pharmpiX
POWERED BY ONEARK

PharmNOTES

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

Date: 04/07/2021

urac
ACCREDITED
Pharmacy
Benefit
Management
Expires 12/01/2022

TABLE OF CONTENTS

NEWS

DRUG ISSUE	DATE	DETAILS
FDA warns that abuse and misuse of the nasal decongestant propylhexedrine causes serious harm	03/25/2021	The FDA is warning that the abuse and misuse of the over-the-counter (OTC) nasal decongestant propylhexedrine (BENZEDREX) can cause serious harm such as heart and mental health problems, which can lead to hospitalization, disability, or death. The FDA is requesting all product's manufacturers to consider product design changes that support its safe use. The FDA continues to evaluate this safety issue and will determine if additional actions are needed. Recommendations for healthcare professionals: • Be aware that some individuals are abusing or misusing propylhexedrine. In the event of a suspected overdose, attempt to determine whether a patient used propylhexedrine alone or with other substances. There is no specific reversal agent in cases of acute intoxication, so symptomatic and supportive care should be provided. • Educate patients. Propylhexedrine is safe and effective when used as directed, and should only be used according to the directions on the Drug Facts label. The use by routes other than inhalation can cause serious harm and can lead to death. • Advise patients to talk with their healthcare provider if they have any questions or concerns. • Advise patients to inform their healthcare provider about all the medications they are taking, including OTC medications. • Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program.
Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine (Lamictal) in patients with heart disease	03/3/2021	The FDA published a drug safety communication notifying that studies have shown a potential increased risk of heart rhythm problems, called arrhythmias, in patients with heart disease who are taking the seizure and mental health medicine Lamictal (lamotrigine). The FDA is requiring safety studies for other drugs in the same drug class to evaluate if they have similar effects on the heart. Recommendations for healthcare professionals: • Advise patient to not stop taking their medications without first talking to their prescriber because stopping lamotrigine can lead to uncontrolled seizures, or new or worsening mental health problems. • Advise patients to talk with their healthcare provider if they have any questions or concerns. • Assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient. • Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
AZSTARYS (DEXMETHYLPHENIDATE AND SERDEXMETHYLPHENIDATE) CAPSULES	COMMCAVE THERAPEUTICS SA	03/02/2021

THERAPEUTIC CLASS
Central nervous system (CNS) agent; CNS stimulant

FDA-APPROVE INDICATION(S)
AZSTARYS is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.

DOSAGE AND ADMINISTRATION
- For pediatric patients 6 to 12 years: The recommended initial dose is 39.2 mg/7.8 mg orally once daily. The dose may be increased to 52.3 mg/10.4 mg daily or decreased to 26.1 mg/5.2 mg daily after one week. The maximum recommended dose is 52.3 mg/10.4 mg once daily.
- For adults and pediatric patients 13 to 17 years: The recommended initial dose is s 39.2 mg/7.8 mg orally once daily. Increase the dose after one week to 52.3 mg/10.4 mg once daily.

DOSAGE FORMS AND STRENGTHS
Capsules (serdexmethylphenidate / dexmethylphenidate): 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, 52.3 mg/10.4 mg.

Orphan status: N/A
Controlled substance: CII [controlled substance schedule pending for serdexmethylphenidate]

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to serdexmethylphenidate, methylphenidate, or product components.
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days.

WARNINGS AND PRECAUTIONS
- Boxed warning: Potential for abuse and dependence
- Serious cardiovascular reactions
- Blood pressure and heart rate increases
- Psychiatric adverse reactions
- Priapism
- Peripheral vasculopathy, including raynaud's phenomenon
- Long-term suppression of growth

ADVERSE REACTIONS
Most common adverse reactions: appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased.

DRUG INTERACTIONS
- Monoamine oxidase inhibitors (MAOIs): Concomitant use can cause hypertensive crisis. Do not administer AZSTARYS concomitantly with MAOIs or within 14 days after discontinuing MAOI treatment.

DRUG INTERACTIONS (continuation)
- Antihypertensive drugs: AZSTARYS may decrease the effectiveness of drugs used to treat hypertension. Blood pressure must be monitored, and antihypertensive drug dose is to be adjusted as needed.
- Halogenated anesthetics: Concomitant use may increase the risk of sudden blood pressure and heart rate increase during surgery. Avoid use of AZSTARYS on the day of surgery if halogenated anesthetics will be used.
- Risperidone: Combined use of methylphenidate with risperidone when there is a change may increase the risk of extrapyramidal symptoms (EPS). Monitor for signs of EPS.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ADHD medications. Healthcare providers are encouraged to register patients.
- Geriatric use: Clinical studies did not include any patients aged 65 years and over.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
FOTIVDA (TIVOZANIB) CAPSULES	AVEO PHARMACEUTICALS INC	03/10/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
FOTIVDA is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

DOSAGE AND ADMINISTRATION
The recommended dose is 1.34 mg once daily for 21 days on treatment followed by 7 days off treatment (28-day cycle) until disease progression or unacceptable toxicity.

