PharmNotes

Monthly Communications

December 2024

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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 December.

New FDA-Approved Drug Products

New Molecular Entity

Specialty | Orphan Drug

Bizengri™ (zenocutumab-zbco) Injection for subcutaneous use

FDA-Approved Indication

[1] For the treatment of adults with advanced, unresectable or metastatic NSCLC harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy; [2] For the treatment of adult patients with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a NRG1 gene fusion with disease progression on or after prior systemic therapy.

Dosage & Administration

750 mg every 2 weeks until disease progression or unacceptable toxicity. Premedication before each infusion should be administered.

Dosage Forms & Strengths

Injection: 375 mg/18.75 mL (20 mg/mL) in a single-dose vial.

Contraindications

None.

Common Adverse Reactions

Diarrhea, musculoskeletal pain, fatigue, nausea, infusion-related reactions (IRR), dyspnea, rash, constipation, vomiting, abdominal pain, edema.

Warnings & Precautions

- ***BBW:*** Embryo-Fetal Toxicity
- Infusion-Related Reactions (IRR)/ Hypersensitivity/Anaphylactic Reactions
- Interstitial Lung Disease (ILD)/Pneumonitis
- Left Ventricular Dysfunction

Use in Specific Populations

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

Clinical Studies

The approval of Bizengri is based on data from the eNRGy trial, a multicenter, open-label clinical trial which involved 64 patients with advanced or metastatic NRG1+ NSCLC and 30 patients with advanced or metastatic NRG1+ PDAC who had shown disease progression after receiving standard treatments. The major efficacy outcome measures were confirmed overall response rate (ORR) and duration of response (DOR). For NSCLC, ORR was 33% (95% CI: 22%, 46%) and median DOR was 7.4 months (95% CI: 4.0, 16.6). For pancreatic adenocarcinoma, ORR was 40% (95% CI: 23%, 59%) and the DOR range was 3.7 months to 16.6 months.

Place in Therapy

Bizengri the first FDA approval of a systemic therapy for patients with NSCLC or pancreatic adenocarcinoma harboring an NRG1 gene fusion. NCCN Guidelines for Non-Small Cell Lung Cancer recommends the use of zenocutuzumab-zbco as subsequent therapy as a single agent for NRG1 gene fusion positive recurrent, advanced, or metastatic disease (category 2A; 2B for locoregional recurrence or symptomatic local disease, excluding mediastinal lymph node recurrence with prior radiation therapy, with no evidence of disseminated disease).

New FDA-Approved Drug Products

New Molecular Entity

Specialty | Orphan Drug

Cressenity™ (crinecerfont) capsules for oral use or oral solution

FDA-Approved Indication

Indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

Dosage & Administration

Continue glucocorticoid replacement therapy for adrenal insufficiency associated with CAH.

- Adults: 100 mg orally, twice daily with a meal in the morning and evening.
- Pediatric Patients (4 years of age and older): Weight-based dosage orally, twice daily with a meal in the morning and evening.

Dosage Forms & Strengths

- Capsules: 25 mg, 50 mg, 100 mg
- Oral Solution: 50 mg/mL

Contraindications

Hypersensitivity to crinecerfont or any excipients of Crenessity.

Common Adverse Reactions

Fatigue, headache, dizziness, arthralgia, back pain, decreased appetite and myalgia.

Warnings & Precautions

- Hypersensitivity Reactions
- Risk of Acute Adrenal Insufficiency or Adrenal Crisis with Inadequate Concomitant Glucocorticoid Therapy

Drug Interactions

- Strong CYP3A4 Inducers
- Moderate CYP3A4 Inducers

Clinical Studies

Crenessity's approval is based on two randomized, double-blind, placebo-controlled studies (CAHtalyst Study). In the first study, 122 adults were given Crenessity twice daily, while 60 received a placebo for 24 weeks. The main measure of effectiveness was the change from baseline in the total daily glucocorticoid dose while keeping androstenedione levels controlled by the end of the trial. The Crenessity group reduced their daily glucocorticoid dose by 27%, maintaining control of androstenedione levels, while the placebo group only reduced their daily glucocorticoid dose by 10%. In the second study, 69 pediatric patients received Crenessity twice daily, and 34 received a placebo for 28 weeks. The main measure of effectiveness was the change from baseline in serum androstenedione levels at week 4. The Crenessity group showed a statistically significant reduction in serum androstenedione from baseline, while the placebo group showed an average increase. By the end of the trial, patients receiving Crenessity reduced their daily glucocorticoid dose by 18%, while still maintaining androstenedione control, compared to nearly a 6% increase in the glucocorticoid dose for those on placebo.

