, application site pruritus, urinary retention, and application site irritation.

Warnings & Precautions

- Urinary Retention
- Control of Body Temperature
- Operating Machinery or an Automobile

Clinical Studies

The FDA approval was supported by results from the two Phase 3 CARDIGAN studies which evaluated the efficacy and safety of Sofdra versus vehicle in 701 patients with primary axillary hyperhidrosis. In the studies, treatment with Sofdra met all primary and secondary endpoints with clinically and statistically meaningful changes from baseline in Gravimetric Sweat Production (GSP) and the Hyperhidrosis Disease Severity Measure-Axillary, 7-item (HDSM-AX7) score. Approximately 85% of patients showed significant improvement in hyperhidrosis symptoms.

Place in Therapy

According to the Archives of Dermatological Research (2016), the prevalence of hyperhidrosis in the United States is about 5%. Treatment options include topical antiperspirants, iontophoresis, oral glycopyrrolate, oral oxybutynin, botulinum toxin and even surgery in refractory cases. Prior to the approval, the only FDA-approved topical anticholinergic for hyperhidrosis was glycopyrronium tosylate (Qbrexza), approved in 2018.

New FDA-Approved Drug Products

New Molecular Entity

Ohtuvayre™ (ensifentrine) Oral Inhalation Suspension

Specialty

FDA-Approved Indication

For the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

Dosage & Administration

3 mg (one ampule) twice daily administered by oral inhalation using a standard jet nebulizer with a mouthpiece.

Dosage Forms & Strengths

Inhalation suspension: 3 mg/2.5 mL aqueous suspension in unit-dose ampules.

Contraindications

In patients with hypersensitivity to ensifentrine or any component of this product.

Common Adverse Reactions

Back pain, hypertension, urinary tract infection, and diarrhea.

Warnings & Precautions

- Should not use Ohtuvayre to treat acute symptoms of bronchospasm
- If paradoxical bronchospasm occurs, discontinue Ohtuvayre and institute alternative therapy
- An increase in psychiatric adverse reactions, including suicidality, were reported with use of Ohtuvayre. Carefully weigh the risks and benefits of treatment with Ohtuvayre in patients with a history of depression and/or suicidal thoughts or behavior.

Clinical Studies

The approval was based on findings from the phase 3 ENHANCE trials, which included 2 replicates randomized, double-blind, placebo-controlled, multicenter trials (ENHANCE-1 and ENHANCE-2). The trials evaluated the efficacy and safety of nebulized ensifentrine in patients with moderate to severe COPD. Results showed that treatment with ensifentrine significantly improved average forced expiratory volume in 1 second (FEV_1) area under the curve over 12 hours ($AUC_{0\text{-}12h}$) at week 12 compared with placebo. Ensifentrine also improved the mean morning trough FEV_1 at week 12 compared with placebo.

Place in Therapy

Ohtuvayre is a first-in-class selective dual inhibitor of the enzymes phosphodiesterase 3 and phosphodiesterase 4 (PDE3 and PDE4). This is the first inhaled product with a novel mechanism of action for chronic obstructive pulmonary disease to be approved in 20 years; it works through both bronchodilator and anti-inflammatory effects. Ohtuvayre was not studied as an add-on treatment to standard-of-care dual LAMA/LABA or triple LAMA/LABA/ICS inhaler maintenance therapies. Regardless, this product will most probably be an add-on therapy in patients not adequately controlled with one or more guideline-directed COPD maintenance therapies.

New FDA-Approved Drug Products

New Molecular Entity

Piasky™ (crovalimab-akkz) Intravenous Injection

Specialty | Orphan Drug

FDA-Approved Indication

For the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg.

Dosage & Administration

For body weight ≥ 40 kg to < 100 kg

- Loading dose on day 1: 1,000 mg (IV)
- Loading dose on day 2,8,15,22: 340 mg (SubQ)
- Maintenance dose (day 29 and every 4 weeks thereafter): 680 mg (SubQ)

For body weight >100 kg

- Loading dose on day 1: 1,500 mg (IV)
- Loading dose on day 2,8,15,22: 340 mg (SubQ)
- Maintenance dose (day 29 and every 4 weeks thereafter): 1,020 mg (SubQ)

Dosage Forms & Strengths

Injection: 340 mg/2 mL (170 mg/mL) in a single-dose vial.

Contraindications

- Initiation during unresolved serious Neisseria meningitidis infection
- Serious hypersensitivity to crovalimab or any of the excipients

Common Adverse Reactions

Infusion-related reaction, respiratory tract infection, viral infection, and Type III hypersensitivity reactions.

