PharmNotes

Monthly Communications

September 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.

FDA adds warning about rare occurrence of serious liver injury with use of Veozah™ (fezolinetant) for hot flashes due to menopause – 9/12/2024

The U.S. Food and Drug Administration (FDA) is warning that Veozah™ (fezolinetant), a medicine used to treat hot flashes due to menopause, can cause rare but serious liver injury. If there are signs and symptoms suggesting liver injury, stopping the medicine could prevent worsening liver injury and potentially return liver function to normal.

New FDA-Approved Drug Products

New Molecular Entity

Ebglyss™ (lebrikizumab-lbkz) Injection for subcutaneous use

Specialty

FDA-Approved Indication

For the treatment of adults and pediatric patients 12 years of age and older with moderate to severe atopic dermatitis.

Dosage & Administration

500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg (one injection) every 2 weeks until Week 16 or later, when adequate clinical response is achieved. The maintenance dose is 250 mg every 4 weeks.

Dosage Forms & Strengths

250 mg/2 mL in a single-dose prefilled pen and syringe with needle shield.

Contraindications

Prior serious hypersensitivity to lebrikizumab-lbkz or any excipients in Ebglyss.

Common Adverse Reactions

Conjunctivitis, injection site reactions, and herpes zoster.

Warnings & Precautions

- Hypersensitivity
- Conjunctivitis and Keratitis
- Parasitic (Helminth) Infections
- Vaccinations

Clinical Studies

The approval was based on results from the ADvocate 1, ADvocate 2, and ADhere studies, which included over 1,000 adults and children (aged 12 and older) with moderate-to-severe eczema who were unable to control their symptoms with topical prescription medicines. The primary endpoint for these studies was evaluated at 16 weeks and measured clear or almost clear skin (IGA 0,1). In an average of two studies (ADvocate 1 and 2), 38% of people who took Ebglyss achieved clear or almost-clear skin at 16 weeks (versus 12 percent with placebo) On average, 43% of people who took Ebglyss felt itch relief at 16 weeks (compared to 12 percent who took placebo).

Place in Therapy

About 16.5 million adults in the U.S. have eczema, with 6.6 million experiencing moderate-to-severe symptoms. Ebglyss is the third biologic approved to treat AD. Dupixent was approved for AD in 2017 and Adbry was approved in 2021. Dupixent is approved to treat patients with AD as young as 6 months of age and Adbry is approved to treat patients with AD 12 years of age and older.

New FDA-Approved Drug Products

New Molecular Entity

Miplyffa™ (arimoclomol) capsules for oral use

Specialty | Orphan Drug

FDA-Approved Indication

For the treatment of neurological manifestations of Niemann-pick disease type C (NPC) in adult and pediatric patents 2 years of age and older.

Dosage & Administration

In combination with miglustat for patients with actual body weight of:

- 8 kg to 15 kg: 47 mg three times a day
- > 15 kg to 30 kg: 62 mg three times a day
- > 30 kg to 55 kg: 93 mg three times a day
- > 55 kg: 124 mg three times a day

Dosage Forms & Strengths

Capsules: 47mg, 62mg, 93mg and 124mg.

Contraindications

None.

Common Adverse Reactions

Upper respiratory tract infection, diarrhea, and decreased weight.

Warnings & Precautions

- Hypersensitivity Reactions
- Embryofetal Toxicity
- Increased Creatinine without Affecting Glomerular Function

Drug Interactions

- Substrates of the Organic Cationic Transporter 2 (OCT2 substrates)

Use In Specific Populations

Females and Males of Reproductive Potential: Based on animal findings, Miplyffa may impair fertility.

Clinical Studies

The safety and effectiveness of Miplyffa were evaluated in a randomized, double-blind, placebo-controlled 12-month trial in patients two to 19 years of age who had a molecularly confirmed diagnosis of NPC. Fifty patients were randomized 2:1 to treatment with weight-adjusted Miplyffa or placebo orally three times per day. Miplyffa resulted in slower disease progression as measured by the rescored four-domain NPC Clinical Severity Scale score (R4DNPCCSS). Miplyffa with miglustat halted disease progression by 12 months through a decrease of 0.2 points from baseline on the R4DNPCCSS compared with 1.9 points for those given miglustat alone.

