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PharmNOTES

Summary of new FDA-approved products,
new indications, first-time generics,
and WHAT'S IN THE PIPELINE
For: **AUGUST 2021**

Date: 09/03/2021

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Pharmacy
Benefit
Management
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NEWS

- No new drug safety communication, excluding recalls, published during August 2021.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
NEXVIAZYME (AVALGLUCOSIDASE ALFA-NGPT) INECTION	SANOFI	08/06/2021

THERAPEUTIC CLASS
Endocrine and metabolic agents

FDA-APPROVED INDICATION(S)
NEXVIAZYME™ is a hydrolytic lysomal glycogen-specific enzyme indicated for the treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency).

DOSAGE AND ADMINISTRATION
The recommended dose is weight-based and administered as an intravenous infusion. For patients that weigh ≥30kg, the recommended dosage is 20mg/kg every 2 weeks. For patients that weigh <30kg, the recommended dosage is 40mg/kg every 2 weeks. Premedication is advised with antihistamines, antipyretics, and/or corticosteroids.

DOSAGE FORMS AND STRENGTHS
For injection: 100 mg of avalglucosidase alfa-ngpt as a lyophilized powder in a single-dose vial for reconstitution

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Boxed warning:
  - Severe hypersensitivity reactions including anaphylaxis
  - Infusion-associated reactions
  - Risk of acute cardiorespiratory failure in susceptible patients

ADVERSE REACTIONS
Most common adverse reactions: headache, fatigue, diarrhea, nausea, arthralgia, dizziness, myalgia, pruritus, vomiting, dyspnea, erythema, paresthesia and urticaria.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Available data from postmarketing reports and published case reports on alglucosidase alfa (another hydrolytic lysosomal glycogen-specific enzyme replacement therapy) use in pregnant women have not identified a drug-associated risk of adverse pregnancy outcomes.
- Lactation: There are no data on the presence of avalglucosidase alfa-ngpt in human or animal milk, the effects on the breastfed infant, or the effects on milk production.
- Pediatric use: The safety and effectiveness of NEXVIAZYME™ for the treatment of late-onset Pompe disease have been established in pediatric patients 1 year of age and older.
- Geriatric use: Clinical studies with NEXVIAZYME™ included 14 patients 65 to 74 years of age and 3 patients 75 years of age and older. The recommended dosage in geriatric patients is the same as the recommended dosage in younger adult patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
WELIREG (BELZUTIFAN) TABLETS	MERCK SHARP DOHME	08/13/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVED INDICATION(S)
Welireg™ is a hypoxia-inducible factor inhibitor indicated for treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.

DOSAGE AND ADMINISTRATION
The recommended dosage is 120mg administered orally once daily with or without food

DOSAGE FORMS AND STRENGTHS
Tablets: 40mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Anemia
- Hypoxia

ADVERSE REACTIONS
Most common (≥ 25%) adverse reactions are laboratory abnormalities, were decreased hemoglobin, anemia, fatigue, increased creatinine, headache, dizziness, increased glucose and nausea.

DRUG INTERACTIONS
- UGT2B17 or CYP2C19 Inhibitors: Monitor for signs and symptoms of anemia and hypoxia and reduce the dosage of WELIREG™ as recommended.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on findings in animal studies, WELIREG™ can cause fetal harm when administered to a pregnant woman.
- Lactation: Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with WELIREG™ and for 1 week after the last dose.
- Pediatric use: Safety and effectiveness of WELIREG have not been established in pediatric patients.
- Geriatric use: Clinical trials of WELIREG™ did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger patients.
- Renal impairment: WELIREG™ has not been studied in patients with severe renal impairment.
- Hepatic impairment: WELIREG™ has not been studied in patients with moderate or severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TICOVAC (TICK-BORNE ENCEPHALITIS VACCINE) INJECTION	PFIZER IRELAND PHARMACEUTICALS	08/13/2021

THERAPEUTIC CLASS
Vaccine

FDA-APPROVED INDICATION(S)
TICOVAC™ is a vaccine indicated for active immunization to prevent tick-borne encephalitis (TBE). TICOVAC™ is approved for use in individuals 1 year of age and older.