Warnings & Precautions

- ***BBW*:** Serious Meningococcal Infections
  - Piasky REMS
- Type III hypersensitivity reactions
- Other Infections
- Infusion and Injection Related Reaction

Use in Specific Population

Lactation: Breastfeeding not recommended

Clinical Studies

The efficacy of Piasky was established in the Phase 3 COMMODORE 2, an active-controlled, open-label, noninferiority study in 204 adult patients with PNH not previously treated with a complement inhibitor. The study evaluated the safety and efficacy of Piasky versus eculizumab in C5 inhibitor-naive patients. The study met its co-primary efficacy endpoints of transfusion avoidance and control of hemolysis. The Phase 3 COMMODORE 1 trial studied people with PNH who switched to Piasky from currently approved C5 inhibitors. The results showed that Piasky maintained disease control in people switching from currently approved complement inhibitors.

Place in Therapy

Paroxysmal nocturnal hemoglobinuria (PNH) is a rare acquired hematopoietic stem cell disorder in which the body's immune system causes destruction of red blood cells. Piasky will compete with Soliris, Ultomiris, and Empaveli. Piasky binds to a different C5 binding site from current treatments, which has the potential to provide an effective treatment option for people with specific C5 gene mutations, who do not respond to current therapies.

New FDA-Approved Drug Products

New Biosimilar Product

Ahzantive™ (aflibercept-mrbb) Intravitreal Injection

Specialty

FDA-Approved Indication

For the treatment of [1] Neovascular (Wet) Age-Related Macular Degeneration (AMD); [2] Macular Edema Following Retinal Vein Occlusion (RVO); [3] Diabetic Macular Edema (DME); [4] Diabetic Retinopathy

Dosage & Administration

2mg (0.05mL) administered by intravitreal injection every 4 to 12 weeks, depending on the indication.

Dosage Forms & Strengths

Injection: 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial.

Contraindications

- Ocular or periocular infections
- Active intraocular inflammation
- Hypersensitivity

Common Adverse Reactions

Conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Warnings & Precautions

- Endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion may occur following intravitreal injections.
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.
- There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.

Clinical Studies

The approval of Ahzantive came from data from the phase 3 MAGELLAN-AMD study which compared aflibercept-mrbb to Eylea in patients with neovascular age related macular degeneration. Results showed that the study met its primary endpoint indicating comparable efficacy between the biosimilar and reference product based on the change from baseline in best corrected visual acuity after 8 weeks. Regarding safety and immunogenicity, no clinically relevant differences were observed between the treatment groups.

Place in Therapy

This is the third approved biosimilar product of Eylea, the other products being Yesafili and Opuviz. In order to gain any significant market share, launch pricing for this Eylea biosimilar will need to represent a significant discount to the brand's price.

New FDA-Approved Drug Products

New Biosimilar Product

Pyzchiva™ (ustekinumab-ttwe) Injection

Specialty

FDA-Approved Indication

[1] For the treatment of adult and pediatric patients 6 years and older with psoriasis; [2] For the treatment of adult and pediatric patients 6 years and older with psoriatic arthritis; [3] For the treatment of adult patients with Crohn's disease; [4] For the treatment of adult patients with ulcerative colitis.

Dosage & Administration

Based on body weight. Please refer to package insert for further information.

Dosage Forms & Strengths

- Subcutaneous Injection: 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe.
- Intravenous Infusion - Injection: 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 Pyzchiva.

Common Adverse Reactions

Nasopharyngitis, upper respiratory tract infection, headache, vomiting, bronchitis, fever, diarrhea, nausea, sinusitis, mycotic infections, injection site erythema, and fatigue.

Warnings & Precautions

- Infections
- Theoretical risk for particular infections
- Tuberculosis (TB)
- Malignancies
- Hypersensitivity Reactions
- Posterior Reversible Encephalopathy Syndrome (PRES)
- Immunizations
- Noninfectious Pneumonia

Clinical Studies

The approval was based on data from a phase 3 study that compared the efficacy and safety of Pyzchiva to the reference product Stelara in patients with moderate to severe plaque psoriasis. Results showed the products were therapeutically equivalent, meeting the primary endpoint for Psoriasis Area and Severity Index percent improvement from baseline to week 12. Pyzchiva was also found to be therapeutically equivalent to Stelara up to week 28. Also, the approval was supported by data from a phase 1 study that compared the pharmacokinetics, safety, tolerability and immunogenicity of Pyzchiva, administered as a single 45mg/0.5mL subcutaneous injection, to Stelara. Findings showed bioequivalence between Pyzchiva and the reference product.

Place in Therapy

Pyzchiva is the third biosimilar referencing Stelara to be approved. This product was approved with an interchangeability designation, allowing for it to be substituted for the reference product at the pharmacy without requiring the physician approval.

