pharmpiX
POWERED BY ONEARK

PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
From: JULY 2020

Date: 08/07/2020

©2020 PharmPix. All rights reserved

urac
ACCREDITED
Pharmacy
Benefit
Management
Expires 12/01/2022

Table of Contents

NEWS

Drug issue	Date	Details

FDA Recommends Health Care Professionals Discuss Naloxone with All Patients when Prescribing Opioid Pain Relievers or Medicines to Treat Opioid Use Disorder	07/23/2020	The FDA is recommending healthcare professionals to discuss naloxone with all patients when prescribing opioid analgesics or medicines to treat opioid use disorder (OUD). The FDA is also requiring that labeling for these medicines be updated with recommendations about naloxone for healthcare professionals prescribing these medicines.
		
		Recommendations for healthcare professionals:
		• Routinely discuss the availability of naloxone with all patients and caregivers, both when beginning and renewing treatment with an opioid analgesic or a medicine to treat OUD.
		• Consider prescribing naloxone:
		  • To patients receiving a prescription for an opioid analgesic or a medicine to treat OUD who are at increased risk of opioid overdose.
		  • To patients NOT receiving a prescription for an opioid analgesic or a medicine to treat OUD, but who are at increased risk of opioid overdose.
		  • When a patient has household members (e.g. children) or other close contacts at risk for accidental ingestion or opioid overdose.
		• Familiarize with the options for obtaining naloxone as permitted by their individual state/U.S. territory dispensing and prescribing requirements or guidelines for naloxone.
		• Provide education to patients and caregivers on:
		  • How to recognize signs and symptoms of opioid overdose (e.g. breathing problems, severe sleepiness, or not being able to respond or wake up).
		  • How to administer naloxone.
		  • How to properly store and dispose opioids.
		  • Options for obtaining naloxone as permitted by their individual state/U.S. territory dispensing and prescribing requirements or guidelines for naloxone.
		  • The importance of calling 911 or getting emergency medical help right away, even if naloxone is administered.
		• Report adverse events or side effects involving naloxone, opioids, or other medicines at MedWatch: The FDA Safety Information and Adverse Event Reporting Program.
		
		Additional information can be found at FDA's Drug Safety and Availability portal and FDA's Press Announcements portal.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Rukobia™ (fostemsavir) Extended-Release Tablets, for oral use	ViiV Healthcare	07/02/2020

THERAPEUTIC CLASS
Antiretroviral; Human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor

FDA-APPROVE INDICATION(S)
Rukobia™ is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

DOSAGE AND ADMINISTRATION
The recommended dose is one tablet taken twice daily with or without food.

DOSAGE FORMS AND STRENGTHS
Extended-release tablets: 600 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Hypersensitivity to fostemsavir or any of the components of the formulation.
- Co-administration with strong cytochrome P450 (CYP)3A inducers as significant decreases in temsavir plasma concentrations may occur, which may result in loss of virologic response.

WARNINGS AND PRECAUTIONS
- Immune reconstitution syndrome
- QTc prolongation
- Elevations in hepatic transaminases in patients with hepatitis B or C virus co-infection
- Risk of adverse reactions or loss of virologic response due to drug interactions

ADVERSE REACTIONS
Most common adverse reactions: nausea.

DRUG INTERACTIONS
The concomitant use of fostemsavir and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to:
- Loss of therapeutic effect of fostemsavir and possible development of resistance due to reduced exposure of temsavir.
- Possible prolongation of QTc interval from increased exposure to temsavir.

Refer to full prescribing information for additional important details related to drug interaction and how to prevent or manage these possible and known significant drug interactions, including dosing recommendations.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to fostemsavir during pregnancy.
- Lactation: Breastfeeding is not recommended due to the potential for HIV-1 transmission.
- Pediatric use: Safety and effectiveness have not been established.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Rukobia™ (fostemsavir) Extended-Release Tablets, for oral use	ViiV Healthcare	07/02/2020

THERAPEUTIC CLASS
Antiretroviral; Human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor

FDA-APPROVE INDICATION(S)
Rukobia™ is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

DOSAGE AND ADMINISTRATION
The recommended dose is one tablet taken twice daily with or without food.

DOSAGE FORMS AND STRENGTHS
Extended-release tablets: 600 mg.

Orphan status: N/A

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS (continuation)

- Geriatric use: Clinical trials did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger subjects. In general, caution should be exercised in administration in elderly patients reflecting greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
- Renal impairment: No adjustment required.
- Hepatic impairment: No adjustment required.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Byfavo™ (remimazolam) Injection, for intravenous use	Cosmo Pharmaceuticals NV	07/02/2020

THERAPEUTIC CLASS
Benzodiazepine

FDA-APPROVE INDICATION(S)
Byfavo™ is indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

DOSAGE AND ADMINISTRATION
The dose is individualized and titrated to desired clinical effect.