DOSAGE AND ADMINISTRATION
For intramuscular use only:
- 1 through 15 years of age: each dose 0.25ml
- 16 years of age and older: each dose 0.5ml

Primary vaccination: three doses

Booster dose (fourth dose) may be given at least 3 years after completion of the primary immunization series if ongoing exposure or re-exposure to tickborne encephalitis virus (TBEV) is expected.

DOSAGE FORMS AND STRENGTHS
Suspension for injection supplied as a 0.25 mL or 0.5 mL single-dose in pre-filled syringes.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Severe allergic reaction (e.g., anaphylaxis) to any component of TICOVAC™

WARNINGS AND PRECAUTIONS
- Dizziness, somnolence, mental status changes and gait disturbances
- Risk of driving and operating machinery

ADVERSE REACTIONS
The most common adverse reactions are as follows:
- 1 through 15 years of age: Local tenderness (18.1%), local pain (11.2%), headache (11.1%), fever (9.6%), and restlessness (9.1%)
- 16 through 65 years of age: Local tenderness (29.9%), local pain (13.2%), fatigue (6.6%), headache (6.3%), and muscle pain (5.1%)

USE IN SPECIFIC POPULATIONS
- Pregnancy: There are no adequate and well-controlled studies of TICOVAC™ in pregnant women. Available human data are insufficient to establish the presence or absence of vaccine-associated risk during pregnancy.
- Lactation: Human data are not available to assess the impact of TICOVAC™ on milk production, its presence in breast milk, or its effects on the breastfed.
- Pediatric use: Safety and effectiveness of TICOVAC™ have not been established in infants below 1 year of age.
- Geriatric use: Clinical studies of TICOVAC™ did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
KORSUVA (DIFELIKEFALIN) INJECTION	CARA THERAPEUTICS, INC.	08/23/2021

THERAPEUTIC CLASS
Kappa opioid receptor (KOR) agonist

FDA-APPROVED INDICATION(S)
Korsuva™ is a kappa opioid receptor agonist indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults underdoing hemodialysis (HD).

DOSAGE AND ADMINISTRATION
The recommended dosage is 0.5mcg/kg administer by intravenous bolus injection into the venous line of dialysis circuit at the end of each HD treatment. The dose must be administered within 60 minutes f the completion of the syringe preparation.

DOSAGE FORMS AND STRENGTHS
Injection: 65mcg/1.3ml (50mcg/ml)

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Dizziness, somnolence, mental status changes and gait disturbances
- Risk of driving and operating machinery

ADVERSE REACTIONS
Most common adverse reactions are diarrhea, dizziness, nausea, gait disturbances, including falls, hyperkalemia, headache, somnolence, and mental health status change.

USE IN SPECIFIC POPULATIONS
- Pregnancy: The limited human data on use of KORSUVA™ in pregnant women are not sufficient to evaluate a drug associated risk for major birth defects or miscarriage.
- Lactation: There are no data regarding the presence of KORSUVA™ in human milk or effects on the breastfed infant or on milk production.
- Pediatric use: The safety and effectiveness of KORSUVA™ in pediatric patients have not been established.
- Geriatric use: No differences in plasma concentrations of KORSUVA™ were observed between subjects 65 years of age and older and younger adult subjects
- Hepatic impairment: The influence of severe hepatic impairment on the pharmacokinetics of KORSUVA™ in subjects undergoing HD has not been evaluated; therefore, use of KORSUVA™ in this population is not recommended.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
COMINARTY (COVID-19 VACCINE, MRNA) INJECTION	PFIZER AND BIONTECH	08/23/2021

THERAPEUTIC CLASS
Vaccine

FDA-APPROVED INDICATION(S)
COMIRNATY™ is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older

DOSAGE AND ADMINISTRATION
For intramuscular use only:
- Administered as a series of 2 doses (0.3ml each) 3 weeks apart

DOSAGE FORMS AND STRENGTHS
Suspension for injection. After preparation, a single dose is 0.3 ml.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Severe allergic reaction (e.g., anaphylaxis) to any component of TICOVAC™

WARNINGS AND PRECAUTIONS
- Dizziness, somnolence, mental status changes and gait disturbances
- Risk of driving and operating machinery

