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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
From: JUNE 2021

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Pharmacy
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NEWS

- No new drug safety communication other that recalls published during June 2021.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
BREXAFEMME (IBREXAFUNGERP) TABLETS	SCYNEXIS, INC	06/01/2021

THERAPEUTIC CLASS
Anti-infective agent; Antifungal

FDA-APPROVED INDICATION(S)
BREXAFEMME is a triterpenoid antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).

DOSAGE AND ADMINISTRATION
The recommended dose is 300 mg (two tablets of 150 mg) twice a day for one day, for a total treatment dosage of 600 mg.

DOSAGE FORMS AND STRENGTHS
Tablets: 150 mg of ibrexafungerp.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Pregnancy
- Hypersensitivity to ibrexafungerp

WARNINGS AND PRECAUTIONS
- Risk of fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: diarrhea, nausea, abdominal pain, dizziness, and vomiting.

DRUG INTERACTIONS
- Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole): Concomitant use of strong CYP3A inhibitors increases the exposure of ibrexafungerp. Reduce BREXAFEMME dose with concomitant use of a strong CYP3A inhibitor to 150 mg twice daily for one day.
- Strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, or etravirine): Concomitant use of strong and moderate CYP3A inducers may significantly reduce the exposure of ibrexafungerp. Avoid concomitant administration of BREXAFEMME with strong or moderate CYP3A inducers.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Use is contraindicated in pregnancy. Verify the pregnancy status in females of reproductive potential prior to initiating treatment.
- Females of reproductive potential: Advise females of reproductive potential to use effective contraception.
- Pediatric use: Safety and efficacy have not been established in pre-menarchal pediatric females.
- Geriatric use: Clinical studies did not include sufficient patients aged 65 and older to determine whether they respond differently from younger subjects.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TEMBEXA (BRINCIDOFOVIR) TABLETS AND ORAL SUSPENSION	CHIMERIX, INC.	06/04/2021

THERAPEUTIC CLASS
Anti-infective agent

FDA-APPROVED INDICATION(S)
TEMBEXA is an orthopoxvirus nucleotide analog DNA polymerase inhibitor indicated for the treatment of smallpox in adult and pediatric patients, including neonates.

DOSAGE AND ADMINISTRATION
The recommended dose is based on weight:

- Adult and pediatric patients weighing 48 kg or above: 200 mg (two 100 mg tablets or 20 mL oral suspension for patients who cannot swallow tablets) once weekly for 2 doses.
- Adult and pediatric patients weighing 10 kg to less than 48 kg: 4 mg/kg oral suspension once weekly for 2 doses.
- Pediatric patients weighing less than 10 kg: 6 mg/kg oral suspension once weekly for 2 doses.

DOSAGE FORMS AND STRENGTHS

- Tablets: 100 mg.
- Oral Suspension: 10 mg/mL.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS

- Boxed warning: Increased risk for mortality when used for longer duration
- Elevations in hepatic transaminases and bilirubin
- Diarrhea and other gastrointestinal adverse events
- Co-administration with related products
- Embryo-fetal toxicity
- Carcinogenicity
- Male infertility

ADVERSE REACTIONS
Most common adverse reactions: diarrhea, nausea, vomiting, and abdominal pain

DRUG INTERACTIONS

- Concomitant use with OATP1B1 and 1B3 inhibitors increase TEMBEXA exposure which may increase TEMBEXA-associated adverse reactions. Consider alternative medication that are not OATP1B1 or 1B3 inhibitors. If concomitant use is necessary, increase monitoring for adverse reactions associated with TEMBEXA and postpone the dosing of OATP1B1 or 1B3 inhibitors at least 3 hours after TEMBEXA administration.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm. Perform pregnancy testing in individuals of childbearing potential before initiation.
- Females and males of reproductive potential: Advise individuals of childbearing potential to use effective contraception.
- Lactation: Breastfeeding not recommended.
- Renal impairment: No dosage adjustment of TEMBEXA is required for patients with mild, moderate, or severe renal impairment or patients with end stage renal disease (ESRD) receiving dialysis.
- Hepatic impairment: Perform hepatic laboratory testing in all patients before starting TEMBEXA and while receiving TEMBEXA, as clinically appropriate. No dosage adjustment is required for patients with mild, moderate, or severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
RYPLAZIM (PLASMINOGEN, HUMAN-TVMH)	LIMINAL BIOSCIENCES INC.	06/04/2021

THERAPEUTIC CLASS
Blood modifier agent

FDA-APPROVED INDICATION(S)
RYPLAZIM is a plasma-derived plasminogen replacement therapy for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenia).

