PharmNOTES

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

ACCREDITED
Pharmacy Benefit Management
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NEWS

DRUG ISSUE	DATE	DETAILS
FDA recommends thyroid monitoring in babies and young children who receive injection of iodine-containing contrast media for medical imaging	3/30/2022	The U.S. FDA is recommending that newborns and children through 3 years old have follow-up thyroid monitoring within 3 weeks after receiving injections of contrast media containing iodine for X-rays and other medical imaging procedures. The FDA reviewed published studies that showed that after the administration of contrast dye there was underactive thyroid or a temporary decrease in thyroid hormone levels. Although it was uncommon, the conditions should be identified and treated early when needed to prevent future complications. The FDA has approved a new warning to the prescribing information for the entire class of iodinated contrast media injections and monitoring recommendations for children 3 years or younger.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
ZTALMY™ (GANAXOLONE) ORAL SUSPENSION	MARINUS PHARMACEUTICALS, INC.	03/18/2022

THERAPEUTIC CLASS
Neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator

FDA-APPROVED INDICATION(S)
Treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older

DOSAGE AND ADMINISTRATION
Dosage for patients weighing 28 kg or less:
- The starting dosage is 6 mg/kg orally three times daily (18 mg/kg/day)
- The maximum dosage is 21 mg/kg three times daily (63 mg/kg/daily).

Dosage for patients weighing over 28 kg:
- The starting dosage is 150 mg orally three times daily (450 mg daily)
- The maximum dosage is 600 mg three times daily (1800 mg daily).

DOSAGE FORMS AND STRENGTHS
Oral suspension 50mg/mL

Orphan status: Orphan
Controlled substance schedule: Pending

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Somnolence and sedation: Monitor for somnolence and sedation and advise patients not to drive or operate machinery until they have gained sufficient experience with Ztalmy™. Concomitant use with other CNS depressants or alcohol could potentiate adverse effects.
- Suicidal behavior and ideation: Monitor patients for suicidal behavior and thoughts.
- Withdrawal of antiepileptic drugs: Ztalmy™ should be withdrawn gradually to minimize the risk of increased seizure frequency and status epilepticus.

ADVERSE REACTIONS
- Most common adverse reactions (incidence of at least 5% and at least twice the rate of placebo) are somnolence, pyrexia, salivary hypersecretion, and seasonal allergy.

DRUG INTERACTIONS
- Cytochrome P450 inducers will decrease ganaxolone exposure. It is recommended to avoid concomitant use with strong or moderate CYP3A4 inducers; if unavoidable, consider a dosage increase of Ztalmy™, but do not exceed the maximum recommended dosage.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on animal studies, ganaxolone may cause fetal harm. Oral administration of ganaxalone to rats on postnatal day (PND) 7 resulted in widespread apoptotic neurodegeneration in the brain (cortex, thalamus, and hippocampus) at all doses; a no-effect dose was not identified.
- Lactation: Ganaxolone is excreted in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Ztalmy™, and any potential adverse effects on the breastfed child from Ztalmy™, or from the underlying maternal condition.
- Pediatric use: Safety and effectiveness of Ztalmy™ in pediatric patients below 2 years of age have not been established.
- Hepatic Impairment: The influence of hepatic impairment on the pharmacokinetics of Ztalmy™ has not been evaluated. Since ganaxolone undergoes clearance via the hepatic route, hepatic impairment can increase ganaxolone exposure.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
OPDUALAG™ (NIVOLUMAB AND RELATLIMAB-RMBW) INJECTION	BRISTOL MYERS SQUIBB	03/18/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Treatment of adults and pediatric patients 12 years of age or older with unresectable or metastatic melanoma

DOSAGE AND ADMINISTRATION
Adult patients and pediatric patients 12 years of age or older who weigh at least 40kg: 480mg nivolumab and 160mg relatlimab intravenously every 4 weeks

DOSAGE FORMS AND STRENGTHS
Injection: 240 mg of nivolumab and 80 mg of relatlimab per 20 mL (12 mg and 4 mg per mL) in a single-dose vial