Place in Therapy

Niemann-Pick disease type C (NPC) is a rare progressive genetic disorder characterized by an inability of the body to transport cholesterol and other lipids inside of cells. The FDA Genetic Metabolic Diseases Advisory Committee (GeMDAC) voted favorably with an 11-5 vote that the data support that arimoclomol is effective in the treatment of patients with NPC. NPC previously had no FDA approved treatment options.

New FDA-Approved Drug Products

New Molecular Entity

Aqneursa™ (levacetylleucine) (granules) suspension for oral use

Specialty | Orphan Drug

FDA-Approved Indication

For the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg.

Dosage & Administration

Recommended dose is based on body weight:

- 15kg to less than 25kg: 1gram in the morning and evening
- 25kg to less than 35kg: 1 gram in the morning, afternoon and evening
- 35kg or more: 2 grams in the morning, 1 gram in the afternoon and evening

Dosage Forms & Strengths

For oral suspension: 1 gram levacetylleucine in a unit-dose packet.

Contraindications

None.

Common Adverse Reactions

Abdominal pain, dysphagia, upper respiratory tract infections, and vomiting.

Warnings & Precautions

- Embryo-Fetal Toxicity

Drug Interactions

- N-acetyl-DL-leucine or N-acetyl-D-leucine
- P-glycoprotein Transporter Substrates

Clinical Studies

Aqneursa was approved based on data from the IB1001-301 multinational, randomized, double-blind, placebo-controlled, pivotal clinical trial. This trial evaluated the impact of Aqneursa™ on neurological symptoms and functioning in pediatric (aged 4 years and older) and adult patients (n=60) with a confirmed diagnosis of NPC. The primary endpoint was a modified version of the Scale for the Assessment and Rating of Ataxia (SARA), referred to as the functional SARA (fSARA), which measures gait, sitting, stance and speech disturbance domains. Patients treated with Aqneursa for 12 weeks showed a better outcome in the fSARA score compared to when they were treated with placebo.

Place in Therapy

Aqneursa is the only FDA-approved stand-alone therapy indicated for the treatment of NPC. Like Miplyffa, this drug is intended to treat the neurological symptoms of NPC, and both drugs are approved in a similar patient demographic. Moreover, it is likely Miplyffa is going to be used in patients slightly younger than Aqneursa given Aqneursa's weight requirement of 15 kg.

New FDA-Approved Drug Products

New Molecular Entity

Cobenfy™ (xanomeline-trospium) capsules for oral use

FDA-Approved Indication

For the treatment of schizophrenia in adults.

Dosage & Administration

Recommended starting dosage is 50 mg/20 mg orally twice daily for at least two days, then increase the dosage to 100 mg/20 mg twice daily for at least five days. Dosage may be increased to 125 mg/30 mg orally twice daily based on patient tolerability and response. The maximum recommended dosage is 100 mg/20 mg twice daily. For geriatric patients, the recommended starting dosage is 50 mg/20 mg orally twice daily.

Dosage Forms & Strengths

Capsules (xanomeline/trospium chloride): 50 mg/20 mg, 100 mg/20 mg, 125 mg/30 mg

Contraindications

- Urinary retention
- Moderate to severe hepatic impairment
- Gastric retention
- History of hypersensitivity to Cobenfy or trospium chloride
- Untreated narrow-angle glaucoma

Common Adverse Reactions

Nausea, dyspepsia, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, and gastrointestinal reflux disease.

Warnings & Precautions

- Risk of urinary retention
- Risk of use in patients with Hepatic Impairment
- Risk of use in patients with Biliary Disease
- Decreased Gastrointestinal Motility
- Risk of Angioedema
- Risk of use in patients with Narrow-angle glaucoma
- Increases in Heart Rate
- Anticholinergic Adverse Reactions in patients with renal impairment
- Central Nervous system effects

Drug Interactions

- Drugs Eliminated by Active Tubular Secretion
- Strong CYP2D6 Inhibitors
- Sensitive Substrates of CYP3A4 or P-glycoprotein
- Antimuscarinic Drugs

Use in Specific Populations

- Moderate or Severe Renal Impairment: Not recommended.
- Mild Hepatic Impairment: Not recommended.

