pharmpiX
POWERED BY ONEARK

PharmNOTES

Summary of New FDA-Approved Products,
New Indications, First-Time Generics,
and WHAT'S IN THE PIPELINE
For: **JUNE 2022**

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 7/8/2022

TABLE OF CONTENTS

	PAGE
NEWS	3
NEW FDA-APPROVED DRUG PRODUCTS	4-15
NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS	5-11
• Priorix™ (measles, mumps, and rubella vaccines, live) injection	5
• Pemetrexed ditromethamine for injection	6-8
• Amvuttra™ (vutrisiran) injection	9
• Venlafaxine besylate extended-release tablets	10-11
NEW BIOSMILAR PRODUCTS	12
NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS	13-14
NEW FIRST-TIME GENERIC APPROVALS	15
NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS	16-20
PIPELINE	21-23
REFERENCES	24

pharmpiX POWERED BY ONEARK

NEWS

DRUG ISSUE	DATE	DETAILS
FDA approval of lymphoma medicine Ukoniq™ (umbralisib) is withdrawn due to safety concerns	6/1/2022	Back in February 2022 the FDA was investigating possible increased risk of death wit Ukoniq™. Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq™. The risks of treatment with umbralisib outweigh its benefits. TG Therapeutics, drug's manufacturer, has announced it was voluntarily withdrawing Ukoniq™ from the market for the approved indications of follicular lymphoma and marginal zone lymphoma.
FDA warns about possible increased risk of death and serious side effects with cancer drug Copiktra™ (duvelisib)	6/30/2022	The FDA is warning that results from a clinical trial show a possible increased risk of death with Copiktra™ compared to monoclonal antibody ofatumumab in patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma. Furthermore, the drug was found to be associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzyme levels in the blood.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PRIORIX™ (MEASLES, MUMPS, AND RUBELLA VACCINE, LIVE) SUSPENSION FOR SUBCUTANEOUS INJECTION	GLAXOSMITHKLINE	6/3/2022

THERAPEUTIC CLASS
Vaccine

FDA-APPROVED INDICATION(S)
Priorix™ is indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older.

DOSAGE AND ADMINISTRATION
For subcutaneous injection only. Each dose is approximately 0.5mL. The first dose is administered at 12 through 15 months of age. The second dose is administered at 4 through 6 years of age.

DOSAGE FORMS AND STRENGTHS
Suspension for injection: single-dose vial of lyophilized antigen component to be reconstituted with the accompanying prefilled syringe of sterile water diluent component. A single dose after reconstitution is approximately 0.5mL.

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Severe allergic reaction (e.g., anaphylaxis) to any component of Priorix™, or after a previous dose of any measles, mumps, and rubella virus-containing vaccine
- Severe immunodeficiency
- Pregnancy

WARNINGS AND PRECAUTIONS
- There is a risk of febrile seizure following administration of Priorix™.
- Thrombocytopenia and thrombocytopenic purpura have been reported following vaccination with Priorix™.
- Syncope (fainting) can occur in association with administration of injectable vaccines, including Priorix™. Procedures should be in place to avoid injury from fainting.
- The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions.

ADVERSE REACTIONS
Most common solicited adverse reactions in clinical trials participants:
- 12 through 15 months of age: local reactions were pain (26%) and redness (25%); systemic reactions were irritability (63%), loss of appetite (45%), drowsiness (45%), and fever(35%)

ADVERSE REACTIONS (CONT.)
- 4 through 6 years of age: local reactions were pain (41%), redness (22%), and swelling (11%); systemic reactions were loss of appetite (21%), drowsiness (27%), and fever(24%)
- 7 years of age and older: local reactions were pain (12%) and redness (12%)

DRUG INTERACTIONS
- Administration of immune globulins and other blood products concurrently with Priorix™ may interfere with the expected immune response to the vaccine.
- Priorix™ may result in a temporary suppression of tuberculin reactivity.