Dose adjustments are recommended to manage adverse reactions and for patients with moderate hepatic impairment.

DOSAGE FORMS AND STRENGTHS
Capsules: 1.34 mg and 0.89 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Hypertension and hypertensive crisis
- Cardiac failure
- Cardiac ischemia and arterial thromboembolic events
- Venous thromboembolic events
- Hemorrhagic events
- Proteinuria
- Thyroid dysfunction
- Risk of impaired wound healing
- Reversible posterior leukoencephalopathy syndrome (RPLS)
- Embryo-fetal toxicity
- Allergic reactions to tartrazine

ADVERSE REACTIONS
Most common adverse reactions: fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis.

Most common Grade 3 or 4 laboratory abnormalities: sodium decreased, lipase increased, and phosphate decreased.

DRUG INTERACTIONS
- CYP3A inducers: Concomitant use decreases tivozanib exposure. Avoid concomitant use.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify pregnancy status of females of reproductive potential prior to starting treatment.
- Females and males of reproductive potential: Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception. FOTIVDA can impair fertility.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety and effectiveness were observed between patients 65 years of age and over versus younger patients.
- Renal impairment: No dose modification is recommended for patients with mild to severe renal impairment. The recommended dose for patients with end-stage renal disease has not been established.
- Hepatic impairment: No dosage modification is recommended for patients with mild hepatic impairment. Adjust dosage in patients with moderate hepatic impairment. Avoid use in patients with severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PONVORY (PONESIMOD) TABLETS	JANSSEN PHARMACEUTICALS, INC.	03/18/2021

THERAPEUTIC CLASS
Immunological agent; Sphingosine 1-Phosphate Receptor Modulator

FDA-APPROVE INDICATION(S)
PONVORY is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSAGE AND ADMINISTRATION
Titration is required for treatment initiation. The recommended maintenance dose is s 20 mg orally once daily.

Important assessments are required prior to initiating. First-dose monitoring is recommended for patients with sinus bradycardia, first- or second-degree [Mobitz type I] atrioventricular (AV) block, or a history of myocardial infarction or heart failure.

DOSAGE FORMS AND STRENGTHS
Tablets: 2 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7 mg, 8 mg, 9 mg, 10 mg, and 20 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
- Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker.

WARNINGS AND PRECAUTIONS
- Infections
- Bradyarrhythmia and atrioventricular conduction delays
- Respiratory effects
- Liver injury
- Increased blood pressure
- Cutaneous malignancies
- Fetal risk
- Macular edema
- Posterior reversible encephalopathy syndrome (PRES)
- Unintended additive immunosuppressive effects from prior treatment with immunosuppressive or immune-modulating therapies
- Severe increase in disability after stopping
- Immune system effects after stopping

ADVERSE REACTIONS
Most common adverse reactions: upper respiratory tract infection, hepatic transaminase elevation, and hypertension.

DRUG INTERACTIONS
- Anti-neoplastic, immune-modulating, or immunosuppressive therapies: Caution should be used during concomitant administration because of the risk of additive immune effects. Consider the half-life and mode of action of drugs with prolonged immune effects to avoid unintended additive effects on the immune system. Initiating treatment with PONVORY after alemtuzumab is not recommended. PONVORY can generally be started immediately after discontinuation of beta interferon or glatiramer acetate.
- Anti-arrhythmic drugs, QT prolonging drugs, drugs that may decrease heart rate: If treatment with PONVORY is considered, advice from a cardiologist should be sought.
- Beta-blockers: Caution should be applied because of the additive effects on lowering heart rate. Temporary interruption of the beta-blocker treatment may be needed prior to initiation of PONVORY. Beta-blocker treatment can be initiated in patients receiving stable doses of PONVORY.
- Vaccines: Avoid live attenuated vaccines during and for up to 1-2 weeks after treatment with PONVORY.
- Strong CYP3A4 and UGT1A1 inducers: Co-administration may decrease the systemic exposure of ponesimod. Co-administration is not recommended.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PONVORY (PONESIMOD) TABLETS	JANSSEN PHARMACEUTICALS, INC.	03/18/2021

THERAPEUTIC CLASS
Immunological agent; Sphingosine 1-Phosphate Receptor Modulator

FDA-APPROVE INDICATION(S)
PONVORY is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSAGE AND ADMINISTRATION
Titration is required for treatment initiation. The recommended maintenance dose is s 20 mg orally once daily.