Clinical Studies

Approval of Cobenfy is supported by data from the EMERGENT clinical program, which includes three placebo-controlled efficacy and safety studies and two open-label trials evaluating the long-term safety and tolerability of Cobenfy for up to 1 year. The Phase 3 EMERGENT-2 and EMERGENT-3 trials demonstrated that Cobenfy significantly reduced schizophrenia symptoms compared to placebo.

Place in Therapy

Cobenfy represents the first new class of medicine and introduces a new approach to treating schizophrenia by selectively targeting M_1 and M_4 receptors in the brain without blocking D_2 receptors. Cobenfy may compete with branded second-generation antipsychotics (SGAs) approved for the treatment of schizophrenia, based on its safety and efficacy profile (i.e., does not have the atypical antipsychotic class warnings and precautions).

New FDA-Approved Drug Products

New Molecular Entity

Flycardo™ (flurpiridaz F 18) injection for intravenous use

FDA-Approved Indication

Is a radioactive diagnostic drug indicated for positron emission tomography (PET) myocardial perfusion imaging (MPI) under rest or stress (pharmacologic or exercise) in adult patients with known or suspected coronary artery disease (CAD) to evaluate for myocardial ischemia and infarction.

Dosage & Administration

When rest and stress imaging are conducted on the same day, the recommended administered activities are:

- Rest imaging: 93 MBq to 111 MBq (2.5 mCi to 3 mCi)
- Pharmacologic stress imaging: 222 MBq to 241 MBq (6 mCi to 6.5 mCi)
- Exercise stress imaging: 333 MBq to 352 MBq (9 mCi to 9.5 mCi)

When rest and stress imaging are conducted over two days, the recommended rest and stress administered activities, for both pharmacologic and exercise stress, are 93 MBq to 111 MBq (2.5 mCi to 3 mCi)

Dosage Forms & Strengths

Injection: 190 MBq/mL to 2,050 MBq/mL (5 mCi/mL to 55 mCi/mL) of flurpiridaz F 18 at end of synthesis in a shielded multiple-dose vial with up to 30 mL fill volume.

Contraindications

None.

Common Adverse Reactions

Dyspnea, headache, angina pectoris, chest pain, fatigue, ST segment changes, flushing, nausea, abdominal pain, dizziness, and arrhythmia.

Warnings & Precautions

- Risk associated with exercise or pharmacologic stress
- Radiation risks

Use in Specific Population

Lactation: Temporarily discontinue breastfeeding. A lactating woman should pump and discard breastmilk for at least 8 hours after administration

Clinical Studies

The safety and effectiveness of Flyrcado were evaluated in two prospective, multicenter, open-label clinical studies in adults with either suspected coronary artery disease (CAD) (Study 1) or known or suspected CAD (Study 2). Both studies showed favorable results.

Place in Therapy

One of the major benefits of Flycardo is its extended half-life of 109 minutes—significantly longer than other currently available PET MPI imaging agents. The longer half-life allows for off-site manufacturing, which has the potential to expand access to PET MPI diagnostics. What's more, the longer half-life would enable providers to conduct multiple cardiac examinations, including exercise stress testing, within the same timeframe, and patients can be rescanned during the same appointment if necessary.

New FDA-Approved Drug Products

New Biosimilar Product

Otulfi™ (ustekinumab-aauz) injection, for subcutaneous or intravenous use

Specialty

FDA-Approved Indication

Indicated for the treatment of: [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 Crohn's disease; [4] Adults with moderate to severe 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: 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 Otulfi.

Common Adverse Reactions

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

Warnings & Precautions

- Infections
- Theoretical risk for infections
- Tuberculosis
- Malignancies
- Hypersensitivity reactions
- Posterior reversible encephalopathy syndrome (PRES)
- Immunizations
- Noninfectious Pneumonia

Clinical Studies

The approval was based on a comprehensive review of evidence that showed Otulfi was highly similar to Stelara. This included data from the phase 3 VESPUCCI study which compared the biosimilar to the reference product Stelara in patients with moderate to severe plaque psoriasis. Results showed comparable efficacy between Otulfi and Stelara based on the percent improvement in Psoriasis Area and Severity Index score at 12 weeks. Additionally, no clinically significant differences in safety or immunogenicity were observed.