DOSAGE AND ADMINISTRATION
The recommended dose is The recommended dosage of RYPLAZIM is 6.6 mg/kg body weight given every 2 to 4 days.

DOSAGE FORMS AND STRENGTHS
RYPLAZIM is available in a single-dose 50-mL vial containing 68.8 mg of plasminogen as a lyophilized powder for reconstitution with 12.5 mL of Sterile Water for Injection, USP (SWFI). After reconstitution, each vial will contain 5.5 mg/mL of plasminogen.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- RYPLAZIM is contraindicated in patients with known hypersensitivity to plasminogen, or other components of RYPLAZIM.

WARNINGS AND PRECAUTIONS
- Bleeding: RYPLAZIM administration may lead to bleeding at lesion sites or worsen active bleeding. Discontinue RYPLAZIM if serious bleeding occurs. Monitor patients during and for 4 hours after infusion when administering RYPLAZIM to patients with bleeding diatheses and patients taking anticoagulants, antiplatelet drugs, and other agents which may interfere with normal coagulation.
- Tissue Sloughing: Respiratory distress due to tissue sloughing may occur in patients with mucosal lesions in the tracheobronchial tree following RYPLAZIM administration. Please monitor appropriately.
- Transmission of Infectious Agents: RYPLAZIM is made from human blood and therefore carries a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the Creutzfeldt-Jakob Disease (CJD) agent.
- Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis, may occur with RYPLAZIM. If symptoms occur, discontinue RYPLAZIM and administer appropriate treatment.
- Neutralizing Antibodies: Neutralizing antibodies (inhibitors) may develop, although were not observed in clinical trials. If clinical efficacy is not maintained (e.g., development of new or recurrent lesions), then determine plasminogen activity levels in plasma.
- Laboratory Abnormalities: Patients receiving RYPLAZIM may have elevated blood levels of D-dimer. D-dimer levels will lack interpretability in patients being screened for venous thromboembolism (VTE).

ADVERSE REACTIONS
Most common adverse reactions: The most frequent (incidence ≥ 10%) adverse reactions in clinical trials were abdominal pain, bloating, nausea, fatigue, extremity pain, hemorrhage, constipation, dry mouth, headache, dizziness, arthralgia, and back pain.

DRUG INTERACTIONS
None specified at this time.

(continued)

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
RYPLAZIM (PLASMINOGEN, HUMAN-TVMH)	LIMINAL BIOSCIENCES INC.	06/04/2021

THERAPEUTIC CLASS
Blood modifier agent

FDA-APPROVED INDICATION(S)
RYPLAZIM is a plasma-derived plasminogen replacement therapy for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenia).

DOSAGE AND ADMINISTRATION
The recommended dose is The recommended dosage of RYPLAZIM is 6.6 mg/kg body weight given every 2 to 4 days.

DOSAGE FORMS AND STRENGTHS
RYPLAZIM is available in a single-dose 50-mL vial containing 68.8 mg of plasminogen as a lyophilized powder for reconstitution with 12.5 mL of Sterile Water for Injection, USP (SWFI). After reconstitution, each vial will contain 5.5 mg/mL of plasminogen.

Orphan status: Orphan

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Pregnancy: There are no clinical trials in pregnant women.
- Lactation: No information available. Consider developmental and health benefits of breastfeeding along with the mother's clinical need for RYPLAZIM.
- Pediatric use: The safety and efficacy of RYPLAZIM has been established in pediatric patients. Use of RYPLAZIM is supported by the two clinical trials, and expanded access and compassionate use programs that included 18 pediatric patients age 11 months to 17 years.
- Geriatric use: The safety and effectiveness of RYPLAZIM have not been established in geriatric patients. Clinical studies of RYPLAZIM for this indication did not include patients age 65 years and over. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

(continuation)

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
ADUHELM (ADUCANUMAB-AVWA) INJECTION	BIOGEN	06/07/2021

THERAPEUTIC CLASS
Central nervous system agent

FDA-APPROVED INDICATION(S)
BADUHELM is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease.

