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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
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TABLE OF CONTENTS

*New Molecular Entity and New Combination

NEWS

DRUG ISSUE	DATE	DETAILS
Due to risk of serious liver injury, FDA restricts use of Ocaliva (obeticholic acid) in primary biliary cholangitis (PBC) patients with advanced cirrhosis	05/26/2021	The FDA is restricting the use of the liver disease medicine Ocaliva in patients having primary biliary cholangitis (PBC) with advanced cirrhosis of the liver because it can cause serious harm. Ocaliva has been found to cause liver failure in some PBC patients with advanced cirrhosis, in some cases resulting in liver transplant. Additional information can be fount at FDA's Drug Safety and Availability portal.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
EMPAVELI (PEGCETACOPLAN) INJECTION	APELLIS PHARMACEUTICALS, INC.	05/14/2021

THERAPEUTIC CLASS
Hematological agent

FDA-APPROVE INDICATION(S)
EMPAVELI is a complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

DOSAGE AND ADMINISTRATION
The recommended dose is 1,080 mg by subcutaneous infusion twice weekly via a commercially available pump. EMPAVELI is intended for use under the guidance of a healthcare professional. After proper training, a patient may self-administer or the patient's caregiver may administer, if a healthcare provider determines that it is appropriate.

Vaccination according to current ACIP guidelines and prophylaxis is recommended prior to initiation of EMPAVELI therapy. Dose adjustment is recommended .

DOSAGE FORMS AND STRENGTHS
Injection: 1,080 mg/20 mL (54 mg/mL) in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Patients with hypersensitivity to pegcetacoplan or any of the
- excipients.
- Patients who are not currently vaccinated against certain encapsulated bacteria unless the risks of delaying EMPAVELI treatment outweigh the risks of developing a serious bacterial infection with an encapsulated organism.
- Patients with unresolved serious infection caused by encapsulated bacteria.

WARNINGS AND PRECAUTIONS
- Boxed warning: Serious infections caused by encapsulated bacteria
- EMPAVELI REMS: Because of the risk of serious infections, EMPAVELI is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)
- Infusion-related reactions
- Monitoring PNH manifestations after discontinuation of EMPAVELI
- Interference with laboratory tests

ADVERSE REACTIONS
Most common adverse reactions: injection-site reactions, infections, diarrhea, abdominal pain, respiratory tract infection, viral infection, and fatigue.

USE IN SPECIFIC POPULATIONS
- Pregnancy: May cause embryo-fetal harm. Pregnancy testing is recommended for females of reproductive potential prior to treatment .
- Females of reproductive potential: Advise female patients of reproductive potential to use effective contraception during treatment with EMPAVELI and for 40 days after the last dose.
- Lactation: Breastfeeding should be discontinued during treatment and for 40 days after the last dose.
- Pediatric use: Safety and efficacy have not been established.
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged ≥65 years to determine whether they respond differently from younger patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
RYBREVANT (AMIVANTAMAB-VMJW) INJECTION	JANSSEN PHARMACEUTICALS, INC.	05/21/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
RYBREVANT is a bispecific EGF receptor-directed and MET receptor-directed antibody indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION
The recommended dose is s based on baseline body weight and it is administered as an intravenous infusion after dilution.

Premedication is recommended

DOSAGE FORMS AND STRENGTHS
Injection: 350 mg/7 mL (50 mg/mL) solution in a single-dose vial.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Infusion-related reactions (IRR)
- Interstitial lung disease (ILD)/pneumonitis
- Dermatologic adverse reactions
- Ocular toxicity
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: rash, IRR, paronychia, musculoskeletal pain, dyspnea, nausea, fatigue, edema, stomatitis, cough, constipation, vomiting, and laboratory abnormalities (decreased lymphocytes, decreased albumin, decreased phosphate, decreased potassium, increased alkaline phosphatase, increased glucose, increased gamma-glutamyl transferase, and decreased sodium).

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify pregnancy status of females of reproductive potential prior to initiating.
- Females of reproductive potential: Advise females of reproductive potential to use effective contraception during treatment and for 3 months after the final dose.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and efficacy have not been established.
- Geriatric use: No clinically important differences in safety or efficacy were observed between patients who were ≥65 years of age and younger patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PYLARIFY (PIFLUFOLASTAT F 18) INJECTION	PROGENICS PHARMACEUTICALS, INC.	05/26/2021

THERAPEUTIC CLASS
Diagnostic agent

FDA-APPROVE INDICATION(S)
PYLARIFY is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (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.

