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PharmNOTES

Summary of New FDA-Approved Products,
New Indications, First-Time Generics,
and WHAT'S IN THE PIPELINE
For: **DECEMBER 2021**

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 01/07/2022

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NEWS

- No drug safety communication, excluding recalls, published during the month of December.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VYVGART™ (EFGARTIGIMOD ALFA-FCAB) INJECTION	ARGENX BV	12/17/2021

THERAPEUTIC CLASS
Neonatal Fc receptor blocker

FDA-APPROVED INDICATION(S)
Vyvgart™ is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

DOSAGE AND ADMINISTRATION
The recommended dosage is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion.

DOSAGE FORMS AND STRENGTHS
Injection: 400mg in 20mL (20mg/mL) single-dose vial

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Infections: Delay administration of Vyvgart™ to patients with an active infection. Monitor for signs and symptoms of infection in patients treated with Vyvgart™. If serious infection occurs, administer appropriate treatment and consider withholding Vyvgart™ until the infection has resolved.
- Hypersensitivity reactions: Angioedema, dyspnea, and rash have occurred. If a hypersensitivity reaction occurs, discontinue the infusion and institute appropriate therapy.

ADVERSE REACTIONS
- Most common adverse reactions (≥ 10%) in patients treated with gMG are respiratory tract infections, headache, and urinary tract infection.

DRUG INTERACTIONS
- Closely monitor for reduced effectiveness of medications that bind to the human neonatal Fc receptor. When concomitant long-term use of such medications is essential for patient care, consider discontinuing Vyvgart™ and using alternative therapies.

USE IN SPECIFIC POPULATIONS
- Pregnancy: No available data on the use of Vyvgart™ during pregnancy.
- Lactation: There is no information regarding the presence of efgartigimod alfa-fcab in human milk, the effects on the breastfed infant, or the effects on milk production..
- Pediatric use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric use: Clinical studies of VYVGART did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger adult patients.
- Renal impairment: No dose adjustment of Vyvgart™ is needed for patients with mild renal impairment. There are insufficient data to evaluate the impact of moderate renal impairment and severe renal impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TEZSPIRE™ (TEZEPELUMAB-EKKO) INJECTION	ASTRAZENECA AB	12/17/2021

THERAPEUTIC CLASS
Thymic stromal lymphopoietin (TSLP) blocker

FDA-APPROVED INDICATION(S)
Tezspire™ is thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

DOSAGE AND ADMINISTRATION
The recommended dosage is 210mg administered by subcutaneous injection once every 4 weeks.

DOSAGE FORMS AND STRENGTHS
Injection:
- 210 mg/1.91 mL (110 mg/mL) solution in a single-dose glass vial.
- 210 mg/1.91 mL (110 mg/mL) solution in a single-dose pre-filled syringe

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to tezepelumab-ekko or excipients.

WARNINGS AND PRECAUTIONS
- Hypersensitivity reactions: Hypersensitivity reactions (e.g., rash, allergic conjunctivitis) can occur after administration of Tezspire™. Initiate appropriate treatment as clinically indicated in the event of a hypersensitivity reaction.
- Risk associated with abrupt reduction in corticosteroid dosage: Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with Tezspire™. Decrease corticosteroids gradually, if appropriate.
- Parasitic (helminth) infection: Treat patients with pre-existing helminth infections before therapy with Tezspire™. If patients become infected while receiving Tezspire™ and do not respond to antihelminth treatment, discontinue Tezspire™ until the parasitic infection resolves.
- Vaccination: Avoid use of live attenuated vaccines.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥ 3%) are pharyngitis, arthralgia, and back pain.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There are no available data on Tezspire™ use in pregnant women to evaluate for any drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.
- Lactation: There is no information regarding the presence of tezepelumab-ekko in human milk, its effects on the breastfed infant, or its effects on milk production.
- Pediatric use: The safety profile and pharmacodynamic responses in pediatric patients were generally similar to the overall study population. The safety and effectiveness in patients younger than 12 years of age have not been established.
- Geriatric use: No overall differences in safety or effectiveness of Tezspire™ have been observed between patients 65 years of age and older and younger patients.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LEQVIO™ (INCLISIRAN) INJECTION	NOVARTIS PHARMACEUTICALS CORP.	12/22/2021

THERAPEUTIC CLASS
Antihyperlipidemics

FDA-APPROVED INDICATION(S)
Leqvio™ is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

DOSAGE AND ADMINISTRATION
The recommended dosage is 284 mg administered as a single subcutaneous injection initially, again at 3 months, and then every 6 months.