DOSAGE AND ADMINISTRATION
Titration is required for treatment initiation. The recommended maintenance dose is 10 mg/kg administered as an intravenous infusion over approximately one hour every four weeks.

DOSAGE FORMS AND STRENGTHS
Injection:
- 170 mg/1.7 mL (100 mg/mL) solution in a single-dose vial.
- 300 mg/3 mL (100 mg/mL) solution in a single-dose vial.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of treatment with ADUHELM, particularly during titration. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated.
- Hypersensitivity Reactions: Angioedema and urticaria have occurred. If a hypersensitivity reaction occurs, promptly discontinue the infusion of ADUHELM and initiate appropriate therapy.

ADVERSE REACTIONS
Most common adverse reactions: ARIA-Edema, headache, ARIA-H microhemorrhage, ARIA-H superficial siderosis, and fall.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and efficacy have not been established.

NEW BIOSMILAR PRODUCTS

- No new biosimilar product approved during June 2021.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
WEGOVY (SEMAGLUTIDE) INJECTION / NOVO NORDISK	Anti-obesity agent	As an adjunct to diet and exercise for chronic weight management in adult patients who are overweight (BMI ≥27 kg/m2) or obese (BMI ≥30 kg/m2)	06/04/2021	WEGOVY is a new formulation of semaglutide. Semaglutide is also available under the brand name OZEMPIC and RYBELSUS. Similar to OZEMPIC, WEGOVY is administered via subcutaneous (SC) injection. RYBELSUS is available as an oral tablet. • OZEMPIC is approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) and to reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease. • RYBELSUS is approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM. Orphan status: N/A
EPCLUSA (SOFOSBUVIR/ VELPATASVIR) / GILEAD SCIENCES INC.	Fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor	Treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6: • Without cirrhosis or with compensated cirrhosis • With decompensated cirrhosis for use in combination with ribavirin	06/10/2021	EPCLUSA's new formulation of sofosbuvir and velpatasvir) as an oral pellet, provides for the treatment of genotypes 1, 2, 3, 4, 5, or 6, chronic hepatitis C virus infection in pediatric patients who are at least 3 years of age. Orphan status: Treatment of pediatric chronic hepatitis C virus (HCV) infection
MAVYRET (GLECAPREVIR/ PIBRENTASVIR) / ABBVIE INC.	Fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A inhibitor, and pibrentasvir, an HCV NS5A inhibitor	Treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A) Treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both	06/10/2021	MAVYRET's new formulation of glecaprevir and pibrentasvir as an oral pellet, provides for the s for the treatment of pediatric patients 3 to less than 12 years of age weighing less than 45 kg with chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis. Orphan status: N/A

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
REZIPRES (EPHEDRINE HYDROCHLORIDE) INJECTION / ETON PHARMACEUTICALS, INC.	Alpha- and beta-adrenergic agonist and norepinephrine-releasing agent	Treatment of clinically important hypotension occurring in the setting of anesthesia	06/14/2021	REZIPRES is a new formulation of epinephrine that comes to be the second FDA-approved ready-to-use hospital injectable product. Orphan status: N/A
SOAANZ (TORSEMIDE) / SARFE PHARMS	Loop diuretic	Treatment of edema associated with heart failure or renal disease in adult patients	06/14/2021	SOAANZ is a new formulation of torsemide, as a once-a-day loop diuretic. The approved oral formulation provides a new treatment option for patients suffering from heart failure who experience persistent edema, swelling in the lower limbs and/or abdomen. Orphan status: N/A
PRADAXA (DABIGATRAN ETEXILATE MESYLATE) / SANTEN	Direct thrombin inhibitor	Treatment of venous thromboembolic events (VTE) in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days To reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated	06/21/2021	PRADAXA'S new formulation of dabigatran is the first FDA-approved blood thinning medication that children can take by mouth; the only other approved blood thinning medication for children is given by injection. Orphan status: N/A
VERKAZIA (CYCLOSPORINE) / SANTEN	Calcineurin inhibitor immunosuppressant	Treatment of vernal keratoconjunctivitis in children and adults	06/23/2021	VERKAZIA is a new formulation of cyclosporine that offers an effective and new treatment for the rare condition of keratoconjunctivitis in children and adults that may allow those affected to continue taking part in everyday activities. Orphan status: Treatment of vernal keratoconjunctivitis