Important assessments are required prior to initiating. First-dose monitoring is recommended for patients with sinus bradycardia, first- or second-degree [Mobitz type I] atrioventricular (AV) block, or a history of myocardial infarction or heart failure.

DOSAGE FORMS AND STRENGTHS
Tablets: 2 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7 mg, 8 mg, 9 mg, 10 mg, and 20 mg.

Orphan status: N/A

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Females of reproductive potential: Advise females of reproductive potential on the potential for a serious risk to the fetus and the need for effective contraception during treatment.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: Clinical studies did not include patients 65 years of age and over to determine whether they respond differently from younger patients.
- Hepatic impairment: No dose adjustment is necessary for mild hepatic impairment. PONVORY is not recommended in patients with moderate or severe hepatic impairment, because the risk of adverse reactions may be greater.

(continuation)

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
ZEGALOGUE (DASIGLUCAGON) INJECTION	ZEALAND PHARMA A/S	03/22/2021

THERAPEUTIC CLASS
Endocrine and metabolic agent; Antihypoglycemic

FDA-APPROVE INDICATION(S)
ZEGALOGUE is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above.

DOSAGE AND ADMINISTRATION
The recommended dose is 0.6 mg administered by subcutaneous injection. If there has been no response after 15 minutes, an additional dose from a new device may be administered while waiting for emergency assistance. When the patient has responded to treatment, give oral carbohydrates.

DOSAGE FORMS AND STRENGTHS
Injection:
- 0.6 mg/0.6 mL single-dose autoinjector.
- 0.6 mg/0.6 mL single-dose prefilled syringe.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Pheochromocytoma
- Insulinoma

WARNINGS AND PRECAUTIONS
- Substantial increase in blood pressure in patients with pheochromocytoma
- Hypoglycemia in patients with insulinoma
- Hypersensitivity and allergic reactions
- Lack of efficacy in patients with decreased hepatic glycogen

ADVERSE REACTIONS
Most common adverse reactions:
- Adults: nausea, vomiting, headache, diarrhea, and injection site pain.
- Pediatrics: nausea, vomiting, headache, and injection site pain.

DRUG INTERACTIONS
- Beta-blockers: Patients taking beta-blockers may have a transient increase in pulse and blood pressure.
- Indomethacin: In patients taking indomethacin, ZEGALOGUE may lose its ability to raise blood glucose or may produce hypoglycemia.
- Warfarin: ZEGALOGUE may increase the anticoagulant effect of warfarin.

USE IN SPECIFIC POPULATIONS
- Geriatric use: Clinical studies included too few patients 65 years of age and older to determine whether these patients respond differently from younger adult patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
ABECMA (IDECABTAGENE VICLEUCEL) SUSPENSION	BRISTOL-MYERS SQUIBB COMPANY	MM/DD/YYYY

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
ABECMA is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

DOSAGE AND ADMINISTRATION
The recommended dose is range is 300 to 460 x 106 CAR-positive T cells, for autologous and intravenous use.

DOSAGE FORMS AND STRENGTHS
- ABECMA is a cell suspension for intravenous infusion.
- A single dose of ABECMA contains a cell suspension of 300 to 460 x 106 CAR-positive T cells in one or more infusion bags.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Boxed warning: Cytokine release syndrome (CRS), neurologic toxicities, Hemophagocytic Lymphohistiocytosis / Macrophage Activation Syndrome (HLH/MAS) and prolonged cytopenia
    - ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.
- Hypersensitivity reactions
- Infections
- Hypogammaglobulinemia
- Secondary malignancies
- Effects on ability to drive and use machines

ADVERSE REACTIONS
Most common adverse reactions: CRS, infections – pathogen unspecified, fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite.

Most common laboratory abnormalities: neutropenia, leukopenia, lymphopenia, thrombocytopenia, and anemia.