Place in Therapy

The mainstay of treatment for classic CAH is hydrocortisone. Crenessity represents an option for patients that need additional intervention for persistent symptoms and severe disease.

New FDA-Approved Drug Products

New Molecular Entity

Specialty

Unloxcyt™ (cosibelimab-ipdl) injection for intravenous use

FDA-Approved Indication

For the treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

Dosage & Administration

1,200 mg as an intravenous infusion over 60 minutes every 3 weeks.

Dosage Forms & Strengths

Injection: 300 mg/5 mL (60 mg/mL) solution in a single-dose vial.

Contraindications

None.

Common Adverse Reactions

Fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection and urinary tract infection.

Warnings & Precautions

- Immune-Mediated Adverse Reactions
- Infusion-Related Reactions
- Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)
- Embryo-Fetal Toxicity

Use in Specific Populations

Lactation: Advise not to breastfeed.

Clinical Studies

The effectiveness of Unloxcyt was demonstrated in the CK-301-101 study, a multicohort, open-label trial involving patients with metastatic mCSCC (n = 78) or laCSCC (n = 31) who were not suitable for curative surgery or radiation. The primary measures of effectiveness were the objective response rate (ORR) and the duration of response (DOR). In the mCSCC group, the ORR was 47% (95% CI: 36, 59), and the median DOR was not reached (ranging from 1.4+ to 34.1+ months). In the laCSCC group, the ORR was 48% (95% CI: 30, 67), with a median DOR of 7.7 months (ranging from 3.7+ to 17.7 months).

Place in Therapy

Unloxcyt is the first and only programmed death ligand-1 (PD-L1)–blocking antibody approved for the CSCC indication. NCCN Guidelines have yet to incorporate this product into their guidelines.

New FDA-Approved Drug Products

New Molecular Entity

Specialty

Ensacove ™ (ensartinib) capsules, for oral use

FDA-Approved Indication

For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK-inhibitor.

Dosage & Administration

225 mg orally once daily with or without food until disease progression or unacceptable toxicity.

Dosage Forms & Strengths

Capsules: 25 mg and 100 mg of ensartinib.

Contraindications

Hypersensitivity reaction to Ensacove, FD&C Yellow No. 5 (tartrazine), or to any of its components.

Common Adverse Reactions

Rash, musculoskeletal pain, constipation, pruritus, cough, nausea, edema, vomiting, fatigue and pyrexia.

Warnings & Precautions

- Interstitial Lung Disease (ILD)/Pneumonitis
- Hepatotoxicity
- Dermatologic Adverse Reaction
- Bradycardia
- Hyperglycemia
- Visual Disturbances
- Increased Creatine Phosphokinase (CPK)
- Hyperuricemia
- Embryo-Fetal Toxicity

Drug Interactions

- Moderate or Strong CYP3A Inhibitors
- Moderate or Strong CYP3A Inducers
- P-gp Inhibitor

Use in Specific Populations

- Lactation: Advise not to breastfeed.
- Severe Hepatic Impairment: Avoid use.

Clinical Studies

The approval was supported by data from the Phase 3 eXALT3 trial, an open-label, randomized, active-controlled, multicenter trial in 290 patients with locally advanced or metastatic ALK-positive NSCLC who had not previously received an ALK-targeted therapy. Patients were randomized 1:1 to receive ensartinib or crizotinib. The results showed a median progression-free survival (PFS) of 25.8 months with Ensacove, compared to 12.7 months with Xalkori (crizotinib) (hazard ratio [HR], 0.56; P = 0.0007). Ensacove demonstrated superior intracranial efficacy, with a response rate of 63.6% compared to 21.1% with Xalkori, and significantly lower rates of central nervous system progression at 12 months (4.2% vs. 23.9%). However, there was no statistically significant difference in the secondary endpoint of overall survival (OS) between the two treatments (HR = 0.88; 95% CI, 0.63–1.23).

Place in Therapy

NCCN Guidelines for NSCLC recommends the use of ensartinib as a single-agent therapy for ALK rearrangement positive recurrent, advanced, or metastatic disease: [1] as preferred first-line therapy (category 1); [2] for those who are intolerant to crizotinib; [3] following disease progression on first-line therapy with ensartinib, as continuation of therapy except in cases of symptomatic systemic disease with multiple lesions; and [4] as subsequent therapy following disease progression on first-line therapy with crizotinib However, there are already several FDA-approved ALK inhibitors, such as Alecensa (alectinib), Alunbrig (brigatinib), and Lorbrena (lorlatinib).