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Immune-mediated adverse reactions: Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, immune-mediated nephritis with renal dysfunction, and immune-mediated myocarditis. Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. Withhold or permanently discontinue based on severity and type of reaction.
- Infusion-relation reactions: Interrupt, slow the rate of infusion, or permanently discontinue Opdualag™ based on severity of reaction.
- Complications of allogeneic HSCT: Fatal and other serious complications can occur in patient who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
- The most common adverse reactions (≥20%) are musculoskeletal pain, fatigue, rash, pruritus, and diarrhea. The most common laboratory abnormalities (≥20%) are decreased hemoglobin, decreased lymphocytes, increased AST, increased ALT, and decreased sodium.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Opdualag™ can cause fetal harm when administered to a pregnant woman.
- Lactation: Because nivolumab and relatlimab may be excreted in human milk and because of the potential for serious adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with Opdualag™ and for at least 5 months after the last dose.
- Females and males of reproductive potential: Verify the pregnancy status of females of reproductive potential prior to initiating Opdualag™. Advise females of reproductive potential to use effective contraception during treatment and for at least 5 months following the last dose.
- Geriatric use: No overall differences in safety or effectiveness were observed between elderly patients and younger patients.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PLUVICTO™ (LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN) INJECTION	ADVANCED ACCELERATOR APPLICATIONS USA, INC.	03/23/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy

DOSAGE AND ADMINISTRATION
Recommended dosage: Administer 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses.
Select patients for treatment using LOCAMETZ® or an approved PSMA-11 imaging agent based on PSMA expression in tumors.

DOSAGE FORMS AND STRENGTHS
Injection: 1,000 MBq/mL (27 mCi/mL) in a single-dose vial

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Risk From Radiation Exposure: Minimize radiation exposure during and after treatment with Pluvicto™ consistent with institutional good radiation safety practices and patient treatment procedures. Ensure patients increase oral fluid intake and advise patients to void as often as possible to reduce bladder radiation.
- Myelosuppression: Perform complete blood counts. Withhold, reduce dose, or permanently discontinue Pluvicto™ and clinically treat based on severity.
- Renal Toxicity: Advise patients to remain well hydrated and to urinate frequently. Perform kidney function laboratory tests. Withhold, reduce dose, or permanently discontinue Pluvicto™ based on severity.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise male patients with female partners of reproductive potential to use effective contraception.
- Infertility: Pluvicto™ may cause temporary or permanent infertility.

ADVERSE REACTIONS
- Most common adverse reactions (≥ 20%) are fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation.

ADVERSE REACTIONS (cont.)
- Most common laboratory abnormalities (≥ 30%) are decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Pluvicto™ can cause fetal harm.
- Lactation: There are no data on the presence of lutetium Lu 177 vipivotide tetraxetan in human milk or its effects on the breastfed child or on milk production.
- Females and males of reproductive potential: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Pluvicto™ and for 14 weeks after the last dose. The recommended cumulative dose of 44.4 GBq of Pluvicto™ results in a radiation absorbed dose to the testes within the range where Pluvicto™ may cause temporary or permanent infertility.
- Geriatric use: No overall differences in effectiveness were observed between patients ≥ 75 years of age and younger patients. Serious adverse reactions occurred in 11% of patients ≥ 75 years of age and in 11% of younger patients. Grade ≥ 3 adverse reactions occurred in 40% of patients ≥ 75 years of age and in 31% of younger patients.
- Renal impairment: The pharmacokinetics and safety of Pluvicto™ have not been studied in patients with severe renal impairment or end-stage renal disease.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LOCAMETZ KIT™ (GALLIUM GA 68 GOZETIDE) INJECTION	ADVANCED ACCELERATOR APPLICATIONS USA, INC.	03/23/2022

THERAPEUTIC CLASS
Radioactive diagnostic agent

FDA-APPROVED INDICATION(S)
For positron emission tomography (PET) of PSMA-positive lesions in men with prostate cancer: with suspected metastasis who are candidates for initial definitive therapy; with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level; for selection of patients with metastatic prostate cancer, for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated.

DOSAGE AND ADMINISTRATION
The recommended amount of radioactivity is 111 MBq to 259 MBq (3 mCi to 7 mCi). Administered as slow intravenous injection.

DOSAGE FORMS AND STRENGTHS
Kit for the preparation of gallium Ga 68 gozetotide injection supplied in a multiple-dose vial containing 25 mcg of gozetotide as a white lyophilized powder. After radiolabeling with gallium-68, the vial contains a sterile solution of gallium Ga 68 gozetotide at a strength up to 1,369 MBq (37 mCi) in up to 10 mL at calibration date and time.

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Risk for misinterpretation: Gallium Ga 68 gozetotide uptake may occur in other tumor types and in non-malignant processes. Interpretation of Locametz™ PET imaging with histopathology and/or other diagnostic procedures is recommended.
- Radiation risk: GalliumGa 68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure.