DRUG INTERACTIONS
- Drug/laboratory test interactions: HIV and the lentivirus used to make ABECMA have limited, short spans of identical genetic material (RNA). Therefore, some commercial HIV nucleic acid tests may yield false-positive results in patients who have received ABECMA.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Pregnancy status of sexually-active females with reproductive potential should be verified via pregnancy testing prior to starting.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No clinically important differences in effectiveness of ABECMA were observed between patients 65 years of age and older versus younger patients.

NEW BIOSMILAR PRODUCTS

- No new biosimilar product approved during March 2021.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
KIMYRSA (ORITAVANCIN) FOR INJECTION / MELINTA THERAPEUTICS	Anti-infective agent; Antibiotic	Treatment of adult patients with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms	03/12/2021	KIMYRSA is a new formulation of the lipoglycopeptide antibiotic oritavancin for intravenous use. Oritavancin was already available under the brand name ORBACTIV. ORBACTIV and KIMYRSA are supplied in different dose strengths of oritavancin, have different recommended durations of infusion (3 hours for ORBACTIV versus 1 hour for KIMYRSA), and have different preparation instructions, including differences in reconstitution, dilution, and compatible diluents. ORBACTIV and KIMYRSA share the same indication. Orphan status: N/A
ROSZET (ROSUVASTATIN AND EZETIMIBE) TABLETS / ALTHERA LIFE SCIENCES, LLC.	Antihyperlipidemic	• As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDLC) • Alone or as an adjunct to other LDL-C lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C	03/23/2021	ROSZET is a new combination of f rosuvastatin, an HMG CoA-reductase inhibitor (statin), and ezetimibe, a dietary cholesterol absorption inhibitor. Both individual components within ROSZET are available in generic. Orphan status: N/A
MYRBETRIQ (MIRABEGRON) GRANULES / ASTELLAS PHARMA GLOBAL DEV INC	Genitourinary agent	Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older	03/25/2021	MYRBETRIQ granules is a line extension of MYRBETRIQ tablets. MYRBETRIQ tablets were already available in the market for the treatment of adult overactive bladder (OAB) and now have also been granted a new indication for the treatment of NDO in pediatric patients aged 3 years and older and weighing 35 kg or more. Orphan status: N/A

NEW FIRST-TIME GENERIC APPROVALS

- No new first-time generic approved during March 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
LORBRENA (LORLATINIB) TABLETS / PFIZER INC.	Antineoplastic agent	Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or whose disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease	First-line treatment patients with ALK-positive NSCLC	03/03/2021
YESCARTA (AXICABTAGENE CILOLEUCEL) SUSPENSION FOR INTRAVENOUS INFUSION / KITE PHARMA, INC.	Antineoplastic agent	To treat adult patients with certain types of large B-cell lymphoma who have not responded to or who have relapsed after at least two other kinds of treatment	Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy	03/05/2021
ARCALYST (RILONACEPT) INJECTION / REGENERON PHARMACEUTICALS, INC.	Immunological agent	Long term treatment of two Cryopyrin-Associated Periodic Syndromes (CAPS) disorders: Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)	Treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older	03/18/2021
KEYTRUDA (PEMBROLIZUMAB) FOR INJECTION / MERCK	Antineoplastic agent	Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer	Treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation in combination with platinum- and fluoropyrimidine-based chemotherapy	03/22/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
MYRBETRIQ (MIRABEGRON) TABLETS / ASTELLAS PHARMA GLOBAL DEV INC	Genitourinary agent	TREATMENT OF ADULT OVERACTIVE BLADDER (OAB)	TREATMENT OF NEUROGENIC DETRUSOR OVERACTIVITY (NDO) IN PEDIATRIC PATIENTS AGED 3 YEARS AND OLDER AND WEIGHING 35 KG OR MORE	03/25/2021
VYXEOS (CYTARABINE AND DAUNORUBICIN) INJECTION / JAZZ PHARMACEUTICALS PLC	Antineoplastic agent	Treatment of adults with two types of acute myeloid leukemia (AML): newly diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC)	Patient population altered to include the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in pediatric patients aged one year and older	03/30/2021