USE IN SPECIFIC POPULATIONS
- Pregnancy: The vaccine is contraindicated for use in pregnant women because infection during pregnancy with the wild-type viruses is associated with maternal and fetal adverse outcomes. Pregnancy should be avoided for 1 month after vaccination.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PEMETREXED DITROMETHAMINE FOR INJECTION	ZYDUS HOSPIRA ONCOLOGY PRIVATE LTD.	6/10/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Pemetrexed ditromethamine is indicated:

- In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC)
- As a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy
- As a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy

Orphan status: No

DOSAGE AND ADMINISTRATION

- The recommended dose, administered as a single agent or with cisplatin, in patients with creatinine clearance of 45 mL/minute or greater is 500 mg/m2 as an intravenous infusion over 10 minutes on Day 1 of each 21-day cycle.
- Initiate folic acid 400 mcg to 1000 mcg orally, once daily, beginning 7 days prior to the first dose of pemetrexed and continue until 21 days after the last dose of pemetrexed.
- Administer vitamin B12, 1 mg intramuscularly, 1 week prior to the first dose of Pemetrexed for Injection and every 3 cycles.
- Administer dexamethasone 4 mg orally, twice daily the day before, the day of, and the day after pemetrexed administration.

DOSAGE FORMS AND STRENGTHS
For Injection: 100-mg, 500-mg or 1-gram lyophilized powder in a single-dose vial

SAFETY PROFILE

CONTRAINDICATIONS

- History of severe hypersensitivity reaction to pemetrexed

WARNINGS AND PRECAUTIONS

- Myelosuppression: Can cause severe bone marrow suppression resulting in cytopenia and an increased risk of infection. Do not administer pemetrexed when the absolute neutrophil count is less than 1500 cells/mm^3 and platelets are less than 100,000 cells/mm^3. Initiate supplementation with oral folic acid and intramuscular vitamin B12 to reduce the severity of hematologic and gastrointestinal toxicity of pemetrexed.
- Renal Failure: Can cause severe, and sometimes fatal, renal failure. Do not administer when creatinine clearance is less than 45mL/min.
- Bullous and Exfoliative Skin Toxicity: Permanently discontinue for severe and life-threatening bullous, blistering or exfoliating skin toxicity.
- Interstitial Pneumonitis: Withhold for acute onset of new or progressive unexplained pulmonary symptoms. Permanently discontinue if pneumonitis is confirmed.
- Radiation Recall: Can occur in patients who received radiation weeks to years previously; permanently discontinue for signs of radiation recall.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Continued next slide

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PEMETREXED DITROMETHAMINE FOR INJECTION	ZYDUS HOSPIRA ONCOLOGY PRIVATE LTD.	6/10/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Pemetrexed ditromethamine is indicated:

- In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC)
- As a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy
- As a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy

Orphan status: No

DOSAGE AND ADMINISTRATION

- The recommended dose, administered as a single agent or with cisplatin, in patients with creatinine clearance of 45 mL/minute or greater is 500 mg/m2 as an intravenous infusion over 10 minutes on Day 1 of each 21-day cycle.
- Initiate folic acid 400 mcg to 1000 mcg orally, once daily, beginning 7 days prior to the first dose of pemetrexed and continue until 21 days after the last dose of pemetrexed.
- Administer vitamin B12, 1 mg intramuscularly, 1 week prior to the first dose of Pemetrexed for Injection and every 3 cycles.
- Administer dexamethasone 4 mg orally, twice daily the day before, the day of, and the day after pemetrexed administration.

DOSAGE FORMS AND STRENGTHS
For Injection: 100-mg, 500-mg or 1-gram lyophilized powder in a single-dose vial

SAFETY PROFILE

ADVERSE REACTIONS

- The most common adverse reactions of pemetrexed, when administered as a single agent, are fatigue, nausea, and anorexia.
- The most common adverse reactions of pemetrexed when administered with cisplatin are vomiting, neutropenia, anemia, stomatitis/pharyngitis, thrombocytopenia, and constipation.

DRUG INTERACTIONS
Effects of ibuprofen on pemetrexed: Ibuprofen increases exposure (AUC) of pemetrexed.