Place in Therapy

Otulfi was approved for both subcutaneous and intravenous formulations which will offer a comprehensive, alternative treatment solution for health care professionals and patients treated with ustekinumab.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs) injection for subcutaneous use

Specialty

FDA-Approved Indication

For the treatment of non-small cell lung cancer, small cell lung cancer, hepatocellular carcinoma, melanoma, and alveolar soft part sarcoma.

Dosage & Administration

15 mL (1,875 mg atezolizumab and 30,000 units hyaluronidase) subcutaneously into the thigh over approximately 7 minutes every 3 weeks.

Dosage Forms & Strengths

Injection: 1,875 mg atezolizumab and 30,000 units hyaluronidase per 15 mL (125 mg/2,000 units per mL) solution in a single-dose vial.

Contraindications

In patients with known hypersensitivity to hyaluronidase or any of its excipients.

Common Adverse Reactions

Fatigue, musculoskeletal pain, cough, dyspnea, decreased appetite, anemia, myalgia, musculoskeletal pain, fatigue, rash, cough, headache, nausea, hypertension, vomiting, constipation, dyspnea, dizziness, hemorrhage, diarrhea, insomnia, abdominal pain hypothyroidism, pyrexia, anxiety, arrhythmia, proteinuria and alopecia.

Warnings & Precautions

- Immune-Mediated Adverse Reactions
- Infusion-Related Reactions
- Complications of allogenic HSCT
- Embryo-Fetal Toxicity

Use in Specific Populations

Lactation: Advise not to breastfeed

Clinical Studies

The FDA approval is based on pivotal data from the Phase IB/III IMscin001 study, which showed comparable levels of Tecentriq in the blood, when administered subcutaneously, and a safety and efficacy profile consistent with the IV formulation. The Phase II IMscin002 study showed that 71% of patients preferred Tecentriq Hybreza over intravenous atezolizumab, and the most common reasons were less time in the clinic, increased comfort during treatment and reduced emotional distress. 4 out of 5 patients chose Tecentriq Hybreza to continue their treatment, after experiencing both formulations.

Place in Therapy

Tecentriq Hybreza is the first and only PD-(L)1 inhibitor for subcutaneous injection available for patients. The administration of Tecentriq Hybreza is notably quicker, taking approximately 7 minutes, compared to the 30–60 minutes required for IV infusion.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Ocrevus Zunovo™ (ocrelizumab, hyaluronidase-ocsq) injection for subcutaneous use

Specialty

FDA-Approved Indication

For the treatment of relapsing forms of multiple sclerosis (MS) and progressive MS in adults.

Dosage & Administration

23mL subcutaneously in the abdomen over approximately 10 minutes every 6 months. Pre-medicate orally with dexamethasone (or an equivalent corticosteroid) and an antihistamine (e.g., desloratadine) at least 30 minutes prior to each injection.

Dosage Forms & Strengths

Injection: 920 mg ocrelizumab and 23,000 units hyaluronidase per 23 mL (40 mg and 1,000 units per mL) solution in a single-dose vial.

Contraindications

- Active hepatitis B virus infection
- History of life-threatening administration reactions to ocrelizumab
- History of hypersensitivity to ocrelizumab, hyaluronidase, or to any component of Ocrevus Zunovo.

Common Adverse Reactions

Upper respiratory tract infections, infusion reactions, skin infections and lower respiratory tract infections.

Warnings & Precautions

- Injection Reactions
- Infections
- Progressive Multifocal Leukoencephalopathy (PML)
- Reduction in Immunoglobulins
- Malignancies
- Immune-Mediated Colitis

Use in Specific Populations

Pregnancy: Based on animal data, may cause fetal harm.

Clinical Studies

The approval of Ocrevus Zunovo is based on results from the Phase 3 OCARINA II trial, which demonstrated noninferior levels of ocrelizumab in the blood after SC administration, as well as a safety and efficacy profile for Ocrevus Zunovo that was comparable to that of Ocrevus in people with RMS and PPMS. Ocrevus Zunovo was also comparable to Ocrevus for the exploratory outcomes of the OCARINA II trial, demonstrating suppression of relapse activity (97%) and magnetic resonance imaging (MRI) lesions (97%) through 48 weeks. In the OCARINA II trial, the safety profile of Ocrevus Zunovo was consistent with that of Ocrevus, with the exception of injection reactions, which were the most common adverse events reported with Ocrevus Zunovo.