DOSAGE FORMS AND STRENGTHS
Each glass, single-patient-use vial contains 20 mg remimazolam lyophilized powder for reconstitution, equivalent to 27.2 mg remimazolam besylate.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Hypersensitivity to dextran.

WARNINGS AND PRECAUTIONS
- Boxed warning: Personnel and equipment for monitoring and resuscitation, and risks from concomitant use with opioid analgesics and other sedative-hypnotics.
- Hypersensitivity reactions
- Neonatal sedation
- Pediatric neurotoxicity

ADVERSE REACTIONS
Most common adverse reactions: hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension

DRUG INTERACTIONS
- Opioid analgesics and other sedative-hypnotics: The sedative effect can be accentuated by concomitantly administered central nervous system depressant medications.

USE IN SPECIFIC POPULATIONS
- Lactation: A lactating woman may pump and discard breast milk for 5 hours after treatment.
- Pediatric use: Should not be used in patients less than
- 18 years of age.
- Geriatric use: Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be observed closely.
- Hepatic impairment: In patients with severe hepatic impairment the dose of remimazolam should be carefully titrated to effect. Depending on the overall status of the patient, reduced doses might be indicated.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Hulio™ (adalimumab-fkjp) Injection, for subcutaneous use	Mylan Pharmaceuticals Inc.	07/06/2020

THERAPEUTIC CLASS
Tumor necrosis factor (TNF) blocker

FDA-APPROVE INDICATION(S)
Hulio™ is indicated for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn's disease (CD), ulcerative colitis (UC), and plaque psoriasis (Ps).

DOSAGE AND ADMINISTRATION
The recommended dose varies depending on patient's diagnosis and/or weight (kg). See full prescribing information for additional details.

DOSAGE FORMS AND STRENGTHS
- Injection: 40 mg/0.8 mL in a single-dose prefilled pen (HULIO Pen).
- Injection: 40 mg/0.8 mL in a single-dose prefilled plastic syringe.
- Injection: 20 mg/0.4 mL in a single-dose prefilled plastic syringe.

Orphan status: N/A
Biosimilar to Humira™ (adalimumab)

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Boxed warning: Serious infections and malignancy.
- Anaphylaxis or serious allergic reactions
- Hepatitis B virus reactivation
- Demyelinating disease
- Cytopenias, pancytopenia
- Heart failure
- Lupus-like syndrome

ADVERSE REACTIONS
Most common adverse reactions: infections (e.g. upper respiratory, sinusitis), injection site reactions, headache and rash.

DRUG INTERACTIONS
- Abatacept: Increased risk of serious infection.
- Anakinra: Increased risk of serious infection.
- Live vaccines: Avoid concomitant use.

pharmpix POWERED BY ONEARK

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Inqovi™ (decitabine and cedazuridine) Tablets, for oral use	Astex Pharmaceuticals, Taiho Oncology, and Otsuka Pharmaceutical	07/07/2020

THERAPEUTIC CLASS
Antineoplastic agent; Combination of a nucleoside metabolic inhibitor and a cytidine deaminase inhibitor

FDA-APPROVE INDICATION(S)
Inqovi™ is indicated for the treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

DOSAGE AND ADMINISTRATION
The recommended dose is one tablet (35 mg decitabine and 100 mg cedazuridine) taken orally once daily on Days 1 through 5 of each 28-day cycle.

DOSAGE FORMS AND STRENGTHS
Tablets: 35 mg decitabine and 100 mg cedazuridine..

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Myelosuppression
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: fatigue, constipation, hemorrhage, myalgia, mucositis, arthralgia, nausea, dyspnea, diarrhea, rash, dizziness, febrile neutropenia, edema, headache, cough, decreased appetite, upper respiratory tract infection, pneumonia, and transaminase increased.

DRUG INTERACTIONS
- Drugs metabolized by cytidine deaminase (CDA): Cedazuridine is an inhibitor of the CDA enzyme. Co-administration with drugs that are metabolized by CDA may result in increased systemic exposure with potential for increased toxicity of these drugs. Avoid co-administration with drugs that are metabolized by CDA.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify the pregnancy status in females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during and after treatment.
- Infertility: May impair male fertility. The reversibility of the effect on fertility is unknown.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between patients age 65 years and older and younger patients.
- Renal impairment: No dose modification recommended for mild or moderate renal impairment. Due to the potential for increased adverse reactions, monitor patients with moderate renal impairment frequently for adverse reactions. Has not been studied in patients with severe renal impairment or end-stage renal disease (ESRD).