- In patients with creatinine clearance between 45mL/min and 79mL/min:
  - Avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of pemetrexed
  - Monitor patients more frequently for myelosuppression, renal, and gastrointestinal toxicity, if concomitant administration of ibuprofen cannot be avoided

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on findings from animal studies and its mechanism of action, pemetrexed can cause fetal harm when administered to a pregnant woman.
- Lactation: Because of the potential for serious adverse reactions in breastfed infants from pemetrexed, advise women not to breastfeed during treatment with Pemetrexed for Injection and for one week after the last dose.

Continued next slide

pharmpiX POWERED BY ONEARK

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PEMETREXED DITROMETHAMINE FOR INJECTION	ZYDUS HOSPIRA ONCOLOGY PRIVATE LTD.	6/10/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Pemetrexed ditromethamine is indicated:

- In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC)
- As a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy
- As a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy

Orphan status: No

DOSAGE AND ADMINISTRATION

- The recommended dose, administered as a single agent or with cisplatin, in patients with creatinine clearance of 45 mL/minute or greater is 500 mg/m2 as an intravenous infusion over 10 minutes on Day 1 of each 21-day cycle.
- Initiate folic acid 400 mcg to 1000 mcg orally, once daily, beginning 7 days prior to the first dose of pemetrexed and continue until 21 days after the last dose of pemetrexed.
- Administer vitamin B12, 1 mg intramuscularly, 1 week prior to the first dose of Pemetrexed for Injection and every 3 cycles.
- Administer dexamethasone 4 mg orally, twice daily the day before, the day of, and the day after pemetrexed administration.

DOSAGE FORMS AND STRENGTHS
For Injection: 100-mg, 500-mg or 1-gram lyophilized powder in a single-dose vial

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Females and Males of Reproductive Potential: Based on animal data, pemetrexed can cause malformations when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to initiating pemetrexed. Because of the potential for genotoxicity, advise females of reproductive potential to use effective contraception during treatment with pemetrexed and for 6 months after the last dose of pemetrexed. Because of the potential for genotoxicity, advise males with female partners of reproductive potential to use effective contraception during treatment with pemetrexed and for 3 months after the last dose. Pemetrexed may impair fertility in males of reproductive potential. It is not known whether these effects on fertility are reversible.
- Pediatric Use: The safety and effectiveness of pemetrexed in pediatric patients have not been established.
- Geriatric Use: No overall differences in effectiveness were observed between these patients and younger patients.
- Renal Impairment: Pemetrexed is primarily excreted by the kidneys. Decreased renal function results in reduced clearance and greater exposure (AUC) to pemetrexed compared with patients with normal renal function. No dose is recommended for patients with creatinine clearance less than 45mL/min.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
AMVUTTRA™ (VUTRISIRAN) INJECTION	ALNYLAM PHARMACEUTICALS, INC.	6/13/2022

THERAPEUTIC CLASS
Transthyretin-directed small interfering RNA

FDA-APPROVED INDICATION(S)
Amvuttra™ is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

DOSAGE AND ADMINISTRATION
The recommended dosage is 25mg administered by subcutaneous injection once every 3 months. Amvuttra™ is for subcutaneous use only and should be administered by a healthcare professional.

DOSAGE FORMS AND STRENGTHS
Injection: 25mg/0.5mL in a single-dose prefilled syringe

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Reduced serum vitamin A levels and recommended supplementation: Supplement with the recommended daily allowance of vitamin A. Refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency occur.

ADVERSE REACTIONS
- The most common adverse reactions (≥5%) were arthralgia, dyspnea, and vitamin A decreased.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VENLAFAXINE BESYLATE EXTENDED-RELEASE TABLETS	ALMATICA PHARMA LLC.	6/29/2022

THERAPEUTIC CLASS
Antidepressants

FDA-APPROVED INDICATION(S)
Venlafaxine besylate is indicated for the treatment of major depressive disorder (MDD) and generalized anxiety disorder (GAD) in adult patients

DOSAGE AND ADMINISTRATION
Venlafaxine besylate can be initiated at 112.5mg orally once daily in patients who have received at least 75mg of another venlafaxine extended-release product for at least 4 days. Maximum recommended dosage is 225mg once daily.

DOSAGE FORMS AND STRENGTHS
Extended-release tablets: 112.5mg

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Hypersensitivity to venlafaxine besylate, venlafaxine hydrochloride, desvenlafaxine succinate, or any excipients in venlafaxine extended-release tablets.
- Concomitant use of monoamine oxidase inhibitors (MAOIs) or within 14 days of discontinuing an MAOI.