ADVERSE REACTIONS
- The adverse reactions (incidence ≥ 0.5%) are fatigue, nausea, constipation, and vomiting.

DRUG INTERACTIONS
- Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga 68 gozetotide in prostate cancer.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Locametz™ is not indicated in females. All radiopharmaceuticals, including Locametz™ have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of radiation dose.
- Lactation: There are no data on the presence of gallium Ga 68 gozetotide in human milk, the effect on the breastfed infant, or the effect on milk production.
- Pediatric use: The safety and effectiveness of gallium Ga 68 gozetotide in pediatric patients have not been established.
- Geriatric use: The efficacy and safety profiles of gallium Ga 68 gozetotide appeared similar in younger adult and geriatric patients with prostate cancer and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Orphan status: N/A

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NEW BIOSMILAR PRODUCTS

- No biosimilar product was approved during the month of March.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
ADLARITY™ (DONEPEZIL HYDROCHLORIDE) TRANSDERMAL SYSTEM / CORIUM, INC.	Psychotherapeutic and neurological agents – misc.	Treatment of mild, moderate and severe dementia of the Alzheimer's type	3/11/2022	Adlarity™ is the first and only once-weekly patch to continuously deliver consistent doses of donepezil through the skin, resulting in a low likelihood of adverse gastrointestinal side effects associated with oral donepezil. Orphan: N/A
HYFTOR™ (SIROLIMUS) TOPICAL GEL / NOBELPHARMA CO., LTD.	Immunosuppressive agents	Treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older	3/22/2022	Hyftor™ is the first topical treatment indicated for the treatment of facial angiofibroma in tuberous sclerosis complex. Orphan: Yes
XELSTRYM™ (DEXTROAMPHETA-MINE) TRANSDERMAL SYSTEM / NOVEN PHARMS INC.	ADHD/anti-narcolepsy/anti-obesity/anorexiants	Treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older	3/22/2022	Xelstrym™ is the first and only FDA-approved, once-daily amphetamine transdermal patch. Orphan: N/A Controlled substance schedule: II

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
OZEMPIC™ (SEMAGLUTIDE) / NOVO NORDISK INC.	Antidiabetics	[1] As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; [2] To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease	3/28/2022	The FDA has approved a 2mg dose of Ozempic™ for type 2 diabetes mellitus, which demonstrated a statistically significant and superior reduction in blood sugar of 2.1% compared to Ozempic™ 1mg. Orphan: N/A
TLANDO™ (TESTOSTERONE UNDECANOATE) CAPSULES / ANTARES PHARMA, INC.	Androgens- anabolic	For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone	3/29/2022	Tlando™ is an oral testosterone replacement therapy that is administered as a fixed dose and does not have a titration requirement. Orphan: N/A Controlled substance schedule: III
TRIUMEQ PD™ (ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE) TABLETS FOR ORAL SUSPENSION / VIIV HEALTHCARE	Antivirals	Treatment of HIV-1 infection in adults and in pediatric patients weighing at least 10kg	3/30/2022	Triumeq PD™ is the first dispersible single tablet regimen and this new formulation allows for the use of this agent in pediatric patients weighing from 10kg to 25kg. Orphan: N/A

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
METHYLPHENIDATE EXTENDED RELEASE TRANSDERMAL FILM 10MG, 15MG, 20MG AND 30MG / MYLAN PHARMACEUTICALS INC.	ADHD/anti-narcolepsy/anti-obesity/anorexiants	Treatment of ADHD	Daytrana™	3/14/2022
BUDESONIDE AND FORMOTEROL FUMARATE DIHYDRATE METERED INHALATION AEROSOL 0.08MG/0.0045MG PER INHALATION AND 0.16MG/0.0045MG PER INHALATION / MYLAN PHARMACEUTICALS INC.	Antiasthmatic and bronchodilator agents	Treatment of asthma and chronic obstructive pulmonary disease (CODP)	Symbicort™	3/15/2022
LACOSAMIDE TABLETS 50MG, 100MG, 150MG AND 200MG / SUN PHARMACEUTICAL INDUSTRIES, INC.	Anticonvulsants	Treatment of seizures	Vimpat™	3/17/2022
IOFLUPANE I-123 INJECTION FOR INTRAVENOUS USE 185 MBQ (5MCI) IN 2.5ML / CURIUM US LLC	Diagnostic products	For striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS)	DaTscan™	3/30/2022