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Tecartus™ (brexucabtagene autoleucel) Suspension, for intravenous use	Kite, a Gilead Company	07/24/2020

THERAPEUTIC CLASS
Antineoplastic agent; Chimeric antigen receptor (CAR) T cell therapy

FDA-APPROVE INDICATION(S)
Brand name™ (generic name) is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

DOSAGE AND ADMINISTRATION
The recommended dose is based on the number of CAR-positive viable T cells; 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

Must be administered in a certified healthcare facility.

DOSAGE FORMS AND STRENGTHS
Available as a cell suspension for infusion; Comprises a suspension of 2×10^6 CAR-positive viable T cells per kg of body weight, with a maximum of 2×10^8 CAR-positive viable T cells in approximately 68mL.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Boxed warning: Cytokine release syndrome (CRS) and neurologic toxicities.
- Risk Evaluation and Mitigation Strategy (REMS): Because of the risk of CRS and neurologic toxicities, it is available only through a restricted program.
- Hypersensitivity reactions
- Severe infections
- Prolonged cytopenias
- Hypogammaglobulinemia
- Secondary malignancies
- Effects on ability to drive and use machines

ADVERSE REACTIONS
Most common adverse reactions: pyrexia, CRS, hypotension, encephalopathy, fatigue, tachycardia, arrhythmia, infection – pathogen unspecified, chills, hypoxia, cough, tremor, musculoskeletal pain, headache, nausea, edema, motor dysfunction, constipation, diarrhea, decreased appetite, dyspnea, rash, insomnia, pleural effusion, and aphasia.

(continuation) ~~– IF APPLY~~

USE IN SPECIFIC POPULATIONS
- Pregnancy: May cause fetal harm. Verify the pregnancy status in females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between patients age 65 years and older and younger patients.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Xeglyze™ (abametapir) Topical Lotion	Dr. Reddy's Laboratories, Inc.	07/24/2020

THERAPEUTIC CLASS
Pediculicide

FDA-APPROVE INDICATION(S)
Xeglyze™ is indicated for the topical treatment of head lice infestation in patients 6 months of age and older. Should be used in the context of an overall lice management program.

DOSAGE AND ADMINISTRATION
Apply to dry hair in an amount sufficient (up to the full content of one bottle) to thoroughly coat the hair and scalp. Massage into the scalp and throughout the hair; leave on the hair and scalp for 10 minutes and then rinse off with warm water. Treatment involves a single application.

DOSAGE FORMS AND STRENGTHS
Lotion: 0.74% [weight by weight].

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Risk of neonatal benzyl alcohol toxicity
- Risk of benzyl alcohol toxicity from accidental ingestion

ADVERSE REACTIONS
Most common adverse reactions: erythema, rash, skin burning sensation, contact dermatitis, vomiting, eye irritation, pruritus, and hair color changes.

DRUG INTERACTIONS
There is a potential for inhibition of CYP3A4, CYP2B6, and CYP1A2 enzymes following a single application. Use with drugs that are substrates of these enzymes may lead to increased systemic concentrations of the interacting drugs. Avoid administration of drugs that are substrates of CYP3A4, CYP2B6, or CYP1A2 within 2 weeks after application of abametapir. If this is not feasible, avoid use of abametapir.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness have not been established in pediatric patients below the age of 6 months.
- Geriatric use: Clinical studies did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Monjuvi™ (tafasitamab-cxix) for Injection, for intravenous use	MorphoSys AG	07/31/2020

THERAPEUTIC CLASS
Antineoplastic agent; CD19-directed cytolytic antibody

FDA-APPROVE INDICATION(S)
Monjuvi™ is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

DOSAGE AND ADMINISTRATION
The recommended dose is 12 mg/kg in the following dosing schedule:

- Cycle 1: Days 1, 4, 8, 15 and 22 of the 28-day cycle.
- Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle.
- Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle.

Administered in combination with lenalidomide for a maximum of 12 cycles and then continued as monotherapy until disease progression or unacceptable toxicity.

DOSAGE FORMS AND STRENGTHS
For injection: 200 mg of tafasitamab-cxix as lyophilized powder in single-dose vial for reconstitution.

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS

- Infusion-related reactions
- Myelosuppression
- Infections
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: neutropenia, fatigue, anemia, diarrhea, thrombocytopenia, cough, pyrexia, peripheral edema, respiratory tract infection, and decreased appetite.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Females and males of reproductive potential: Advise females of reproductive potential to use effective contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between patients age 65 years and older and younger patients.