ADVERSE REACTIONS
The most common adverse reactions are as follows:
- 1 through 15 years of age: Local tenderness (18.1%), local pain (11.2%), headache (11.1%), fever (9.6%), and restlessness (9.1%)
- 16 through 65 years of age: Local tenderness (29.9%), local pain (13.2%), fatigue (6.6%), headache (6.3%), and muscle pain (5.1%)

USE IN SPECIFIC POPULATIONS
- Pregnancy: There are no adequate and well-controlled studies of TICOVAC™ in pregnant women. Available human data are insufficient to establish the presence or absence of vaccine-associated risk during pregnancy.
- Lactation: Human data are not available to assess the impact of TICOVAC™ on milk production, its presence in breast milk, or its effects on the breastfed.
- Pediatric use: Safety and effectiveness of TICOVAC™ have not been established in infants below 1 year of age.
- Geriatric use: Clinical studies of TICOVAC™ did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
SKYTROFA (LONAPEGSOMATROPIN-TCGD) INJECTION	ASCENDIS PHARMA	08/25/2021

THERAPEUTIC CLASS
Human growth hormone

FDA-APPROVED INDICATION(S)
SKYTROFA™ is a human growth hormone indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).

DOSAGE AND ADMINISTRATION
SKYTROFA™ should be administered subcutaneously into the abdomen, buttock, or thigh with regular rotation of the injection sites (2.5). The recommended dose is 0.24 mg/kg body weight once-weekly.

DOSAGE FORMS AND STRENGTHS
SKYTROFA™ is a lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, Water for Injection.

- For injection: 3 mg, 3.6 mg, 4.3 mg, 5.2 mg, 6.3 mg, 7.6 mg, 9.1 mg, 11 mg and 13.3 mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS

- Acute critical illness
- Hypersensitivity to somatropin or any of the excipients in SKYTROFA™
- Children with closed epiphyses
- Active malignancy
- Active proliferative or severe non-proliferative diabetic retinopathy
- Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment due to risk of sudden death

WARNINGS AND PRECAUTIONS

- Severe Hypersensitivity
- Increased Risk of Neoplasms
- Glucose Intolerance and Diabetes Mellitus
- Intracranial Hypertension
- Fluid Retention (i.e., edema, arthralgia, carpal tunnel syndrome)
- Hypoadrenalism
- Hypothyroidism
- Slipped Capital Femoral Epiphysis
- Progression of Preexisting Scoliosis
- Pancreatitis

ADVERSE REACTIONS

- Most common adverse reactions (≥5%) in pediatric patients include viral infection, pyrexia, cough, nausea and vomiting, hemorrhage, diarrhea, abdominal pain, and arthralgia and arthritis

DRUG INTERACTIONS

- Replacement Glucocorticoid Treatment: Patients treated with glucocorticoid for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of SKYTROFA™
- Pharmacologic Glucocorticoid Therapy and Supraphysiologic Glucocorticoid Treatment: Adjust glucocorticoid replacement dosing in pediatric patients receiving glucocorticoid treatment to avoid both hypoadrenalism and an inhibitory effect on growth
- Cytochrome P450-Metabolized Drugs: SKYTROFA™ may alter the clearance. Monitor carefully if used with SKYTROFA™
- Oral Estrogen: Larger doses of SKYTROFA™ may be required
- Insulin and/or Other Antihyperglycemic Agents: Dose adjustment of insulin or antihyperglycemic agent may be required

(continues on the next slide)

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
SKYTROFA (LONAPEGSOMATROPIN-TCGD) INJECTION	ASCENDIS PHARMA	08/25/2021

THERAPEUTIC CLASS
Human growth hormone

FDA-APPROVED INDICATION(S)
SKYTROFA™ is a human growth hormone indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).

DOSAGE AND ADMINISTRATION
SKYTROFA™ should be administered subcutaneously into the abdomen, buttock, or thigh with regular rotation of the injection sites (2.5). The recommended dose is 0.24 mg/kg body weight once-weekly.

DOSAGE FORMS AND STRENGTHS
SKYTROFA™ is a lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, Water for Injection.