Place in Therapy

Ocrevus Zunovo is administered every 6 months by a healthcare provider, like the intravenous formulation of Ocrevus. However, the SC administration of Ocrevus Zunovo is notably faster, taking approximately 10 minutes, compared to the 2 hours or more required for IV infusion of Ocrevus. Ocrevus Zunovo becomes the first and only twice-a-year, subcutaneous injection for people with relapsing and progressive multiple sclerosis.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Tremfya™ (guselkumab) injection, for intravenous use

Specialty

FDA-Approved Indication

For the treatment of moderately to severely active ulcerative colitis.

Dosage & Administration

As an induction dose: 200 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8.

- The recommended maintenance dose is 100 mg subcutaneously at Week 16 and every 8 weeks thereafter, or 200 mg SC at Week 12 and every 4 weeks thereafter.

Dosage Forms & Strengths

Injection: 200 mg/20 mL (10 mg/mL) solution in a single-dose vial.

Contraindications

Serious hypersensitivity reactions to guselkumab or to any of the excipients.

Common Adverse Reactions

Respiratory tract infections.

Warnings & Precautions

- Hypersensitivity Reactions
- Infections
- Tuberculosis (TB)
- Immunizations

Clinical Studies

The approval to treat UC was based on results from the ongoing QUASAR trial (NCT04033445), which included a Phase 2b dose-ranging induction study, a confirmatory Phase 3 induction study, and a Phase 3 maintenance study. Eligible participants demonstrated inadequate response or intolerance to other therapies for UC, including corticosteroids, other biologic agents, and Janus kinase (JAK) inhibitors. In the maintenance study, 50% of participants who received Tremfya 200 mg SC every 4 weeks, and 45% of participants who received Tremfya 100 mg SC every 8 weeks achieved the primary endpoint of clinical remission at Week 44, compared with 19% of participants who received placebo. Additionally, 34% of patients who received Tremfya 200 mg SC and 35% of those who received Tremfya 100 mg SC achieved endoscopic remission at Week 44, compared with 15% who received placebo.

Place in Therapy

For the treatment of UC, other available therapies include Humira (adalimumab), Remicade (infliximab), Zymfentra (infliximab SC), Simponi (golimumab), Stelara (ustekinumab), Skyrizi (Risankizumab), Zeposia (ozanimod), among others. In adult outpatients with moderate to severe UC who are naïve to biologic agents, the AGA suggests using infliximab or vedolizumab rather than adalimumab, for induction of remission.

Other notable new approvals include:

***FluMist*™ (influenza vaccine live)**

FluMist is the first influenza vaccine that does not need to be administered by a healthcare provider. It is an intranasal spray, for self or caregiver administration. The new self-administration option will soon allow individuals aged 18 years and above to have FluMist delivered to their homes through the FluMist Home service. For the current 2024-2025 influenza season, FluMist is available for administration by a healthcare provider only. The manufacturer of FluMist anticipates that this vaccine will be available for the 2025-2026 influenza season for self or caregiver administration.

Boruzu™ (bortezomib) Injection

Boruzu, a new presentation of bortezomib, is ready-to-use for subcutaneous administration or intravenous administration. This new ready-to-use oncology product reduces the compounding preparation steps typically required with administration.

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)
Drospirone Tablets 4mg	Lupin Ltd	Slynd	Progestin Contraceptives – Oral	Prevention of pregnancy