DOSAGE AND ADMINISTRATION
The recommended dose is 333 MBq (9 mCi) with an acceptable range of 296 MBq to 370 MBq (8 mCi to 10 mCi), administered as a bolus intravenous injection.

DOSAGE FORMS AND STRENGTHS
333 MBq (9 mCi) with an acceptable range of 296 MBq to 370 MBq (8 mCi to 10 mCi), administered as a bolus intravenous injection.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS

- Risk of image misinterpretation
- Hypersensitivity reactions
- Radiation risk

ADVERSE REACTIONS
Most common adverse reactions: headache, dysgeusia, and fatigue.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Not indicated for use in females.
- Lactation: Not indicated for use in females.
- Pediatric use: Safety and efficacy have not been established.
- Geriatric use: The efficacy and safety of PYLARIFY appear similar in adult and geriatric patients with prostate cancer, although the number of patients in the trials was not large enough to allow definitive comparison.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
CAMCEVI (LEUPROLIDE MESYLATE) INJECTION	FORESEE PHARMACEUTICALS	05/26/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
CAMCEVI is a ready-to-use, 6-month depot formulation of the approved gonadotropin releasing hormone (GnRH) agonist leuprolide indicated for the treatment of adult patients with advanced prostate cancer.

DOSAGE AND ADMINISTRATION
The recommended dose is 42 mg subcutaneously every 6 months. Must be administered by a healthcare provider.

DOSAGE FORMS AND STRENGTHS
Injectable emulsion: 42 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Hypersensitivity to GnRH, GnRH agonist analogs, or any of the components of CAMCEVI.

WARNINGS AND PRECAUTIONS
- Tumor flare
- Hyperglycemia and diabetes
- Cardiovascular diseases
- QT/QTc prolongation
- Convulsions
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: hot flush, hypertension, injection site reactions, upper respiratory tract infections, musculoskeletal pain, fatigue, and pain in extremity.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm.
- Males of reproductive potential: May impair fertility in males.
- Pediatric use: Safety and efficacy have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between patients aged ≥65 years and younger patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LYBALVI (OLANZAPINE AND SAMIDORPHAN) TABLETS*	ALKERMES, INC.	05/28/2021

THERAPEUTIC CLASS
Central nervous system agent; Antipsychotic

FDA-APPROVE INDICATION(S)
LYBALVI is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of:

- Schizophrenia in adults
- Bipolar I disorder in adults
  - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance monotherapy treatment

DOSAGE AND ADMINISTRATION
The recommended dose varies depending on patient diagnosis, with a lower initial dose and adjustments depending upon clinical response and tolerability. For bipolar I disorder, the dose also varies depending on whether LYBALVI will be used as monotherapy or combination therapy. Refer to full prescribing information for details.

LYBALVI is to be administered orally once daily.

DOSAGE FORMS AND STRENGTHS
Tablets (olanzapine/samidorphan): 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS

- Patients using opioids.
- Patients undergoing acute opioid withdrawal.
- If LYBALVI is administered with lithium or valproate, refer to the lithium or valproate full prescribing information for the contraindications for those products.

WARNINGS AND PRECAUTIONS

- Increased mortality in elderly patients with dementia-related psychosis
- Cerebrovascular adverse reactions, including stroke in elderly patients with dementia-related psychosis
- Precipitation of severe opioid withdrawal in patients who are physiologically dependent on opioids
- Vulnerability to life-threatening opioid overdose
- Neuroleptic malignant syndrome
- Drug reaction with eosinophilia and systemic symptoms
- Metabolic changes
- Tardive dyskinesia
- Orthostatic hypotension and syncope
- Falls
- Leukopenia, neutropenia, and agranulocytosis
- Dysphagia
- Seizures
- Potential for cognitive and motor impairment
- Body temperature dysregulation
- Anticholinergic (antimuscarinic) effects

WARNINGS AND PRECAUTIONS (continuation)

- Hyperprolactinemia
- Risks associated with combination treatment with lithium or valproate

ADVERSE REACTIONS
Most common adverse reactions:

- Schizophrenia (LYBALVI): weight increased, somnolence, dry mouth, and headache.
- Bipolar I Disorder, Manic or Mixed Episodes (olanzapine): asthenia, dry mouth, constipation, increased appetite, somnolence, dizziness, tremor.
- Bipolar I Disorder, Manic or Mixed Episodes, adjunct to Lithium or Valproate (olanzapine): dry mouth, dyspepsia, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, paresthesia.