Orphan status: Orphan

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Qwo™ (collagenase clostridium histolyticum-aaes) for Injection / **Endo International plc**	Combination of bacterial collagenases	Treatment of moderate to severe cellulite in the buttocks of adult women	07/06/2020	Qwo™ is the first FDA-approved injectable treatment for cellulite. The active ingredient contained in Qwo™, collagenase clostridium histolyticum, was already available in the market under the brand name Xiaflex™. However, Xiaflex™ have different FDA-approved indications: • Dupuytren's contracture • Peyronie's disease Orphan status: N/A
Upneeq™ (oxymetazoline hydrochloride) Ophthalmic Solution / **Osmotica Pharmaceuticals plc**	Direct-acting alpha adrenergic receptor agonist	Treatment of acquired blepharoptosis in adults	07/08/2020	Upneeq™ is the first FDA-approved treatment indicated for the treatment of acquired blepharoptosis. The active ingredient contained in Upneeq™, oxymetazoline, was already available in the market as a nasal spray (in generic and various brands) and a topical cream. However, these formulations have different FDA-approved indications. Orphan status: N/A
Wynzora™ (calcipotriene and betamethasone dipropionate) Cream / **MC2 Therapeutics**	Dermatological agent; Antipsoriatic	Topical treatment of plaque psoriasis in patients 18 years of age and older	07/20/2020	Wynzora™ cream-based fixed dose combination of the vitamin D analog calcipotriene, and the corticosteroid betamethasone dipropionate. Orphan status: N/A
Xywav™ (calcium, magnesium, potassium, and sodium oxybates) Oral Solution / **Jazz Pharmaceuticals plc**	Central nervous system agent	Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy	07/21/2020	Xywav™ is an oxybate product with a unique composition of cations resulting in 92% less sodium than another oxybate product from Jazz Pharmaceuticals, Xyrem™ (sodium oxybate). Xyrem™ shares the same indication as Xywav™. Orphan status: Orphan Controlled substance: CIII

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Breztri Aerosphere™ (budesonide / glycopyrrolate / formoterol fumarate) Metered Dose Inhalation / AstraZeneca	Respiratory agent	Treatment of patients with chronic obstructive pulmonary disease (COPD)	07/23/2020	Breztri Aerosphere™ is a fixed dose triple-combination of the inhaled corticosteroid budesonide, the long-acting muscarinic antagonist (LAMA) glycopyrrolate, and the long-acting beta2-agonist (LABA) formoterol fumarate. Orphan status: N/A

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Dysport™ (abobotulinumtoxinA) Injection / Ipsen Biopharmaceuticals, Inc.	Acetylcholine release inhibitor and neuromuscular blocking agent	• Treatment of cervical dystonia in adults • Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age • Treatment of spasticity in patients 2 years of age and older	Treatment of lower and upper limb spasticity in patients 2 years of age and older, including spasticity caused by cerebral palsy (CP) Note: Dysport™ was first approved specifically for pediatric lower limb spasticity caused by CP. Later, Dysport™ was granted with an additional indication for pediatric upper limb spasticity, excluding upper limb spasticity caused by CP, due to Orphan Drug exclusivity granted to another manufacturer. An orphan exclusivity waive by manufacturers permit the indication expansion.	07/08/2020
Botox™ (onabotulinumtoxinA) Injection / Allergan plc	Acetylcholine release inhibitor and neuromuscular blocking agent	Treatment for Hyperhidrosis, Cervical Dystonia, Urinary Incontinence, Migraine Prevention, Upper Limb Spasticity, Lower Limb Spasticity, Blepharospasm, Strabismus, Spasticity	Treatment of lower and upper limb spasticity in patients 2 years of age and older, including spasticity caused by cerebral palsy (CP) Note: Botox™ was first approved specifically for pediatric patients with upper limb spasticity. Later, Botox™ was granted with an additional indication for pediatric lower limb spasticity, excluding spasticity caused by CP. An orphan exclusivity waive by manufacturers permit the indication expansion.	07/08/2020
Tremfya™ (guselkumab) Injection / Janssen Biotech, Inc.	Interleukin-23 blocker	Treatment of moderate-to-severe plaque psoriasis in adults	Treatment of active psoriatic arthritis in adults	07/13/2020
Qutenza™ (capsaicin) Transdermal Patch / Averitas Pharma, Inc.	TRPV1 channel agonist	Treatment of neuropathic pain associated with post-herpetic neuralgia (PHN)	Treatment of neuropathic pain associated with diabetic peripheral neuropathy of the feet	07/17/2020