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING:** Suicidal thoughts and behaviors
  - Increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors.
  - Venlafaxine extended-release tablets are not approved for use in pediatric patients.
- Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g., SSRIs, SNRIs, triptans), but also when taken alone. If it occurs, discontinue Venlafaxine Extended-Release Tablets and initiate supportive treatment
- Elevated Blood Pressure: Control hypertension before initiating treatment. Monitor blood pressure regularly during treatment

WARNINGS AND PRECAUTIONS (CONT.)
- Increased Risk of Bleeding: Concomitant use of aspirin, NSAIDs, other antiplatelet drugs, warfarin, and other anticoagulants may increase risk.
- Angle Closure Glaucoma: Angle closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.
- Activation of Mania/Hypomania: Screen patients for bipolar disorder.
- Discontinuation Syndrome: Taper dose and monitor for discontinuation symptoms.
- Seizure: Can occur. Use with caution in patients with seizure disorder.
- Hyponatremia: Can occur in association with SIADH.
- Interstitial Lung Disease and Eosinophilic Pneumonia: Can occur.
- Sexual Dysfunction: Venlafaxine Extended-Release Tablets may cause symptoms of sexual dysfunction.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo): nausea, somnolence, dry mouth, sweating, abnormal ejaculation, anorexia, constipation, impotence (men), and libido decreased.

Continued next slide

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VENLAFAXINE BESYLATE EXTENDED-RELEASE TABLETS	ALMATICA PHARMA LLC.	6/29/2022

THERAPEUTIC CLASS
Antidepressants

FDA-APPROVED INDICATION(S)
Venlafaxine besylate is indicated for the treatment of major depressive disorder (MDD) and generalized anxiety disorder (GAD)

DOSAGE AND ADMINISTRATION
Venlafaxine besylate can be initiated at 112.5mg orally once daily in patients who have received at least 75mg of another venlafaxine extended-release product for at least 4 days. Maximum recommended dosage is 225mg once daily.

DOSAGE FORMS AND STRENGTHS
Extended-release tablets: 112.5mg

Orphan status: No

SAFETY PROFILE

DRUG INTERACTIONS

- Alcohol: Increases the release rate of venlafaxine extended-release tablets. Avoid concomitant use of alcohol during treatment with venlafaxine extended-release tablets.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Third trimester use may increase risk for symptoms of poor neonatal adaptation (respiratory distress, temperature instability, feeding difficulty, hypotonia, tremor, irritability) in the neonate.
- Hepatic Impairment: Dosage reduction is recommended in patients with mild, moderate, severe, hepatic impairment or hepatic cirrhosis.
- Renal Impairment: Dosage reduction is recommended in patients with mild or moderate renal impairment, and in patients undergoing hemodialysis o with severe renal impairment.

NEW BIOSIMILAR PRODUCTS

- No biosimilar product was approved by the FDA in June.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
SKYRIZI™ (RISANKIZUMAB-RZAA) INJECTION / ABBVIE	Dermatologicals	Treatment of moderately to severely active Crohn's disease in adults	6/16/2022	An intravenous formulation of Skyrizi™ was approved by the FDA for the treatment of moderately to severely Crohn's disease, a new indication for Skyrizi™. The intravenous formulation is recommended as induction therapy (3 doses total). Orphan: Yes
PHEBURANE™ (SODIUM PHENYLBUTYRATE) ORAL PELLETS / MEDUNIK	Endocrine and metabolic agents	As adjunctive therapy to standard of care for the chronic management of adult and pediatric patients with urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinic acid synthase	6/17/2022	This is the first oral pellet dosage form of sodium phenylbutyrate approved by the FDA. Pheburane™ treatment should be supervised by a healthcare provider experienced in the treatment of urea cycle disorders. Orphan: Yes