DRUG INTERACTIONS

- Strong CYP3A4 Inducers: Not recommended.
- Strong CYP1A2 Inhibitors: Consider dosage reduction of olanzapine component of LYBALVI.
- CYP1A2 Inducer: Consider dosage increase of the olanzapine component of LYBALVI.
- CNS Acting Drugs: May potentiate orthostatic hypotension.

*New Molecular Entity and New Combination

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LYBALVI (OLANZAPINE AND SAMIDORPHAN) TABLETS*	ALKERMES, INC.	05/28/2021

THERAPEUTIC CLASS
Central nervous system agent; Antipsychotic

FDA-APPROVE INDICATION(S)
LYBALVI is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of:

- Schizophrenia in adults
- Bipolar I disorder in adults
  - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance monotherapy treatment

DOSAGE AND ADMINISTRATION
The recommended dose varies depending on patient diagnosis, with a lower initial dose and adjustments depending upon clinical response and tolerability. For bipolar I disorder, the dose also varies depending on whether LYBALVI will be used as monotherapy or combination therapy. Refer to full prescribing information for details.

LYBALVI is to be administered orally once daily.

DOSAGE FORMS AND STRENGTHS
Tablets (olanzapine/samidorphan): 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg.

Orphan status: N/A

SAFETY PROFILE (continuation)

DRUG INTERACTIONS (continuation)

- Anticholinergic Drugs: Can increase risk for severe gastrointestinal adverse reactions.
- Antihypertensive Agents: Monitor blood pressure.
- Levodopa and Dopamine Agonists: Not recommended.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to atypical antipsychotics, including LYBALVI, during pregnancy. Healthcare providers are encouraged to register patients.
- Females of reproductive potential: May lead to a reversible reduction in fertility in females of reproductive potential.
- Pediatric use: Safety and efficacy have not been established.
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged ≥65 years to determine whether they respond differently from younger patients.
- Hepatic impairment: No dose adjustment is needed in patients with hepatic impairment.
- Renal impairment: No dose adjustment is needed in patients with mild, moderate, or severe renal impairment. Use is not recommended in patients with end-stage renal disease.

(continuation)

*New Molecular Entity and New Combination

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TRUSELTIQ (INFIGRATINIB) CAPSULES	BRIDGEBIO PHARMA, INC.	05/28/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
TRUSELTIQ is a kinase inhibitor indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
The recommended dose is : 125 mg orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles.

Dose adjustment is recommended for mild and moderate renal impairment, mild and moderate hepatic impairment, and adverse reactions.

DOSAGE FORMS AND STRENGTHS
Capsules: 25 mg and 100 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Ocular toxicity
- Hyperphosphatemia and soft tissue mineralization
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: nail toxicity, stomatitis, dry eye, fatigue, alopecia, palmar-plantar erythrodysesthesia syndrome, arthralgia, dysgeusia, constipation, abdominal pain, dry mouth, eyelash changes, diarrhea, dry skin, decreased appetite, vision blurred, vomiting, and laboratory abnormalities (increased creatinine, increased phosphate, decreased phosphate, increased alkaline phosphatase, decreased hemoglobin, increased alanine aminotransferase, increased lipase, increased calcium, decreased lymphocytes, decreased sodium, increased triglycerides, increased aspartate aminotransferase, increased urate, decreased platelets, decreased leukocytes, decreased albumin, increased bilirubin and decreased potassium).

DRUG INTERACTIONS
- Strong or Moderate CYP3A Inhibitors: Avoid coadministration.
- Strong or Moderate CYP3A Inducers: Avoid coadministration.