- For injection: 3 mg, 3.6 mg, 4.3 mg, 5.2 mg, 6.3 mg, 7.6 mg, 9.1 mg, 11 mg and 13.3 mg

Orphan status: Orphan

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Pregnancy: There are no available data on lonapegsomatropin-tcgd use in pregnant patients to evaluate a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Available published data over several decades for somatropin, the active component of lonapegsomatropin-tcgd, have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.
- Lactation: There are no data on the presence of lonapegsomatropin-tcgd in human milk, effects on the breastfed infant, or effects on milk production.
- Pediatric use:
  - Safety and effectiveness of SKYTROFA™ have been established in pediatric patients 1 year and older and who weigh at least 11.5 kg.
  - The safety and effectiveness of SKYTROFA™ in children less than 1 year of age have not been established.

NEW BIOSMILAR PRODUCTS

- No new biosimilar product approved during August 2021.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
LOREEV XR™ (LORAZEPAM) / ALMATICA PHARMA, LLC.	Antianxiety agents	Treatment of anxiety disorders in adults	08/27/2021	Loreev XR is an extended-release capsule for the treatment of anxiety disorders in adults who are already receiving stable, evenly divided three times daily dosing with lorazepam tablets. Orphan status: N/A Controlled substance: Yes

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
IBUPROFEN AND FAMOTIDINE TABLETS 800MG-26.6MG / ALKEM LABORATORIES LTD.	Analgesic, nonsteroidal anti-inflammatory agents (NSAIDs)	Treatment of rheumatoid arthritis and osteoarthritis	Duexis™	08/03/2021
DIFLUPREDNATE OPHTHALMIC EMULSION 0.05% / CIPLA LTD.	Ophthalmic agents	Treatment of eye pain and inflammation caused by surgery and treatment of anterior uveitis	Durezol™	08/09/2021
GLYCOPYRROLATE ORAL SOLUTION 1MG/5ML / PAR PHARMACEUTICAL INC.	Antispasmodics/Anticholinergics	Treatment of sialorrhea and peptic ulcer disease	Cuvposa™	08/09/2021
ENALAPRIL MALEATE ORAL SOLUTION 1MG/ML / BIONPHARMA INC	Antihypertensive agents	Treatment of hypertension	Epaned™	08/10/2021
VARENICLINE TABLETS 0.5MG AND 1MG / PAR PHARMACEUTICAL INC	Smoking deterrents	Treatment of smoking cessation	Chantix™	08/11/2021
SUNITINIB MALATE CAPSULES 12.5MG, 25MG, 37.5MG, AND 50MG / SUN PHARMACEUTICAL INDUSTRIES, INC.	Antineoplastics and adjunctive therapies	Treatment of certain types of advanced or progressive tumors of the stomach, intestines, esophagus, pancreas, or kidneys	Sutent™	08/16/2021
LINAGLIPTION AND METFORMIN HYDROCHLORIDE 2.5MG/500MG, 2.5MG/850MG, 2.5MG/1000MG TABLETS / SUNSHINE LAKE PHARMA CO., LTD.	Antidiabetic agents	Treatment of diabetes mellitus type 2	Jentadueto™	08/30/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