NEW FIRST-TIME GENERIC APPROVALS

GENERIC NAME	MANUFACTURER	THERAPEUTIC CLASS	INDICATION	BRAND NAME	DATE
TOFACITINIB CITRATE	Ajanta Pharma Limited	Antirheumatic agent; Gastrointestinal agent	• Polyarticular juvenile idiopathic arthritis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis	Xeljanz	6/1/2021
BEPOTASTINE BESILATE	Bausch + Lomb (AG) Mylan	Histamine H1 receptor antagonist	Treatment of itching associated with allergic conjunctivitis	Bepreve	6/1/2021
ARFORMOTEROL TARTRATE	Lupin (AG)	Long-acting beta2-adrenergic agonist (beta2-agonist)	Long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema	Brovana	6/3/2021
PERAMPANEL	Accord Healthcare Inc.; Teva Pharmaceuticals USA Inc.	• Central nervous system agent; Anticonvulsant	• Partial seizure • Tonic-clonic seizure; Adjunct	Fycompa	06/08/2021
LOPINAVIR; RITONAVIR	Hetero	HIV-1 protease inhibitor	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients (14 days and older)	Kaletra (tablets)	6/7/2021
ETRAVIRINE	Amneal	Human immunodeficiency virus type 1 (HIV-1) non-nucleoside reverse transcriptase inhibitor (NNRTI)	Treatment of HIV-1 infection in treatment-experienced patients 2 years of age and older	Intelence	6/16/2021
FORMOTEROL FUMARATE	Mylan (AG) Teva	Long-acting beta2-adrenergic agonist (beta2-agonist)	Long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema	Perforomist	6/22/2021

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
COSENTYX (SECUKINUMAB) INJECTION / NOVARTIS PHARMACEUTICALS CORPORATION	Dermatological agent; Antipsoriatic	Plaque psoriasis, ankylosing spondylitis, psoriatic arthritis, and non-radiographic axial spondyloarthritis	Patient population altered: Treatment of moderate to severe plaque psoriasis in pediatric patients six years and older who are candidates for systemic therapy or phototherapy	05/28/2021
ULTOMIRIS (RAVULIZUMAB-CWVZ) INJECTION / ALEXION PHARMACEUTICALS, INC.	Blood modifier agent	• Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) • Treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)	Patient population altered: To include children (one month of age and older) and adolescents with paroxysmal nocturnal hemoglobinuria (PNH)	06/07/2021
TRIKAFTA (ELEXACAFTOR/TEZACAFTOR / IVACAFTOR AND IVACAFTOR) TABLETS / VERTEX PHARMACEUTICALS INCORPORATED	Respiratory gent	Treatment of cystic fibrosis (CF) in patients ages 12 years and older who have at least one copy of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data	Patient population altered: To include children with CF ages 6 through 11 years who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data	06/08/2021
AYVAKIT (AVAPRITINIB) / BLUEPRINT MEDICINES	Kinase inhibitor	Gastrointestinal Stromal Tumor (GIST) • The treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.	Advanced Systemic Mastocytosis (AdvSM) • The treatment of adult patients with AdvSM. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL)	06/16/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
TOVIAZ (FESOTERODINE FUMARATE) / PFIZER	Muscarinic receptor antagonist	Overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency	Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older and weighing greater than 25 kg	06/17/2021
NOXAFIL (POSACONAZOLE) / MERCK SHARP DOHME	Azole antifungal	Noxafil is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows: Noxafil injection: adults and pediatric patients 2 years of age and older Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg Noxafil oral suspension: adults and pediatric patients 13 years of age and older Noxafil Powder Mix for delayed-release oral suspension: pediatric patients 2 years of age and older (who weigh 40 kg or less) Noxafil oral suspension is indicated for the treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adult and pediatric patients aged 13 years and older.	Noxafil (posaconazole) delayed release tablets, 100 mg and Noxafil (posaconazole) injection, 18 mg/mL for the treatment of invasive aspergillosis in patients 13 years of age and older and provide updates to sections of prescribing information (PI) relevant to the use of Noxafil delayed release tablets and Noxafil (posaconazole) injection for the treatment of Invasive aspergillosis in patients 13 years of age and older	06/17/2021
SOLOSEC (SECNIDAZOLE) / LUPIN	Nitroimidazole antimicrobial	Treatment of bacterial vaginosis in adult women	Treatment of trichomoniasis caused by Trichomonas vaginalis in adults	06/30/2021