DRUG INTERACTIONS (continuation)
- Gastric Acid Reducing Agents: Avoid coadministration. If coadministration cannot be avoided, stagger administration of TRUSELTIQ from H2 antagonist or locally-acting antacid.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify pregnancy status of females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise females of reproductive potential and males that are partnered with females of reproductive potential to use effective contraception during treatment and for 1 month after the final dose.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and efficacy have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between patients aged ≥65 years and younger patients.
- Hepatic impairment: Reduce the dose for mild or moderate renal impairment. The recommended dose has not been established for severe renal impairment or end-stage renal disease receiving intermittent hemodialysis.
- Renal impairment: Reduce the dose for mild or moderate hepatic impairment. The recommended dose has not been established for severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LUMAKRAS (SOTORASIB) TABLETS	AMGEN INC.	05/28/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
LUMAKRAS is an inhibitor of the RAS GTPase family indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

DOSAGE AND ADMINISTRATION
The recommended dose is 960 mg orally once daily.

DOSAGE FORMS AND STRENGTHS
Tablets: 120 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Hepatotoxicity
- Interstitial Lung Disease (ILD)/Pneumonitis

ADVERSE REACTIONS
Most common adverse reactions: diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, cough, and laboratory abnormalities (decreased lymphocytes, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, decreased calcium, increased alkaline phosphatase, increased urine protein, and decreased sodium).

DRUG INTERACTIONS
- Acid-Reducing Agents: Avoid co-administration with proton pump inhibitors (PPIs) and H2 receptor antagonists. If an acid-reducing agent cannot be avoided, administer LUMAKRAS 4 hours before or 10 hours after a local antacid.
- Strong CYP3A4 Inducers: Avoid co-administration with strong CYP3A4 inducers.
- CYP3A4 Substrates: Avoid coadministration with CYP3A4 substrates for which minimal concentration changes may lead to therapeutic failures of the substrate. If co-administration cannot be avoided, adjust the substrate dosage in accordance to its full prescribing information.

DRUG INTERACTIONS (continuation)
- P-gp substrates: Avoid coadministration with P-gp substrates for which minimal concentration changes may lead to serious toxicities. If co-administration cannot be avoided, decrease the substrate dosage in accordance to its full prescribing information.

USE IN SPECIFIC POPULATIONS
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and efficacy have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between patients aged ≥65 years and younger patients.

NEW BIOSMILAR PRODUCTS

- No new biosimilar product approved during May 2021.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
ZYNRELEF (BUPIVACAINE AND MELOXICAM) INJECTION / HERON THERAPEUTICS, INC.	Analgesic	For soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty	05/12/2021	ZYNRELEF is a new extended-release, fixed-dose combination of the local anesthetic bupivacaine and the non-steroidal anti-inflammatory drug (NSAID) meloxicam. ZYNRELEF comes to be the first and only extended-release dual-acting local anesthetic (DALA). The synergy between bupivacaine and meloxicam in ZYNRELEF has resulted in patients experiencing significantly less pain, including severe pain, and significantly more patients requiring no opioids (opioid-free) after surgery as compared to bupivacaine solution, the current standard-of-care. Orphan status: N/A
MYFEMBREE (RELUGOLIX, ESTRADIOL AND NORETHINDRONE ACETATE) TABLETS / MYOVANT SCIENCES	Endocrine and metabolic agent	For the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	05/26/2021	MYFEMBREE is a new combination of an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, estrogen, and progestin. The use of MYFEMBREE should be limited to 24 months due to the risk of continued bone loss which may not be reversible. Orphan status: N/A
NOXAFIL POWDERMIX (POSACONAZOLE) FOR DELAYED-RELEASE ORAL SUSPENSION / MERCK SHARP DOHME	Anti-infective agent; Antifungal	In pediatric patients 2 years of age and older (who weigh 40 kg or less), for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy	05/31/2021	NOXAFIL POWDERMIX is a line extension of the already available NOXAFIL intravenous solution, oral suspension, and delayed-release oral tablet. NOXAFIL POWDERMIX is a new delayed-release oral suspension. Pozaconazole delayed-release oral tablet is available in generic. Orphan status: N/A

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
ENZALUTAMIDE CAPSULES 40 MG / ACTAVIS PHARMA, INC.	Antineoplastic agent	• Castration-resistant prostate cancer • Castration-sensitive prostate cancer	Xtandi	05/14/2021
LENALIDOMIDE CAPSULES 5 MG, 10 MG, 15 MG AND 25 MG / NATCO PHARMA LTD.	Antineoplastic agent	• Follicular lymphoma, Previously treated, in combination with a rituximab product • Mantle cell lymphoma, Relapse or progression after 2 prior therapies, 1 of which included bortezomib • Marginal zone lymphoma, Previously treated, in combination with a rituximab product • Multiple myeloma, In combination with dexamethasone • Multiple myeloma, Maintenance therapy following autologous hematopoietic stem cell transplantation • Myelodysplastic syndrome, Transfusion-dependent anemia in patients at low or intermediate-1 risk with deletion 5q abnormality	Revlimid	05/21/2021