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
RELEXXII™ (METHYLPHENIDATE HYDROCHLORIDE) EXTENDED-RELEASE TABLETS / OSMOTICA PHARM CORP	ADHD / anti-narcolepsy / ant-obesity / anorexiants	Treatment of attention deficit hyperactivity disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older	6/23/2022	This new formulation of methylphenidate hydrochloride allows for a once-daily dosing and is available in 7 strengths. Orphan: No Controlled substance schedule: CII
DROSPIRENONE CHEWABLE TABLETS / EXELTIS USA INC.	Contraceptives	For use by females of reproductive potential to prevent pregnancy	6/29/2022	Drospirenone chewable tablets provide an alternative to individuals that have difficulties or are unable to swallow pills. Orphan: No

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
BRIVARACETAM TABLETS 10MG, 25MG, 50MG, 75MG, 100MG / SUNSHINE LAKE PHARMA CO., LTD.	Anticonvulsants	Epilepsy	Briviact™	6/9/2022

NEW
FDA-APPROVED INDICATIONS
FOR EXISTING DRUGS

pharmpix
POWERED BY ONEARK

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
RIABNI™ (RITUXIMAB-ARRX) INJECTION / AMGEN	Antineoplastics and adjunctive therapies	Treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis and microscopic polyangiitis	Treatment of rheumatoid arthritis in combination with methotrexate in adult patients with moderately-to-severely-active RA who have inadequate response to one or more TNF antagonist therapies	6/3/2022
CELLCEPT™ (MYCOPHENOLATE MOFETIL) TABLETS, CAPSULES, ORAL SUSPENSION, INJECTION / GENENTECH USA, INC.	Immunosuppressive agents	For the prophylaxis of organ rejection in adult recipients of allogeneic heart, or liver transplants, and should be used in combination with other immunosuppressants; for the prophylaxis of organ rejection in adult and pediatric patients 3 months of age and older of allogeneic kidney transplant in combination with other immunosuppressants	For the prophylaxis of organ rejection in adult and pediatric patients 3 months of age and older of allogeneic kidney, heart, or liver transplants, in combination with other immunosuppressants	6/6/2022
DUPIXENT™ (DUPILUMAB) INJECTION / REGENERON PHARMACEUTICALS	Dermatologicals	Treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe atopic dermatitis; add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma; add-on maintenance treatment in adult patients with chronic rhinosinusitis with nasal polyposis; treatment of adult and pediatric patients aged 12 years and older with eosinophilic esophagitis	Treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	6/7/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
OLUMIANT™ (BARICITINIB) TABLETS / ELI LILLY	Analgesics – Anti-inflammatory	Treatment of adult patients with moderately to severely active rheumatoid arthritis and COVID-19 in hospitalized adults	Treatment of adult patients with severe alopecia areata	6/13/2022
SKYRIZI™ (RISANKIZUMAB-RZAA) INJECTION / ABBVIE	Dermatologicals	Treatment of moderate-to-severe plaque psoriasis in adults and active psoriatic arthritis in adults	Treatment of moderately to severely active Crohn's disease in adults	6/16/2022
IMCIVREE™ (SETMELANOTIDE) INJECTION / RHYTHM PHARMACEUTICALS, INC.	ADHD / anti-narcolepsy / anti-obesity / anorexiants	For chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to: 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	For chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to: Bardet-Biedl syndrome	6/16/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
VAXNEUVANCE™ (PNEUMOCOCCAL 15-VALENT CONJUGATE VACCINE) / MERCK	Vaccines	For active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in adult patients	For active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older	6/22/2022
TAFINLAR™ (DABRAFENIB) CAPSULES / NOVARTIS	Antineoplastics and adjunctive therapies	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation; in combination with trametinib for: unresectable or metastatic melanoma with BRAF V600E or V600K mutations, adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations and involvement of lymph node(s), following complete resection, treatment of patients with metastatic non-small cell lung cancer with BRAF V600E mutation, treatment of patients with locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation and with no satisfactory locoregional treatment options	In combination with trametinib for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options	6/23/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
QSYMIA™ (PHENTERMINE AND TOPIRAMATE EXTENDED-RELEASE) CAPSULES / VIVUS LLC	ADHD / anti-narcolepsy / anti-obesity / anorexiants	As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: 30kg/m^2 or greater (obese) or 27kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension type 2 diabetes mellitus, or dyslipidemia	As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex	6/24/2022
BREYANZI™ (LISOCABTAGENE MARALEUCEL) SUSPENSION FOR INTRAVENOUS INFUSION / JUNO THERAPEUTICS, INC., A BRISTOL-MYERS SQUIBB COMPANY	Antineoplastics and adjunctive therapies	For the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B	For treatment of adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have: Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age	6/24/2022