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
Tremfya (guselkumab) From: Janssen Biotech	[1] For the treatment of adult patients with moderate to severe plaque psoriasis; [2] For the treatment of adult patients with active psoriatic arthritis	For the treatment of adult patients with moderately to severe active ulcerative colitis.
Kisqali (ribociclib) From: Novartis	For the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy or fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy	For the adjuvant treatment of adults with hormone receptor (HR) -positive, human epidermal growth factor receptor 2 (HER2) -negative stage II and III early breast cancer at high risk of recurrence.
Keytruda (pembrolizumab) From: Merck Sharp Dohme	[1] Melanoma, [2] Non-small cell lung cancer; [3] head and neck squamous cell cancer; [4] classical Hodgkin lymphoma; [5] primary mediastinal large B-cell lymphoma; [6] urothelial carcinoma; [7] microsatellite instability-high or mismatch repair deficient cancer; [8] microsatellite instability-high or mismatch repair deficient colorectal cancer; [9] gastric cancer; [10] esophageal cancer; [11] cervical cancer; [12] hepatocellular carcinoma; [13] Merkel cell carcinoma; [14] renal cell carcinoma; [15] endometrial carcinoma; [16] tumor mutational burden-high cancer; [17] cutaneous squamous cell carcinoma; [18] triple-negative breast cancer; [19] adult classical Hodgkin lymphoma and adult primary mediastinal large B-cell lymphoma: additional dosing regimen of 400mg every 6 weeks; [21] biliary tract cancer; [22] Figo 2014 stage III-IVA cervical cancer; [23] for the treatment of adult	In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM).

	patients with primary advanced or recurrent endometrial carcinoma	
Fasenra (benralizumab) From: AstraZeneca	[1] For the maintenance treatment of patients with severe asthma aged 12 years or older with eosinophilic phenotype; [2] For the treatment of children aged 6-11 years with severe asthma.	For the treatment of adult patients with eosinophilic granulomatosis and polyangiitis (EGPA).
Cimzia (certolizumab pegol) From: UCB Inc.	[1] To reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who had an inadequate response to conventional therapy; [2] For the treatment of adults with moderately to severely active rheumatoid arthritis; [3] For the treatment of adults with active ankylosing spondylitis; [4] For the treatment of adults with active non-radiographic axial spondylarthritis with objective signs of inflammation; [5] For the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.	For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.
Rybrevant (amivantamab-vmjw) From: Johnson & Johnson	[1] For treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (eGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy; [2] in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (eGFR) exon 20 insertion mutations, as detected by an FDA-approved test	In combination with carboplatin and pemetrexed, for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with eGFR EXON 19 deletions or EXON 21 L858R substitution mutations, whose disease has progresses on or after treatment with an eGFR tyrosine kinase inhibitor (TKI).
Sarclisa (isatuximab-irfc) From: Sanofi Aventis	[1] Indicated in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at	Indicated in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who

	least 2 prior therapies including lenalidomide and a proteasome inhibitor; [2] Indicated in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy	are not eligible for autologous stem cell transplant (ASCT)
Bimzelx (bimekizumab) From: UCB Inc	For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or photo therapy	[1] For the treatment of adult patients with active psoriatic arthritis (PSA); [2] For the treatment of adult patients with active non-radiographic axial spondylarthritis 9NR-AXSPA) with objective signs of inflammation; [3] For the treatment of adult patients with active ankylosing spondylitis (AS)
Tagrisso (osimertinib) From: AstraZeneca	[1] Adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test; [2] First-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test; [3] In combination with pemetrexed and platinum-based chemotherapy, the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test; [4] The treatment of adult patients with metastatic EGFR T790M mutation positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy.	For the treatment of adult patients with unresectable, Stage III epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy (CRT). For patients with exon 19 deletions or exon 21 (L858R) mutations, as detected by an FDA-approved test.
Dupixent (dupilumab) From: Regeneron Pharmaceuticals, Inc	[1] Atopic dermatitis; [2] Asthma; [3] Chronic rhinosinusitis with nasal polyposis; [4] Eosinophilic esophagitis: for adult and pediatric patients aged 1 year and older	[3] For the maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps

	weighing at least 15 kg; [5] Prurigo nodularis	(CRSWNP); [4] For the treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

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
Oxylanthanum carbonate From: Unicycive Therapeutics, Inc.	For the treatment of Hyperphosphatemia of Renal Failure	NDA submitted	Moderate
Sebetralstat From: KalVista Pharmaceuticals, Inc	For the treatment of Hereditary Angioedema	NDA accepted	High
AXS-07 (meloxicam and rizatriptan) From: Axsome Therapeutics	Acute treatment of migraine	NDA resubmitted	Low