New FDA-Approved Drug Products

New Molecular Entity

Specialty | Orphan Drug

Ryoncil™ (remestemcel-L-rknd) suspension for intravenous use

FDA-Approved Indication

For the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

Dosage & Administration

2×10^6 MSC/kg body weight per intravenous infusion given twice per week for 4 consecutive weeks. Assess response 28 ± 2 days after the first dose and administer further treatment as appropriate [please refer to package insert for further information].

Dosage Forms & Strengths

Cell suspension for intravenous infusion in a target concentration of 6.68 X 10^6 MSCs per mL in 3.8 mL contained in a 6 mL cryovial.

Contraindications

Known hypersensitivity to dimethyl sulfoxide (DMSO) or Porcine and Bovine proteins.

Common Adverse Reactions

Viral infectious disorders, bacterial infectious disorders, infection – pathogen unspecified, pyrexia, hemorrhage, edema, abdominal pain and hypertension

Warnings & Precautions

- Hypersensitivity/Acute Infusion Reactions
- Transmission Of Infectious Agents
- Ectopic Tissue Formation

Clinical Studies

The safety and efficacy of Ryoncil were assessed in a multicenter, single-arm trial involving 54 pediatric participants with SR-aGVHD who had undergone allo-HSCT. Participants received intravenous infusions of Ryoncil twice a week for four consecutive weeks, totaling eight infusions. The effectiveness of Ryoncil was primarily determined by the rate and duration of response 28 days after the start of treatment. Participants who showed a partial or mixed response—where one organ improved but another either showed no change (partial) or worsened (mixed)—received additional infusions once a week for another four weeks. After 28 days of treatment, 16 participants (30%) achieved a complete response, while 22 participants (41%) had a partial response.

Place in Therapy

Ryoncil provides a novel mechanism of action for patients who do not respond to other immunosuppressive treatments for aGVHD. It will directly compete with Jakafi, which is currently the sole FDA-approved therapy for SR-aGVHD. However, Jakafi is only FDA-approved for patients aged 12 and older. Orencia (abatacept) is approved for prophylaxis of aGVHD.

New FDA-Approved Drug Products

New Molecular Entity

Specialty | Orphan Drug

Tryngolza™ (olezarsen sodium) injection for subcutaneous use

FDA-Approved Indication

Indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

Dosage & Administration

80 mg administered subcutaneously once monthly.

Dosage Forms & Strengths

Injection: 80 mg/0.8 mL in a single dose autoinjector.

Contraindications

History of serious hypersensitivity reactions to olezarsen or any of the excipients in Tryngolza.

Common Adverse Reactions

Injection site reactions, decreased platelet count, and arthralgia.

Warnings & Precautions

Hypersensitivity reactions.

Clinical Studies

The effectiveness and safety of Tryngolza were assessed in a randomized, placebo-controlled, double-blind clinical Phase 3 BALANCE study, involving 66 adult patients with FCS and fasting triglyceride (TG) levels of at least 880 mg/dL (the average baseline TG level was about 2600 mg/dL). The primary objective was the percentage change in fasting TG levels from baseline to month 6 (averaging weeks 23, 25, and 27) in comparison to placebo. The Tryngolza treatment group showed an average reduction of 42.5% in TG levels from baseline to month 6, compared to the placebo group. Both median percentage and absolute reductions in TG levels over time revealed a consistent decrease throughout the 12-month treatment period.

Place in Therapy

FCS is an uncommon, hereditary type of severe hypertriglyceridemia that can result in potentially life-threatening acute pancreatitis (AP) and impacts around 3,000 people in the United States. Tryngolza is the first-ever FDA-approved treatment that significantly and substantially reduces triglyceride levels in adults with FCS and provides clinically meaningful reduction in AP events when used with an appropriate diet (≤20 grams of fat per day).

New FDA-Approved Drug Products

New Molecular Entity

Specialty | Orphan Drug

Alyftrek™ (vanzacaftor, tezacaftor and deutivacaftor) tablets for oral use

FDA-Approved Indication

For the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene.

Dosage & Administration

Prior to initiating Alyftrek obtain liver function tests in all patients. Monitor liver function tests every month during the first 6 months of treatment, then every 3 months during the next 12 months, then at least annually thereafter. Recommended dose is based on patient body weight. Please refer to package insert for details.