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NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
KEYTRUDA™ (PEMBROLIZUMAB) INJECTION / MERCK	Antineoplastic agent	Treatment of melanoma, non-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, locally advanced cutaneous squamous cell carcinoma (cSCC) that is not curable by surgry or radiation, advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) with disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation in combination with Lenvima (lenvatinib), high-risk early-stage triple-negative breast cancer in combination with chemotherapy as neoadjuvant treatment, then continued as single agent as adjuvant treatment after surgery	Treatment of adult patients with advanced renal cell carcinoma (RCC) in combination with Lenvima™ (lenvatinib)	08/10/2021
XYWAX™ (CALCIUM, MAGNESIUM, POTASSIUM AND SODIUM OXYBATES) ORAL SOLUTION / JAZZ PHARMACEUTICALS	Central nervous system depressant	Treatment of cataplexy and excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy	Treatment of idiopathic hypersomnia in adults	08/12/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
JEMPERLI™ (DOSTARLIMABB-GXLY) INJECTION / GLAXOSMITHKLINE (GSK)	Antineoplastics and adjunctive therapies	Treatment of adult patients with mismatch repair deficient (DMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen	Treatment of adult patients with mismatch repair deficient (DMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that has progressed on or following prior treatment and who have no satisfactory alternative treatment options	08/17/2021
JARDIANCE™ (EMPAGLIFLOZIN) TABLETS / BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	Antidiabetic agents	Treatment of diabetes mellitus type 2	Treatment of heart failure with reduced ejection fraction (HFrEF) to reduce the risk of cardiovascular death plus hospitalization	08/18/2021
OPDIVO™ (NIVOLUMAB) INJECTION / BRISTOL MYERS SQUIBB	Antineoplastics and adjunctive therapies	Treatment of melanoma, non-small cell lung cancer (NSCLC), malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin Lymphoma (cHL), colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma	Adjuvant treatment of patients with high-risk urothelial carcinoma	08/20/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
XARELTO™ (APIXABAN) TABLETS / JANSSEN PHARMACEUTICALS, INC.	Anticoagulant agents	Treatment of nonvalvular atrial fibrillation, peripheral or coronary artery disease, venous thromboembolism and venous thromboembolism prophylaxis	Treatment of symptomatic peripheral artery disease (PAD) in patients following recent lower-extremity revascularization in combination with aspirin	08/24/2021
TIBSOVO™ (IVOSIDENIB) TABLETS /	Antineoplastics and adjunctive therapies	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test	Treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation as detected by an FDA-approved test	08/25/2021

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
PRIORIX (MEASLES, MUMPS, AND RUBELLA VIRUS VACCINE, LIVE) INJECTION / GLAXOSMITHKLINE (GSK)	08/02/2021	Active immunization against infection by measles, mumps, and rubella (MMR)	In recent years, measles outbreaks have occurred in the United States and globally with more than 400,000 cases confirmed in 2019, reversing decades of progress toward measles elimination in many countries. The BLA submission will allow for the US to have more than one option for the prevention of this disease. BLA submitted.	High
GANAXOLONE / MARINUS PHARMACEUTICALS, INC.	08/03/2021	Treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder	CDKL5 deficiency disorder is a serious and rare genetic disorder that is characterized by early-onset, difficult-to-control seizures and severe neuro-developmental impairment. Currently, there are no therapies approved specifically for this disorder. NDA submitted.	High High
DARE-BV1 / DARÉ BIOSCIENCE, INC.	08/09/2021	Treatment of bacterial vaginosis	DARE-BV1 is an investigational thermosetting bioadhesive hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application. It is a viscous liquid designed to undergo solution to gel (sol-to-gel) transition using body temperature as the trigger. This property allows the product to be more easily directed to the site of infection. NDA accepted.	Moderate

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
TAPINAROF / DERMAVANT SCIENCES	08/10/2021	Treatment of plaque psoriasis and atopic dermatitis	Tapinarof is an investigational, novel, therapeutic aryl hydrocarbon receptor modulating agent, in development as a once-daily, steroid-free and cosmetically elegant topical cream for the treatment of plaque psoriasis and atopic dermatitis. NDA accepted.	Moderate
MITAPIVAT / AGIOS PHARMACEUTICALS, INC.	08/17/2021	Treatment of Adults with pyruvate kinase (PK) deficiency	Mitapivat has the potential to become the first disease-modifying therapy for people with PK deficiency, a chronic, lifelong hemolytic anemia characterized by serious complications affecting multiple organs. NDA accepted.	High High
ELAMIPRETIDE / STEALTH BIOTHERAPEUTICS, INC.	08/24/2021	Treatment of Barth Syndrome	Elamipretide is an experimental drug that has been shown to reduce debilitating fatigue and potentially improve important baseline health measures, including various heart components, in people with the ultra-rare genetic disease Barth syndrome. NDA submitted.	High High
mRNA-1273 / MODERNA, INC.	08/25/2021	Active immunization to prevent COVID-19 in individuals 18 years of age and older	The Moderna COVID-19 is showing durable efficacy of 93% through six months after dose 2. The completed submission includes clinical data from the Phase 3 COVE study of the Moderna COVID-19 vaccine, which enrolled more than 30,000 participants in the U.S. BLA submitted.	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)