New FDA-Approved Drug Products

New Biosimilar Product

Nypozi™ (filgrastim-txid) Injection

Specialty

FDA-Approved Indication

[1] Decrease the incidence of infection, as manifested by febrile neutropenia; [2] Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML); [3] Reduce the duration of neutropenia and neutropenia-related clinical sequelae; [4] Reduce the incidence and duration of sequelae of severe neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Dosage & Administration

Based on body weight. Please refer to package insert for further information

Dosage Forms & Strengths

- Injection: 300 mcg/0.5 mL in a single-dose prefilled syringe.
- Injection: 480 mcg/0.8 mL in a single-dose prefilled syringe.

Contraindications

Patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim products or peg filgrastim products.

Common Adverse Reactions

Pyrexia, pain, rash, cough, bone pain, headache, dyspnea, anemia, epistaxis, diarrhea, hypoesthesia and alopecia.

Warnings & Precautions

- Fatal splenic rupture
- Acute respiratory distress syndrome (ARDS)
- Serious allergic reactions, including anaphylaxis
- Fatal sickle cell crises
- Glomerulonephritis
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML)
- Thrombocytopenia

Clinical Studies

The approval of Nypozi is based on evidence demonstrating a high degree of similarity to its reference product Neupogen.

Place in Therapy

Nypozi is the fourth FDA-approved biosimilar to Neupogen. Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi) and Releuko (filgrastim-ayow) are other available filgrastim products.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Tepylute™ (thiotepa) Intravenous Injection

FDA-Approved Indication

For the treatment of adenocarcinoma of the breast or ovary.

Dosage & Administration

0.3 mg/kg to 0.4 mg/kg intravenously.

Dosage Forms & Strengths

Injection: 15 mg/1.5 mL (10 mg/mL) of thiotepa solution in single dose vial.

Contraindications

Hypersensitivity to the active substance

Warnings & Precautions

- ***BBW:*** Severe Myelosuppression and Carcinogenicity
- Cutaneous Toxicity
- Polyethylene Glycol 400 Toxicity
- Embryo-fetal Toxicity

Common Adverse Reactions

Neutropenia, anemia, thrombocytopenia, elevated alanine aminotransferase, elevated aspartate aminotransferase, elevated bilirubin, mucositis, cytomegalovirus infection, hemorrhage, diarrhea, hematuria and rash.

Use in Specific Population

- Lactation: Advise not to breastfeed
- Moderate or severe renal impairment: Monitor patients more frequently for toxicity
- Moderate or severe hepatic impairment: Monitor patients more frequently for toxicity

Clinical Studies

Tepylute was approved under a 505(b)(2) NDA pathway.

Place in Therapy

This new, ready-to-use liquid formulation of thiotepa, a standard oncology product, removes the requirement for complex reconstitution. It provides clinicians easier administration of the product to the patients by eliminating the reconstitution process of the current lyophilized powder formulation.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Vigafyde™ (vigabatrin) Oral Solution

Orphan Drug

FDA-Approved Indication

For the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

Dosage & Administration

Initiate at a daily dosage of 50 mg/kg (25 mg/kg twice daily); increase total daily dosage every 3 days, in increments of 25 mg/kg/day to 50 mg/kg/day, up to a maximum daily dosage of 150 mg/kg (75 mg/kg twice daily).

Dosage Forms & Strengths

Oral Solution: 100 mg/Ml.

Contraindications

None

Warnings & Precautions

- ***BBW:*** Permanent Vision Loss
  - Vigabatrin REMS
- Abnormal MRI signal changes and intramyelinic edema
- Withdrawal of AEDs
- Anemia

Common Adverse Reactions

Somnolence, bronchitis, ear infection, and acute otitis media.

Drug Interactions

Decreased phenytoin plasma levels: Dosage adjustment may be needed.

Clinical Studies

Vigafyde was approved under a 505(b)(2) NDA pathway. The efficacy of Vigafyde is based upon a comparison of the compositional differences between vigabatrin for oral solution and Vigafyde oral solution.

Place in Therapy

Infantile spasms (IS) is a rare, severe form of epilepsy that typically begins in children less than one year old. Vigafyde is the first and only ready-to-use vigabatrin oral solution. Compared with other vigabatrin products, Vigafyde is a concentrated solution containing 100mg/mL of vigabatrin and requires a smaller volume than other vigabatrin products to obtain the same dosage.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Chewtadzy™ (tadalafil) Chewable Tablets

FDA-Approved Indication

[1] Erectile disfunction (ED); [2] The signs and symptoms of benign prostatic hyperplasia (BPH).