DOSAGE FORMS AND STRENGTHS
Injection: 284 mg/1.5 mL (189 mg/mL) in a single-dose prefilled syringe

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- None.

ADVERSE REACTIONS
- Common adverse reactions in clinical trials (≥ 3%): injection site reaction, arthralgia, urinary tract infection, diarrhea, bronchitis, pain in extremity, and dyspnea.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Leqvio™ may cause fetal harm when administered to pregnant patients based on the mechanism of action.
- Lactation: There is no information on the presence of inclisiran in human milk, the effects on the breastfed infant, or the effects on milk production.
- Pediatric use: The safety and effectiveness of Leqvio™ have not been established in pediatric patients.
- Geriatric use: No overall differences in safety or effectiveness were observed between these patients and younger patients, but greater sensitivity to adverse reactions of some older individuals cannot be ruled out.
- Renal impairment: No dose adjustments are necessary for patients with mild, moderate, or severe renal impairment. Leqvio™ has not been studied in patients with end stage renal disease.
- Hepatic impairment: No dose adjustment is necessary in patients with mild to moderate hepatic impairment. Leqvio™ has not been studied in patients with severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
ADBRY™ (TRALOKINUMAB-LDRM) INJECTION	LEO PHARMA INC.	12/27/2021

THERAPEUTIC CLASS
Dermatologicals

FDA-APPROVED INDICATION(S)
Adbry™ is an interleukin-13 antagonist indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry™ can be used with or without topical corticosteroids.

DOSAGE AND ADMINISTRATION
The recommended dosage is an initial dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week. A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment. Administer by subcutaneous injection.

DOSAGE FORMS AND STRENGTHS
Injection: 150 mg/mL solution in a single-dose prefilled syringe with needle guard

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to tralokinumab-ldrm or any excipients in Adbry™.

WARNINGS AND PRECAUTIONS
- Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, and angioedema have occurred after administration of Adbry™. Discontinue Adbry™ in the event of a hypersensitivity reaction.
- Conjunctivitis and keratitis: Patients should report new onset or worsening eye symptoms to their healthcare provider.
- Parasitic (helminth) infections: Treat patients with pre-existing helminth infections before initiating treatment with Adbry™. If patients become infected while receiving Adbry™ and do not respond to anti-helminth treatment, discontinue treatment with Adbry™ until the infection resolves.
- Risk of infection with live vaccines: Avoid use of live vaccines.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥ 1%) are upper respiratory tract infections, conjunctivitis, injection site reactions, and eosinophilia.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There are limited data from the use of Adbry™ in pregnant women to inform a drug-associated risk of adverse developmental outcomes
- Lactation: There are no data on the presence of tralokinumab-ldrm in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is present in breast milk.
- Pediatric use: The safety and effectiveness of Adbry™ have not been established in pediatric patients.
- Geriatric use: Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
RECORLEV™ (LEVOKETOCONAZOLE) TABLETS	XERIS PARMACEUTICALS, INC.	12/30/2021

THERAPEUTIC CLASS
Endocrine and metabolic agents

FDA-APPROVED INDICATION(S)
Recorlev™ is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.

DOSAGE AND ADMINISTRATION
Initiate dosage at 150 mg orally twice daily, with or without food. Titrate dosage by 150 mg daily, no more frequently than every 2-3 weeks. Maximum recommended dosage is 1200 mg daily, administered as 600 mg twice daily.

DOSAGE FORMS AND STRENGTHS
Tablets: 150 mg

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Cirrhosis, acute liver disease or poorly controlled chronic liver disease, baseline AST or ALT > 3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease.
- Taking drugs that cause QT prolongation associated with ventricular arrythmias, including torsades de pointes.
- Prolonged QTc interval > 470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or prolonged QT syndrome.
- Hypersensitivity to levoketoconazole, ketoconazole or any excipient in Recorlev™.
- Taking certain drugs that are sensitive substrates of CYP3A4 or CYP3A4 and P-gp.