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
FT218 (SODIUM OXYBATE) / AVADEL PHARMACEUTICALS PLC	03/01/2021	Treatment for: Narcolepsy	FT218 (sodium oxybate) is a once-nightly formulation of the approved central nervous system depressant sodium oxybate in development for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. FDA accepted NDA.	Moderate
BARDOXOLONE / REATA PHARMACEUTICALS, INC.	03/01/2021	Treatment for: Alport Syndrome	Bardoxolone is an investigational, once-daily, orally administered activator of Nrf2 in development for the treatment of Alport syndrome and autosomal dominant polycystic kidney disease (ADPKD). NDA submitted to the FDA and granted orphan drug designation.	High High
GEFAPIXANT / MERCK	03/01/2021	Treatment for: Cough	Gefapixant is an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory chronic cough (RCC) or unexplained chronic cough (UCC) in adults. FDA accepted NDA.	Moderate
MYDCOMBI (PHENYLEPHRINE AND TROPICAMIDE) OPHTHALMIC SOLUTION / EYENOVIA, INC.	03/02/2021	Treatment for: Pharmacologic Mydriasis	MydCombi (phenylephrine and tropicamide) is a fixed-combination microdose formulation of the approved mydriatics phenylephrine and tropicamide in development for pharmacologic mydriasis in the eye care practitioner's office. FDA accepted NDA.	Low
RECORLEV (LEVOKETOCONAZOLE) / STRONGBRIDGE BIOPHARMA PLC	03/02/2021	Treatment for: Cushing's Syndrome	Recorlev (levoketoconazole) is an investigational cortisol synthesis inhibitor in development for the treatment of patients with endogenous Cushing's syndrome. NDA submitted to the FDA.	Moderate

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
OC-01 (varenicline) Nasal Spray / Oyster Point Pharma, Inc.	03/02/2021	Treatment for: Dry Eye Disease	OC-01 (varenicline) is a nasal spray formulation of the highly selective cholinergic agonist varenicline in development for the treatment of the signs and symptoms of dry eye disease. FDA accepted NDA.	Moderate
Korsuva (difelikefalin) / Cara Therapeutics, Inc.	03/08/2021	Treatment for: Chronic Kidney Disease-Associated Pruritus	Korsuva (difelikefalin) is a selective peripheral kappa opioid receptor agonist in development for the treatment of moderate-to-severe pruritus in hemodialysis patients. FDA accepted FDA.	Moderate
Daridorexant / Idorsia Ltd.	03/10/2021	Treatment for: Insomnia	Daridorexant is a dual orexin receptor antagonist (DORA) in development for the treatment of insomnia. FDA accepted FDA.	Moderate
BXCL501 (dexmedetomidine) / BioXcel Therapeutics, Inc.	03/11/2021	Treatment for: Agitation Associated with Schizophrenia and Bipolar Disorders	BXCL501 (dexmedetomidine) is an orally dissolving thin film formulation of the approved alpha2-adrenergic agonist dexmedetomidine in development for the acute treatment of agitation associated with schizophrenia and bipolar disorders I and II. NDA summitted to the FDA.	Moderate
Nefecon (budesonide) / Calliditas Therapeutics AB	03/15/2021	Treatment for: Primary IgA Nephropathy	Nefecon (budesonide) is an oral, targeted release formulation of the approved anti-inflammatory corticosteroid budesonide in development for the treatment of primary IgA nephropathy (IgAN). NDA summitted to the FDA.	High High

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
Belzutifan / Merck	03/16/2021	Treatment for: Renal Cell Carcinoma	Belzutifan (MK-6482) is a novel, potent and selective inhibitor of HIF-2α in development for the treatment of patients with von Hippel-Lindau (VHL) disease-associated renal cell carcinoma (RCC). NDA summitted to the FDA.	High
Mavacamten / Bristol Myers Squibb	03/19/2021	Treatment for: Hypertrophic Cardiomyopathy	Mavacamten is a first-in-class, oral, allosteric modulator of cardiac myosin in development for the treatment of patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM). NDA summitted to the FDA.	High
Udenafil / Mezzion Pharma Co. Ltd.	03/28/2021	Treatment for: Single Ventricle Heart Disease	Udenafil is a long acting, highly selective phosphodiesterase-5 inhibitor in development for the treatment of patients who have undergone the Fontan operation for single ventricle heart disease. NDA re-submitted to the FDA and the FDA granted orphan drug designation.	High High
Maralixibat / Mirum Pharmaceuticals, Inc.	03/29/2021	Treatment for: Cholestatic Pruritus in Patients with Alagille Syndrome	Maralixibat is an inhibitor of the apical sodium dependent bile acid transporter (ASBT) in development for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS). FDA accepted NDA.	High High
Atogepant / Allergan plc	03/30/2021	Treatment for: Migraine Prophylaxis	Atogepant is a novel, highly potent, orally-administered CGRP receptor antagonist in development for the prevention of migraine. FDA accepted NDA.	Moderate
Vadadustat / Akebia Therapeutics, Inc.	03/30/2021	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 submitted to the FDA.	Moderate

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)