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
OPDIVO™ (NIVOLUMAB) INJECTION / BRISTOL MYERS SQUIBB	Antineoplastics and adjunctive therapies	Treatment of melanoma, non-small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer gastroesophageal junction cancer, and esophageal adenocarcinoma	Adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy	3/4/2022
LYNPARZA™ (OLAPARIB) TABLETS / ASTRAZENECA	Antineoplastics and adjunctive therapies	Treatment of ovarian cancer, breast cancer, pancreatic cancer and prostate cancer	For the adjuvant treatment of adult patients with deleterious or suspected deleterious g*BRCA*m human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza™.	3/11/2022
RINVOQ™ (UPADACITINIB) EXTENDED-RELEASE TABLETS / ABBVIE	Analgesics – Anti-inflammatory	Treatment of rheumatoid arthritis, psoriatic arthritis and atopic dermatitis	Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers	3/16/2022

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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	Antineoplastics and adjunctive therapies	Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high or mismatch repair deficient cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer	As a single agent, for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation	3/21/2022
FINTEPLA™ (FENFLURAMINE) ORAL SOLUTION / ZOGENIX INC	Anticonvulsants	Treatment of seizures associated with Dravet syndrome in patients 2 years of age and older	Treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older	3/25/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
CABENUVA™ (CABOTEGRAVIR EXTENDED-RELEASE INJECTABLE SUSPESION; RILPIVIRINE EXTENDED-RELEASE INJECTABLE SUSPESION) CO-PACKAGE FOR INTRAMUSCULAR USE / VIIV HEALTHCARE	Antivirals	As a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA<50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine	As a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA<50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine	3/29/2022

PIPELINE

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
FEXAPOTIDE TRIFLUTATE / NYMOX PHARMACEUTICAL CORP.	3/3/2022	Treatment of men with benign prostatic hyperplasia (BPH)	This drug is delivered through an injection directly into the prostate. It acts by shrinking the enlarged prostate tissue without damaging neighboring tissues and nerves. With only one injection, it leads to a natural cell death within the enlarged prostate, which is believed to reduce the prostatic volume and therefore eliminate symptoms. NDA submitted.	Moderate
VONOPRAZAN / PHANTOM PHARMACEUTICALS, INC.	3/14/2022	Treatment for adults for the healing of all grades of erosive esophagitis (EE) and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn	Vonoprazan is an investigational, oral small molecule potassium-competitive acid blocker (P-CAB). P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to have rapid, potent, and durable anti-secretory effects as a single agent in the treatment of gastroesophageal reflux disease (GERD) and in combination with antibiotics for the treatment of Helicobacter pylori (H. pylori) infection. NDA submitted.	High
SPARSENTAN / TRAVERE THERAPEUTICS, INC.	3/21/2022	Treatment of IgA nephropathy (IgAN)	The NDA submission is supported by positive interim results from the ongoing pivotal Phase 3 PROTECT Study, a global, randomized, active-controlled study evaluating the safety and efficacy of sparsentan in a total of 404 patients with IgAN, as well as data from additional clinical trials and pre-clinical testing of sparsentan. The Company expects to receive notice regarding the acceptance of the NDA, as well as the timeline for NDA review, from the FDA in May 2022. NDA submitted.	Moderate

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
PEDMARK™ (SODIUM THIOSULFATE) / FENNEC PHARMACEUTICALS INC.	3/24/2022	For the prevention of platinum-induced toxicity in pediatric patients one month to less than 18 years of age with localized, non-metastatic, solid tumors	Platinum-based therapies may cause ototoxicity which is permanent, irreversible and particularly harmful. If approved, Pedmark™ will be the first preventive agent to reduce the risk of ototoxicity in pediatric patients. NDA resubmitted.	High
DEFENCATH™ (TAUROLIDINE/CITRATE/HEPARIN) / CORMEDIX INC.	3/28/2022	For the reduction of catheter-related bloodstream infections in patients with renal failure who are receiving chronic hemodialysis via a central venous catheter	DefenCath™ is being developed as a catheter lock solution. The active ingredient taurolidine is an antimicrobial agent has been shown to be effective in the prevention of catheter-related bloodstream infections. NDA accepted.	Moderate
OMAVELOXOLONE / REATA PHARMACEUTICALS, INC.	3/31/2022	Treatment of patients with Friedreich's ataxia	The FDA has granted Fast Track Designation and Orphan Drug Designation to omaveloxolone for the treatment of Friedreich's ataxia. NDA submitted.	High high

REFERENCES

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