WARNINGS AND PRECAUTIONS
- Boxed warning: Hepatotoxicity and QT prolongation
  - Cases of hepatotoxicity with fatal outcome or requiring liver transplantation have been reported with oral ketoconazole. Some patients had no obvious risk factors for liver disease. RECORLEV is associated with serious hepatotoxicity. Evaluate liver enzymes prior to and during treatment.
  - Recorlev™ is associated with dose-related QT interval prolongation. QT interval prolongation may result in life-threatening ventricular dysrhythmias such as torsades de pointes. Perform ECG prior to and during treatment.

ADVERSE REACTIONS
- Most common adverse reactions (incidence > 20%) are nausea/vomiting, hypokalemia, hemorrhage/contusion, systemic hypertension, headache, hepatic injury, abnormal uterine bleeding, erythema, fatigue, abdominal pain/dyspepsia, arthritis, upper respiratory infection, myalgia, arrhythmia, back pain, insomnia/sleep disturbances, and peripheral edema.

Continues on the next slide.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
RECORLEV™ (LEVOKETOCONAZOLE) TABLETS	XERIS PARMACEUTICALS, INC.	12/30/2021

THERAPEUTIC CLASS
Endocrine and metabolic agents

FDA-APPROVED INDICATION(S)
Recorlev™ is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.

DOSAGE AND ADMINISTRATION
Initiate dosage at 150 mg orally twice daily, with or without food. Titrate dosage by 150 mg daily, no more frequently than every 2-3 weeks. Maximum recommended dosage is 1200 mg daily, administered as 600 mg twice daily.

DOSAGE FORMS AND STRENGTHS
Tablets: 150 mg

Orphan status: N/A

SAFETY PROFILE

DRUG INTERACTIONS

- Consult approved product labeling for drugs that are substrates of CYP3A4, P-gp, OCT2, and MATE prior to initiating Recorlev™.
- Sensitive CYP3A4 or CYP3A4 and P-gp Substrates: Concomitant use of Recorlev™ with these substrates is contraindicated or not recommended.
- Atorvastatin: Use lowest atorvastatin dose possible and monitor for adverse reactions for dosages exceeding 20 mg daily.
- Metformin: Monitor glycemia, kidney function, and vitamin B12 and adjust metformin dosage as needed.
- Strong CYP3A4 Inhibitors or Inducers: Avoid use of these drugs 2 weeks before and during Recorlev™ treatment.
- Gastric Acid Modulators: See Full Prescribing Information for recommendations regarding concomitant use with Recorlev™.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Advise pregnant women of the potential risk to a fetus and consider whether the benefits of treatment with Recorlev™ outweigh the risks.
- Lactation: Because of the potential for serious adverse reactions in the breastfed infant, including liver toxicity, advise patients not to breastfeed during treatment with Recorlev™ and for one day (5 times the half-life) after the final dose.
- Females and males of reproductive potential: Recorlev™ may lower testosterone levels and impair male and female fertility.

USE IN SPECIFIC POPULATIONS (cont.)

- Pediatric use: The safety and effectiveness of Recorlev™ in pediatric patients below the age of 18 have not been established.
- Geriatric use: Clinical studies of Recorlev™ did not include sufficient number of patients 65 years of age and older to determine whether they respond differently from younger adult patients.
- Renal Impairment: There is no experience with Recorlev™ in patients with renal impairment. The overall pharmacokinetics of racemic ketoconazole in patients with renal impairment were not significantly different when compared with healthy subjects.
- Hepatic impairment: The use of RECORLEV is contraindicated in patients with cirrhosis, acute liver disease or poorly controlled chronic liver disease, recurrent symptomatic cholelithiasis, a prior history of drug induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease

NEW BIOSMILAR PRODUCTS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
REZVOGLAR™ (INSULIN GLARGLINE-AGLR) INJECTION / ELI LILLY AND CO.	Antidiabetics	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus	12/17/2021	This is the second biosimilar insulin product approved by the FDA. Rezvoglar™ is a biosimilar to Lantus™ (insulin glargine). The list price and launch date for this product have yet to be determined.
YUSIMRY™ (ADALIMUMAB-AQVH) INJECTION / COHERUS BIOSCIENCES INC.	Analgesics – Anti-inflammatory	Treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn's disease (CD), ulcerative colitis (UC), plaque psoriasis (Ps)	12/17/2021	Yusimry™ is the seventh biosimilar to Humira™ (adalimumab). The earliest Yusimry™ can launch is July 1, 2023.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
XACIATO™ (CLINDAMYCIN PHOSPHATE) VAGINAL GEL / DARE BIOSCIENCE, INC.	Vaginal and related products	Treatment of bacterial vaginosis in female patients 12 years of age and older	12/7/2021	Xaciato™ is a clear, colorless, viscous gel, which contains clindamycin at a concentration of 2% (present as clindamycin phosphate). A single-dose user-filled disposable applicator delivers 5 g of vaginal gel containing 100 mg of clindamycin.
ENTADFI™ (FINASTERIDE AND TADALAFIL) CAPSULES / VERU INC.	Genitourinary agents	Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks	12/9/2021	Entadfi™ has shown to be more effective in treating urinary tract symptoms caused by BPH with less potential for adverse sexual side effects compared to finasteride monotherapy.
TARPEYO™ (BUDESONIDE) DELAYED RELEASE CAPSULES / CALLIDITAS THERAPEUTICS AB	Corticosteroids	To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5g/g	12/15/2021	Tarpeyo™ is approved under accelerated approval based on achieving its primary endpoint of reduction in proteinuria in Part A of the NeflgArd pivotal Phase 3 study, an ongoing, randomized, double-blind, placebo-controlled, multicenter study conducted to evaluate the efficacy and safety of Tarpeyo™ 16 mg once daily vs placebo in adult patients with primary IgAN.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
DARTISLA ODT™ (GLYCOPYRROLATE) ORALLY DISINTEGRATING TABLETS / EDENBRIDGE PHARMACEUTICALS, LLC.	Anticholinergic agents	To reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer	12/16/2021	Dartisla ODT™ is manufactured using the proprietary Zydis™ orally disintegrating tablet delivery technology to create a freeze-dried tablet that disperses almost instantly in the mouth without water.
OXBRYTA™ (VOXELOTOR) TABLETS FOR ORAL SUSPENSION / GLOBAL BLOOD THERAPEUTICS, INC.	Hematopoietic agents	Treatment of sickle cell disease in adults and pediatric patients 4 years of age and older	12/17/2021	Oxbryta™ tablets for oral suspension is a new dispersible, once-daily tablet dosage form suitable for patients ages 4 to less than 12 years as well as for older patients who have difficulty swallowing whole tablets.
APRETUDE™ (CABOTEGRAVIR) EXTENDED-RELEASE INJECTABLE SUSPENSION / VIIV HEALTHCARE	Antivirals	For pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at risk adults and adolescents weighing at least 35kg	12/20/2021	Apretude™ is the first and only long-acting injectable pre-exposure prophylaxis (PrEP) option to reduce the risk of sexually acquired HIV-1. The medicine was studied in men who have sex with men, as well as women and transgender women who have sex with men, who were at increased risk of sexually acquiring HIV.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
XARELTO™ (RIVAROXABAN) FOR ORAL SUSPENSION / JANSSEN PHARMACEUTICALS, INC.	Anticoagulants	To reduce the risk of stroke and systemic embolism in nonvalvular atrial fibrillation; for treatment of deep vein thrombosis (DVT); for treatment of pulmonary embolism (PE); for reduction in the risk of recurrence of DVT or PE; for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery; for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients; to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD); to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD; treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years and for thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after then Fontan procedure	12/20/2021	Xarelto™ is the only direct oral anticoagulant (DOAC) FDA-approved for primary prevention of clots in pediatric patients following the Fontan procedure and the only DOAC in the U.S. to offer an oral suspension formulation for flexible, body weight-adjusted dosing options for pediatric patients.