PIPELINE

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
OTESECONAZOLE / MYCOVIA PHARMACEUTICALS, INC.	06/01/2021	Treatment for: Vaginal Candidiasis	Oteseconazole (VT-1161) is a novel, investigational oral therapy in development for the treatment of recurrent vulvovaginal candidiasis (RVVC). NDA submitted.	Moderate
VADADUSTAT / AKEBIA THERAPEUTICS, INC.	06/01/2021	Treatment for: Anemia Associated with Chronic Renal Failure	Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor in development for the treatment of anemia due to chronic kidney disease (CKD) in adults. NDA accepted by FDA.	Moderate
PACRITINIB / CTI BIOPHARMA CORP.	06/01/2021	Treatment for: Myelofibrosis	Pacritinib is an investigational oral JAK2/FLT3 multikinase inhibitor in development for the treatment of myelofibrosis patients with severe thrombocytopenia. NDA accepted by FDA.	High
PLINABULIN / BEYONDSPRING INC.	06/01/2021	Treatment for: Neutropenia Associated with Chemotherapy	Plinabulin is a selective immunomodulating microtubule-binding agent (SIMBA) in development for use in combination with granulocyte colony-stimulating factor (G-CSF) for the prevention of chemotherapy-induced neutropenia (CIN). NDA accepted by FDA.	High
ZIMHI (NALOXONE) / ADAMAIS PHARMACEUTICALS CORPORATION	06/09/2021	Treatment of: Opioid Overdose	ZIMHI is a naloxone product and opioid antagonist used to treat narcotic overdoses. Naloxone is generally considered the treatment of choice for immediate administration in instances of opioid overdose. The FDA also provided a target action date under the Prescription Drug User Fee Act (PDUFA date) of November 12, 2021. NDA accepted by FDA.	Moderate

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
RUXOLITINIB / INCYTE CORPORATION	06/11/2021	Treatment of: Atopic Dermatitis (AD)	Ruxolitinib cream is a proprietary formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib that has been designed for topical application. Ruxolitinib cream is currently in Phase 3 development for the treatment of adolescents and adults with atopic dermatitis (TRuE-AD) and vitiligo (TRuE-V). The Prescription Drug User Fee Act (PDUFA) action date has been extended by three months to September 21, 2021. FDA has extended the review period for ruxolitinib cream.	High
PEDMARK / FENNEC PHARMACEUTICALS	06/22/2021	Prevention of: Ototoxicity	PEDMARK is a unique formulation of sodium thiosulfate for the prevention of ototoxicity induced by cisplatin chemotherapy in patients one month to < 18 years of age with localized, non-metastatic, solid tumors. The Prescription Drug User Fee Act (PDUFA) target action date has been set for November 27, 2021. Pedmark has been granted both Fast Track Designation and Breakthrough Therapy Designation by the FDA. NDA accepted by FDA.	High High
LENACAPAVIR / GILEAD	06/28/2021	Treatment of: HIV-1 in people with limited therapy options	Lenacapavir is a first-in-class long-acting every-six-month subcutaneous HIV-1 capsid inhibitor injection for the treatment of HIV-1 infection in heavily treatment-experienced (HTE) people with multi-drug resistant (MDR) HIV-1 infection. Lenacapavir has been granted a Breakthrough Therapy Designation by the FDA.	High

REFERENCES

- U.S. Food and Drug Administration (https://www.fda.gov/)
- Drugs.com (https://www.drugs.com/)
- IBM Micromedex® (https://www.micromedexsolutions.com)
- Pharmacist Letter (https://www.pharmacistletter.com)