Dosage Forms & Strengths

Tablets:

- Fixed-dose combination containing vanzacaftor 4 mg, tezacaftor 20 mg, and deutivacaftor 50 mg
- Fixed-dose combination containing vanzacaftor 10 mg, tezacaftor 50 mg, and deutivacaftor 125 mg

Contraindications

None.

Common Adverse Reactions

Cough, nasopharyngitis, upper respiratory tract infection, headache, oropharyngeal pain, influenza, fatigue, increased ALT, rash, increased AST, and sinus congestion.

Warnings & Precautions

- Drug-Induced Liver Injury and Liver Failure
- Hypersensitivity Reactions
- Patients Who Discontinued or Interrupted Elexacaftor-, Tezacaftor-, or Ivacaftor-Containing Drugs Due to Adverse Reactions
- Reduced Effectiveness in Patients with Concomitant Use with CYP3A Inducers
- Adverse Reactions with Concomitant Use with CYP3A Inhibitors
- Cataracts

Clinical Studies

The approval of Alyftrek is based on data from the Phase 3 SKYLINE 102, SKYLINE 103, and RIDGELINE 105 studies, which assessed the safety and effectiveness of Alyftrek in comparison to Trikafta in patients with CF. In all three studies, participants initially received at least 4 weeks of treatment with Trikafta to establish baselines for the endpoint measures, including percent predicted forced expiratory volume in 1 second (ppFEV1) and sweat chloride (SwCl). In the randomized, double-blind, active-controlled SKYLINE 102 and SKYLINE 103 studies, patients were treated with either Alyftrek or Trikafta for 52 weeks. In both studies, Alyftrek was found to be noninferior to Trikafta in the primary endpoint of change in ppFEV1 through Week 24. Alyftrek also achieved positive results for secondary endpoints at 24 weeks, including three measures where it was superior to Trikafta: a reduction in SwCl levels, and the percentage of patients with SwCl levels below 60 mmol/L (the diagnostic threshold for CF) and below 30 mmol/L. The results at 52 weeks were consistent with those at 24 weeks. RIDGELINE 105, a 24-week, open-label trial, evaluated Alyftrek in younger children aged 6 to 11 years with CF, carrying at least one mutation responsive to triple combination CFTR modulators. The primary endpoint of the RIDGELINE 105 study was safety. It also assessed similar secondary endpoints as the SKYLINE trials, with 95% of patients who received Alyftrek achieving SwCl levels below 60 mmol/L. The study assessed similar secondary endpoints as the SKYLINE trials, and 95% of patients who received Alyftrek achieved SwCl levels below 60 mmol/L.

Place in Therapy

Alyftrek is the first, once-daily CFTR modulator. Given its enhanced efficacy in reducing SwCl and convenient once-daily dosing, eligible patients may transition from Trikafta to Alyftrek.

New FDA-Approved Drug Products

New Molecular Entity

Specialty | Orphan Drug

Alhemo™ (concizumab-mtci) 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 12 years of age and older with: [1] hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors; [2] hemophilia B (congenital factor IX deficiency) with FIX inhibitors.

Dosage & Administration

- Day 1: Loading dose of 1 mg/kg
- Day 2: Once-daily dose of 0.2 mg/kg until individualization of maintenance dose

See full Prescribing Information for more information.

Dosage Forms & Strengths

Injection:

- 60 mg/1.5 mL (40 mg/mL) in a single-patient-use prefilled pen
- 150 mg/1.5 mL (100 mg/mL) in a single-patient-use prefilled pen
- 300 mg/3 mL (100 mg/mL) in a single-patient-use prefilled pen

Contraindications

Alhemo is contraindicated in patients with a history of known serious hypersensitivity to Alhemo or its components or the inactive ingredients.

Common Adverse Reactions

Injection site reactions and urticaria.

Warnings & Precautions

- Thromboembolic Events
- Hypersensitivity Reactions
- Increased Laboratory Values of Fibrin D dimer and Prothrombin Fragment 1+2

Drug Interactions

Bypassing agents (e.g., rFVIIa or aPCC).

Clinical Studies

The effectiveness and safety of Alhemo were assessed in a global, multi-center, open-label Phase 3 study involving 91 adult and 42 adolescent male patients with hemophilia A or B who had inhibitors and required or were prescribed therapies that bypass the inhibitor effect. Efficacy was measured by comparing the number of treated bleeding episodes between the Alhemo treatment group and the no prophylaxis group. The estimated ratio of the annualized bleeding rates (ABR) was 0.14, reflecting an 86% reduction in ABR for the Alhemo treatment group compared to the no prophylaxis group.