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Stelara™ (ustekinumab) Injection / Janssen Biotech, Inc.	Interleukin-12 and -23 blocker	Treatment of moderate to severe plaque psoriasis (Ps), active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis (UC)	Patient population altered: To include pediatric patients (6-11 years of age) with moderate to severe Ps.	07/30/2020
Tecentriq™ (atezolizumab) Injection / Genentech, Inc.	Antineoplastic agent; Programmed death-ligand 1 (PD-L1) blocking antibody	Treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), small cell lung cancer (SCLC), and heptatocellular carcinoma	In combination with Cotellic™ (cobimetinib) and Zelboraf™ (vemurafenib) for the treatment of BRAF V600 mutation-positive advanced melanoma	07/30/2020
Spravato™ (esketamine) Nasal Spray / Janssen Pharmaceuticals, Inc.	Antidepressant; Non-competitive N-methyl D-aspartate (NMDA) receptor antagonist	In conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults	In conjunction with an oral antidepressant, for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.	7/31/2020
Epidiolex™ (cannabidiol) Oral Solution / GW Pharmaceuticals plc	Antiepileptic	Treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome	Treatment of seizures associated with tuberous sclerosis complex (TSC) in patients one year of age and older	7/31/2020

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Indication(s)	Date	Generic for:
Deferasirox Oral Granules 90 mg, 180 mg and 360 mg / Alkem Laboratories Ltd.	Antidote	• Treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older • Treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes, and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (Fe/g dw) and a serum ferritin greater than 300 mcg/L	07/14/2020	Jadenu Sprinkle
Metyrosine Capsules 250 mg / Amneal Pharmaceuticals LLC		Treatment of patients with pheochromocytoma for: • Preoperative preparation of patients for surgery • Management of patients when surgery is contraindicated • Chronic treatment of patients with malignant pheochromocytoma	07/24/2020	Demser

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Pralsetinib / Blueprint Medicines Corporation	07/01/2020	Treatment for: Thyroid Cancer	Pralsetinib is an oral selective RET kinase inhibitor in development for the treatment of patients with advanced or metastatic RET mutant medullary thyroid cancer (MTC) and RET fusion-positive thyroid cancers. Blueprint Medicines submits NDA	High
Aducanumab / Biogen	07/08/2020	Treatment for: Alzheimer's Disease	Aducanumab (BIIB037) is an investigational human recombinant monoclonal antibody (mAb) in development for the treatment of early Alzheimer's disease (AD). Biogen submits BLA.	High High
Avacopan / ChemoCentryx, Inc.	07/09/2020	Treatment for: ANCA-Associated Vasculitis	Avacopan is an orally administered small-molecule C5aR antagonist in development for the treatment of patients with ANCA-associated vasculitis. ChemoCentryx submits NDA and FDA granted orphan drug designation to avacopan.	High High
Vericiguat / Merck	07/16/2020	Treatment for: Heart Failure with Reduced Ejection Fraction (HFrEF)	Vericiguat is an orally administered soluble guanylate cyclase (sGC) stimulator in development for the treatment of patients with symptomatic chronic heart failure with reduced ejection fraction (HFrEF). FDA accepted for priority review the NDA for vericiguat.	High
Arimoclomol / Orphazyme A/S	07/20/2020	Treatment for: Niemann-Pick Disease, type C	Arimoclomol is an investigational Heat-Shock Protein amplifier in development for the treatment of Niemann-Pick disease Type C (NPC). Orphazyme completes rolling submission of NDA and FDA granted orphan drug designation to arimoclomol.	High High

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Voclosporin / Aurinia Pharmaceuticals Inc.	07/21/2020	Treatment for: Lupus Nephritis	Voclosporin is a next-generation calcineurin inhibitor in development for the treatment of lupus nephritis. FDA accepted NDA.	High
Furoscix (furosemide) / scPharmaceuticals, Inc.	07/01/2020; 07/27/2020	Treatment for: Congestive Heart Failure	Furoscix (furosemide) is a subcutaneous formulation of the approved diuretic furosemide delivered via a wearable, pre-programmed on-body drug delivery system. Furoscix is in development for treatment of congestion in patients with heart failure, and has the potential to provide an outpatient alternative for the treatment of worsening heart failure due to congestion. NDA re-submitted and accepted.	Moderate
Idecabtagene vicleucel / Bristol Myers Squibb	07/29/2020	Treatment for: Multiple Myeloma	Idecabtagene vicleucel (ide-cel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T cell immunotherapy in development for the treatment of adult patients with multiple myeloma who have received at least three prior therapies. Bristol Myers Squibb submits BLA.	High High

References

- Food and Drug Administration (www.fda.gov)
- Drugs.com (www.drugs.com)
- IBM Micromedex® (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)