PIPELINE

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
LANDIOLOL / EAGLE PHARMACEUTICALS, INC.	6/1/2022	Short-term reduction of ventricular rate in patients with supraventricular tachycardia ("SVT"), including atrial fibrillation and atrial flutter	Landiolol is an ultra-short-acting, cardio-selective, beta-1 adrenoceptor blocker, which reduces heart rate and has a minimal effect over cardiac contractility (inotropy). It is designed for use in emergency, critical care, and operating room settings. NDA submitted.	Moderate
TERLIPRESSIN / MALLINCKRODT PLC	6/13/2022	Hepatorenal syndrome (HRS) involving rapid reduction in kidney function	Terlipressin is an investigational agent being evaluated for the treatment of HRS in the U.S., and its safety and effectiveness have not yet been established by the FDA. The NDA was resubmitted following discussions with the FDA and the need to identify a new third-part packaging and labeling facility. NDA resubmitted.	High
MOMELOTINIB / SIERRA ONCOLOGY, INC.	6/17/2022	Myelofibrosis	Momelotinib is a potent, selective and orally bioavailable ACVR1/ALK2, JAK1 and JAK2 inhibitor under investigation for the treatment of myelofibrosis in symptomatic, anemic patients previously treated with an approved JAK inhibitor. It is the first and only JAK inhibitor to demonstrate positive date for all key hallmarks of the disease – symptoms, splenic response and anemia. NDA submitted.	Moderate
ELACESTRANT / MENARINI GROUP AND RADIUS HEALTH, INC.	6/22/2022	ER+/HER2- advanced or metastatic breast cancer	Elacestrant is an investigational selective estrogen receptor degrader (SERD) that is being evaluated for potential use as a once daily oral treatment in patient with ER+/HER2- advanced breast cancer. The company has requested Priority Review. NDA submitted.	Moderate

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
FEZOLINETANT / ASTELLAS PHARMA INC.	6/23/2022	Moderate to severe vasomotor symptoms associated with menopause	Fezolinetant is an investigational selective neurokinin 3 (NK3) receptor antagonist. The safety and efficacy of fezolinetant are under investigation and have not been established. NDA submitted.	Moderate
LENACAPAVIR / GILEAD SCIENCES, INC.	6/27/2022	HIV-1 infection in heavily treatment-experienced people with multi-drug resistant HIV-1 infection	Lenacapavir is a potential first-in-class, investigational long-acting HIV-1 capsid inhibitor. Lenacapavir's multi-stage mechanism of action is distinguishable from currently approved classes of antiviral agents and is designed to provide a new avenue for the development of long-acting therapy options for people living with or at risk for HIV-1. NDA submitted.	High
PAXLOVID™ (NIRMATRELVIR TABLETS AND RITONAVIR TABLETS)	6/27/2022	Treatment of COVID-19 in both vaccinated and unvaccinated individuals at high risk for progression to severe illness from COVID-19	Paxlovid™ is currently authorized for emergency use for the treatment of mild-to-moderate COVID-19. The NDA submission provides the longer-term follow-up data necessary for acceptance and potential approval. NDA submitted.	High

REFERENCES

- *New Drug Approvals*. Drugs.com. (2022). https://www.drugs.com/newdrugs.html.
- *Latest Generic Drug Approvals*. Drugs.com. (2022). https://www.drugs.com/generic-approvals.html.
- *New Indications & Dosage Forms for Existing Drugs*. Drugs.com. (2022). https://www.drugs.com/new-indications.html.
- *New Drug Applications*. Drugs.com. (2022). https://www.drugs.com/new-drug-applications.html.
- *Drugs@FDA: FDA-Approved Drugs. Accessdata.FDA.gov. (2022). https://www.accessdata.fda.gov/scripts/cder/daf/.*