Place in Therapy

Hemophilia is typically treated by replacing the missing clotting factor. However, over time, individuals with hemophilia may develop inhibitors (antibodies) that interfere with the function of factor VIII or IX (clotting factors). These inhibitors can hinder the ability to control excessive bleeding and may decrease the effectiveness of factor replacement treatments. Currently, many treatments for hemophilia A or B with inhibitors are administered via intravenous infusions, and Alhemo is the first subcutaneous injection treatment of its kind for this population.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Steqeyma™ (ustekinumab-stba) injection, for subcutaneous or intravenous use

FDA-Approved Indication

[1] Moderate to severe plaque psoriasis in adult and pediatric patients 6 years and older; [2] Active plaque psoriasis in adult and pediatric patients 6 years and older; [3] Adults with moderate to severe active Crohn's disease; [4] Adults with moderate to severe active ulcerative colitis.

Dosage & Administration

Based on body weight and indication. 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 Steqeyma.

Common Adverse Reactions

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

Warnings & Precautions

- Infections
- Theoretical Risk for Particular Infections
- Tuberculosis
- Malignancies
- Hypersensitivity Reactions
- Posterior Reversible Encephalopathy Syndrome (PRES)
- Immunizations
- Noninfectious Pneumonia

Clinical Studies

The approval was supported by a comprehensive review of scientific evidence that the product was highly similar to Stelara.

Place in Therapy

Steqeyma (ustekinumab-stba) making it the seventh biosimilar available to compete against Stelara (reference ustekinumab). Steqeyma follows Selarsdi (ustekinumab-aekn), Pyzchiva (ustekinumab-ttwe), Otulfi (ustekinumab-aauz), Imuldosa (ustekinumab-srlf), Wezlana (ustekinumab-auub), and Yesintek (ustekinumab-kfce).

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Specialty

Opdivo Qvantig™ (nivolumab and hyaluronidase -nvhy) injection for subcutaneous use

FDA-Approved Indication

[1] Renal Cell Carcinoma; [2] Non-Small Cell Lung Cancer; [3] Melanoma; [4] Squamous Cell Carcinoma of the Head and Neck (SCCHN); [4] Urothelial Carcinoma (UC); [5] Colorectal Cancer; [6] Hepatocellular Carcinoma (HCC); [7] Esophageal Cancer; [8] Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma.

Dosage & Administration

Recommended dosage varies per indication. Please refer to package insert for details.

Dosage Forms & Strengths

Injection: 600 mg nivolumab and 10,000 units hyaluronidase per 5 mL (120 mg/2,000 units per mL) in a single-dose vial.

Contraindications

None.

Common Adverse Reactions

Same adverse reactions as intravenous nivolumab (varies by indications).

Warnings & Precautions

- Immune-Mediated Adverse Reactions
- Complications of Allogeneic HSCT
- Embryo-Fetal Toxicity
- Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

Use in Specific Populations

Lactation: Advise not to breastfeed.

Clinical Studies

The approval is based on the results from the Phase 3 randomized, open-label CheckMate-67T trial, which demonstrated non-inferior co-primary pharmacokinetic (PK) exposures, similar efficacy in overall response rate (ORR), and showed a comparable safety profile vs. intravenous (IV) Opdivo.

Place in Therapy

Opdivo Qvantig is the first and only subcutaneously administered PD-1 inhibitor. It is given in about 5 minutes. The subcutaneous version could transform the way this drug is delivered to patients, as it allows providers to spend less time preparing and administering treatment.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Ontralfy™ (tizanidine oral solution)

FDA-Approved Indication

Indicated for the treatment of spasticity in adults.

Dosage & Administration

2 mg by mouth every 6 to 8 hours, as needed, up to a maximum of 3 doses in 24 hours. Dosage can be increased by 2 mg to 4 mg per dose every 1 to 4 days; maximum total daily dosage is 36 mg.

Dosage Forms & Strengths

Oral Solution: 2 mg/5 mL tizanidine

Contraindications

- Concomitant use with strong CYP1A2 inhibitors.
- Patients with a history of hypersensitivity to tizanidine or the ingredients in Ontralfy.

Common Adverse Reactions

Dry mouth, somnolence, asthenia, and dizziness.