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
FERRIPROX (DEFERIPRONE) TABLETS AND ORAL SOLUTION / APOPHARMA INC.	Antidote; Iron chelator	Treatment of transfusional iron overload in thalassemia syndromes	Treatment of transfusional iron overload in sickle cell disease or other anemias	05/01/2021
KEYTRUDA (PEMBROLIZUMAB) FOR INJECTION / MERCK	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	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	In combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma	05/05/2021
OPDIVO (NIVOLUMAB) INJECTION / BRISTOL-MYERS SQUIBB COMPANY	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	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, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer, and gastroesophageal junction cancer	For the adjuvant treatment of completely resected esophageal or gastroesophageal junction (GEJ) cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy (CRT)	05/20/2021
ZEPOSIA (OZANIMOD) CAPSULES / BRISTOL-MYERS SQUIBB COMPANY	Sphingosine 1-phosphate receptor modulator	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults	Treatment of adults with moderately to severely active ulcerative colitis (UC), a chronic inflammatory bowel disease (IBD)	05/27/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
NURTEC ODT (RIMEGEPANT) ORALLY DISINTEGRATING TABLETS (ODT) / BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.	Antimigraine; Calcitonin gene-related peptide (CGRP) receptor antagonist	Acute treatment of migraine with or without aura	Preventive treatment of migraine	05/27/2021

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
XIPERE (TRIAMCINOLONE ACETONIDE) INJECTION / CLEARSIDE BIOMEDICAL, INC.	05/03/2021	Treatment for: Macular Edema, Uveitis	Xipere (triamcinolone acetonide) is a proprietary corticosteroid suspension for suprachoroidal injection in development for the treatment of macular edema associated with uveitis. NDA resubmitted.	Moderate
LIQ861 (TREPROSTINIL) INHALATION POWDER / LIQUIDIA TECHNOLOGIES, INC.	05/10/2021	Treatment for: Pulmonary Arterial Hypertension (PAH)	LIQ861 (treprostinil) is an investigational inhaled dry powder formulation of treprostinil in development for the treatment of pulmonary arterial hypertension (PAH). NDA resubmitted.	Moderate
TEZEPELUMAB / AMGEN AND ASTRAZENECA	05/10/2021	Treatment for: Asthma	Tezepelumab is an investigational, potential first-in-class anti-thymic stromal lymphopoietin (TSLP) monoclonal antibody in development for the treatment of severe asthma. BLA submitted.	High
RECORLEV (LEVOKETOCONAZOLE) / STRONGBRIDGE BIOPHARMA PLC	05/13/2021	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. FDA accepted NDA.	Moderate
ZIMHI (NALOXONE HYDROCHLORIDE) INJECTION / ADAMIS PHARMACEUTICALS CORPORATION	05/17/2021	Treatment for: Opioid Overdose	Zimhi (naloxone hydrochloride) is a high-dose formulation of the approved opioid antagonist naloxone in development for the treatment of opioid overdose NDA resubmitted.	Moderate

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
BXCL501 (DEXMEDETOMIDINE) / BIOXCEL THERAPEUTICS, INC.	05/19/2021	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. FDA accepted NDA.	Moderate
UBLITUXIMAB / TG THERAPEUTICS, INC.	05/25/2021	Treatment for: Chronic Lymphocytic Leukemia	Ublituximab (TG-1101) is an investigational glycoengineered anti-CD20 monoclonal antibody in development for the treatment of non-Hodgkin lymphoma (NHL), chronic lymphocytic leukemia (CLL), and relapsing forms of multiple sclerosis (RMS). FDA accepted BLA.	High
PEDMARK (SODIUM THIOSULFATE) / FENNEC PHARMACEUTICALS INC.	05/28/2021	Treatment for: Prevention of Cisplatin-Induced Ototoxicity	Pedmark (sodium thiosulfate) is a cisplatin neutralizing agent in development for the protection against hearing loss in pediatric patients receiving cisplatin chemotherapy. NDA resubmitted. Orphan drug designation granted.,	High 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)