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
IVABRADINE HYDROCHLORIDE TABLETS 5MG (BASE) AND 7.5MG (BASE) / CENTAUR PHARMACEUTICALS PRIVATE LIMITED	Cardiovascular agents	To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ejection fraction; for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older	Corlanor™	12/30/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
ZYNRELEF (BUPIVACAINE AND MELOXICAM) INJECTION / HERON THERAPEUTICS, INC.	Analgesics – Anti-inflammatory	Soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty	Soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures	12/8/2021
RINVOQ (UPADACITNIB) EXTENDED-RELEASE TABLETS / ABBVIE	Analgesics – Anti-inflammatory	Treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers	Treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers	12/14/2021
XELJANZ (TOFACITINIB) TABLETS AND ORAL SOLUTION / PFIZER INC.	Analgesics – Anti-inflammatory	Treatment of moderately to severely active rheumatoid arthritis, psoriatic arthritis, ulcerative colitis or polyarticular course juvenile idiopathic arthritis in patients who have had an inadequate response or intolerance to one or more TNF blockers	Treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers	12/14/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
ORENCIA (ABATACEPT) INJECTION / BRISTOL MYERS SQUIBB	Analgesics – Anti-inflammatory	Treatment of moderately to severely active rheumatoid arthritis, moderately to severely active polyarticular juvenile idiopathic arthritis and active psoriatic arthritis	The prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor	12/15/2021
CAPLYTA (LUMATEPERONE) CAPSULES / INTRA-CELLULAR THERAPIES, INC.	Antipsychotics/antimanic agents	Treatment of schizophrenia in adults	Treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate	12/17/2021
OXBRYTA (VOXELOTOR) TABLETS / GLOBAL BLOOD THERAPEUTICS, INC.	Hematopoietic agents	Treatment of sickle cell disease in adults and pediatric patients 12 years of age and older	Treatment of sickle cell disease in adults and pediatric patients 4 years of age and older	12/17/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
OTEZLA (APREMILAST) TABLETS / AMGEN	Analgesics – Anti-inflammatory	The treatment of adult patients with active psoriatic arthritis or adult patients with oral ulcers associated with Behçet's disease	Treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy	12/20/2021
XARELTO (RIVAROXABAN) TABLETS AND ORAL SUSPENSION / JANSSEN PHARMACEUTICALS	Anticoagulants	To reduce the risk of stroke and systemic embolism in nonvalvular atrial fibrillation; for treatment of deep vein thrombosis (DVT); for treatment of pulmonary embolism (PE); for reduction in the risk of recurrence of DVT or PE; for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery; for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients; to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD); to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD	Treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years and for thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after then Fontan procedure	12/20/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
COSENTYX (SECUKINUMAB) INJECTION / NOVARTIS	Dermatologicals	Treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy; treatment of active psoriatic arthritis (PsA) in adult patients; treatment of active ankylosing spondylitis in adult patients; treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) in adult patients	Treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older and treatment of active PsA in patients 2 years of age and older	12/22/2021

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PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
POZIOTINIB / SPECTRUM PHARMACEUTICALS, INC.	12/6/2021	Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with HER2 exon 20 insertion mutations in previously-treated patients	Poziotinib has received Fast Track designation based on positive results of Cohort 2 from the ZENITH20 clinical trial, which assessed the safety and efficacy of poziotinib. Cohort 2 enrolled 90 patients who received an oral once daily dose of 16 mg of poziotinib. The intent-to-treat analysis demonstrated a confirmed objective response rate (ORR) of 27.8% (95% Confidence Interval (CI), 18.9%-38.2%). The observed lower bound of 18.9% exceeded the pre-specified lower bound of 17%. The median duration of response was 5.1 months and the median progression free survival was 5.5 months. NDA submitted.	High
COMIRNATY (COVID-19 VACCINE, MRNA) INJECTION / PFIZER INC. AND BIONTECK SE	12/16/2021	Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Adolescents 12 through 15 years of age	The supplemental BLA includes updated longer-term follow-up date from the companies pivotal Phase 3 clinical trials of 2,228 participants 12 through 15 years of age. In the trial, a two-dose series of the Pfizer-BioNTech COVID-19 Vaccine (30-µg per dose) was 100% effective (95% confidence interval [CI, 87.5, 100.0]) against COVID-19, measured seven days through over four months after the second dose. sBLA submitted.	High
ARQ-151 (ROFLUMILAST) CREAM / ARCUTIS BIOTHERAPEUTICS, INC.	12/22/2021	Treatment of mild-to-severe plaque psoriasis	Roflumilast cream (ARQ-151) is a once-daily topical formulation of roflumilast, a highly potent and selective inhibitor of phosphodiesterase type 4 (PDE4), an enzyme that drives overactive immune responses. PDE4 is an established target in dermatology.. NDA accepted.	Moderate

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