Warnings & Precautions

- Hypotension
- Risk of liver injury
- Sedation
- Hallucinations

Drug Interactions

Moderate or weak CYP1A2 inhibitors.

Use in Specific Populations

- Pregnancy: May cause fetal harm.
- Geriatric use: Ontralfy should be used with caution in elderly patients.

Clinical Studies

The efficacy of Ontralfy is supported by evidence from a relative bioavailability study in healthy adult subjects comparing Ontralfy to tizanidine tablets under fasted and fed conditions.

Place in Therapy

Tizanidine is a medication commonly used to treat spasticity, which is the condition of muscle stiffness and spasms often resulting from conditions like multiple sclerosis, spinal cord injury, or other neurological disorders.

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)
Aripiprazole for extended-release injectable suspension 300mg mg/vial and 400mg/vial	Mylan Pharmaceuticals Inc.	Abilify Maintena	Quinolone Derivatives	Schizophrenia: Bipolar I Disorder
Baclofen Oral Solution 5mg/ 5mL	Rubicon Research Private Limited	Ozobax	Central Muscle Relaxants	Spasticity
Tromethamine Injection 18g/500mL (3.6g/100mL)	B. Braun Medical Inc.	Tham	Bicarbonates	Metabolic Acidosis
Iobenguane Sulfate I-123 Injection 10 mCi/5mL (2 mCi/mL)	BWXT Medical Ltd.	AdreView	Diagnostic Radiopharmaceuticals	Diagnostic
Cefixime Tablets 400mg	FDC Limited	Suprax	Cephalosporins – 3rd Generation	Bacterial Infections
Raltegravir Potassium Tablets 400mg (base)	Hetero Labs Limited	Isentress	Antiretrovirals	HIV Infection
Liraglutide Subcutaneous Injection 18 mg/3 mL (6mg/mL)	Hikma Pharmaceuticals USA Inc.	Victoza	Incretin Mimetic Agents	Type 2 Diabetes
Deutetrabenzine Tablets 6mg, 9mg and 12mg	Aurobindo Pharma Limited	Austedo	Movement Disorder Drug Therapy	Huntington's Disease
Prucalopride Succinate Tablets 1mg (base) and 2 mg (base)	Novitium Pharma LLC	Motegrity	5-HT4 Receptor Agonists	Chronic Idiopathic Constipation

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
Imfinzi (durvalumab) From: AstraZeneca LTD	Several indications, including Imfinzi, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).	As a single agent, is indicated 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).
Vtama (tapinarof) From: Dermavant Sciences	For the treatment of plaque psoriasis in adults.	For the topical treatment of atopic dermatitis in adult and pediatric patients 2 years of age and older.
Nemluvio (nemolizumab) From: Galderma Labs	For the treatment of adult patients with prurigo nodularis.	For the treatment of adult and pediatric patients 12 years of age and older with moderate to severe atopic dermatitis.
Zepbound (tirzepatide) From: Eli Lilly and Co	Indicated to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.	To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.
Gemtesa (vibegron) From: Urovant	For the treatment of overactive bladder with symptoms or urge urinary incontinence, urgency, and urinary frequency in adults.	Overactive bladder with symptoms or urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia.
Imcivree (setmelanotide) *From: Rhythm Pharmaceuticals*	For chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to:[1] Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS); [2] Bardet Biedl syndrome (BBS).	To reduce excess body weight and maintain weight reduction long term by reducing hunger and food intake and increasing energy expenditure in adults and pediatric patients 2 years of age and older with syndromic or monogenic obesity due to: [1] Bardet-Biedl syndrome (BBS); [2] Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in

		POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).
Braftovi (encorafenib) *From: Array Biopharma Inc.*	[1] BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma; [2] BRAF V600E mutation-positive metastatic non-small cell lung cancer (NSCLC); [3] In combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.	In combination with cetuximab and mFOLFOX6, for the treatment of patients with metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test.
Tevimbra (tislelizumab-jsgr) *From: Beigene*	For the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.	In combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first line treatment of unresectable or metastatic HER2- negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1.

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
Aficamten From: Cytokinetics, Incorporated.	For the treatment of hypertrophic cardiomyopathy.	NDA accepted	Moderate
TNX-102 (cyclobenzprine hydrovhloride) From: Tonix Pharmaceuticals Holding Corp.	For the treatment of fibromyalgia.	NDA accepted	Moderate
Avutometinib From: Verastem Oncology	For the treatment of adults with recurrent KRAS mutant low-grade serous ovarian cancer.	NDA accepted	High