Dosage & Administration

- Use as Needed for ED: 10 mg orally.
- Once Daily Use for BPH (and BPH with ED): 5 mg orally once daily.

Dosage Forms & Strengths

Chewable Tablets: 5 mg, 10 mg, 20 mg

Contraindications

- Concomitant use of any form of organic nitrate. Tadalafil was shown to potentiate the hypotensive effect of nitrates
- History of known serious hypersensitivity reaction to tadalafil or any component of Chewtadzy
- Administration with guanylate cyclase (GC) stimulators, such as riociguat

Warnings & Precautions

- Cardiovascular Risk
- Hypotension When Used in Combination with Other Drugs and Alcohol
- Prolonged Erection and Priapism
- Ocular Adverse Reactions
- Sudden Hearing Loss
- Consideration of Other Urological Conditions Prior to Initiating Treatment for BPH

Common Adverse Reactions

Headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, and pain in limb.

Drug Interactions

Chewtadzy can potentiate the hypotensive effects of nitrates, alpha-blockers, antihypertensives or alcohol.

Clinical Studies

Chewtadzy was approved under a 505(b)(2) NDA pathway.

Place in Therapy

Tadalafil is a phosphodiesterase 5 (PDE5) inhibitor. It is currently available in several formulations, including a generic tablet for the same indications as Chewtadzy.

Other notable new approvals include:

Adbry™ (tralokinumab-ldrm) Injection, for subcutaneous use

- The FDA approved Adbry (tralokinumab-ldrm) injection (autoinjector), for subcutaneous use for the treatment of adult patients with moderate to severe atopic dermatitis.

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)
Palbociclib tablets 75mg, 100mg and 125mg	Synthon Pharmaceuticals, Inc.	Ibrance	Antineoplastic Enzyme Inhibitor	Breast Cancer
Avanafil tablets 50mg, 100mg and 200mg	Hetero Labs Limited	Stendra	Impotence Agents	Erectile Dysfunction
Phentermine Hydrochloride and Topiramate Extended-Release Capsules 3.75mg (base)/23mg, 7.5mg (base)/46mg, 11.25mg (base)/69mg and 15mg (base)/ 92mg	Actavis Laboratories FL, Inc.	Qsymia	Anorexiants Non-Amphetamine	Obesity

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
Blincyto (blinatumomab) From: Amgen	[1] For the treatment of adult and pediatric patients with CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than equal to 0.1%; [2] For the treatment of adult and pediatric patients with relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL)	For the treatment of adult and pediatric patients one month and older with CD19-positive Philadelphia chromosome - negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy
Keytruda (pembrolizumab) From: Merck Sharp Dohma	Several including melanoma, non-small cell lung cancer, urothelial cancer, biliary tract cancer, renal cell carcinoma, cervical cancer, among others.	For the treatment of adult patients with primary advanced or recurrent endometrial carcinoma
Skyrizi (risankizumab-rzaa) From: Abbie Inc	[1] For the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy; [2] For the treatment of active psoriatic arthritis in adults; [3] For the treatment of moderately to severely active Crohn's disease in adults	For the treatment of moderately to severely active ulcerative colitis in adults
Kevzara (sarilumab) From: Sanofi	[1] For the treatment of adult patients with moderately to severe active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease modifying antirheumatic drugs (DMARDS); [2] For the treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot	For the treatment of patients who weigh 63kg or greater with active polyarticular juvenile idiopathic arthtritis (PJJA)

	tolerate corticosteroid information	
Motpoly (lacosamide) From: Aucta Pharmaceutical	For the treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50kg	Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and in pediatric weighing at least 50kg
Augtyro (repotrectinib) From: Bristol Myers Squibb	For the treatment of adult patients with locally advanced or metastatic ros1-positive non-small cell lung cancer	For the treatment of patients with NTRK-positive locally advanced or metastatic solid tumors
Vyvgart Hytrulo (ergartimod alfa and hyaluronidase-qvfc) From: Argenx BV	For the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive	For the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)
Krazati (adagrasib) From: Bristol Myers Squibb	Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA -approved test, who have received at least one prior systemic therapy	Indicated in combination with cetuximab for adult patients with previously treated KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC)
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] 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	Indicated in combination with carboplatin and paclitaxel 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)

	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)	
Epkinly (epcoritamab-bysp) From: Genmab US, Inc	For the treatment of adult patients with relapsed or refractory diffuse large b-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high -grade b cell lymphoma after two or more lines of systemic therapy	For the treatment of adult patients with relapsed or refractory ocular lymphoma (FL) after two or more lines of systemic therapy

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 drugs were in the Pipeline during June.