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PharmNOTES

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

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 6/7/2022

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NEWS

- No drug safety alert published by the FDA in May.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VOQUEZNA TRIPLE PAK™ (VONOPRAZAN TABLETS; AMOXICILLIN CAPSULES; CLARITHROMYCIN TABLETS) FOR ORAL USE	PHANTOM PHARMACEUTICALS, INC.	5/3/2022

THERAPEUTIC CLASS
Potassium-competitive acid blocker (PCAB), penicillin class antibacterial and macrolide antibacterial

FDA-APPROVED INDICATION(S)
Treatment of *Helicobacter pylori (H. pylori)* infection in adults

DOSAGE AND ADMINISTRATION
The recommended dosage regimen is vonoprazan 20mg plus amoxicillin 1,000mg plus clarithromycin 500mg each given twice daily (morning and evening, 12 hours apart) with or without food for 14 days.

DOSAGE FORMS AND STRENGTHS
Carton of 14 daily administration packs for morning and evening dosing, each containing the following three drug products:
- Tablets: Vonoprazan 20mg
- Tablets: Clarithromycin 500mg
- Capsules: Amoxicillin 500mg

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to vonoprazan, amoxicillin, or any other beta-lactams, clarithromycin or any other macrolide antimicrobial or any component of Voquezna Triple Pak™.
- Rilpivirine-containing products
- Due to the clarithromycin component:
  - Pimozide
  - Lomitapide, lovastatin, and simvastatin
  - Ergot alkaloids (ergotamine or dihydroergotamine)
  - Colchicine in renal or hepatic impairment
  - History of cholestatic jaundice/hepatic dysfunction with use of clarithromycin

WARNINGS AND PRECAUTIONS
- Hypersensitivity reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of Voquezna Triple Pak™.
- Severe cutaneous adverse reactions (SCAR): Discontinue Voquezna Triple Pak™ at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation.
- Clostridioides difficile-associated diarrhea (CDAD): Evaluate if diarrhea occurs with Voquezna Triple Pak™.

WARNINGS AND PRECAUTIONS (cont.)
- Due to clarithromycin component:
  - QT Prolongation: Avoid Voquezna Triple Pak™ in patients with known QT prolongation or receiving drugs known to prolong the QT interval, ventricular arrhythmia (torsades de pointes), hypokalemia/hypomagnesemia, significant bradycardia, or taking Class IA or III antiarrhythmics.
  - Hepatotoxicity: Discontinue if signs and symptoms of hepatitis occur with Voquezna Triple Pak™.
  - Serious adverse reactions due to concomitant use with other drugs: Serious adverse reactions can occur with Voquezna Triple Pak™ due to drug interactions of clarithromycin with colchicine, some lipid lowering agents, some calcium channel blockers, and other drugs.
  - Embryo-Fetal toxicity: Based on the findings from animal studies and human observational studies in pregnant women treated with clarithromycin, Voquezna Triple Pak™ is not recommended for use in pregnant women except in clinical circumstances where no alternative therapy is appropriate.
  - Myasthenia gravis: Exacerbation of myasthenia gravis can occur with Voquezna Triple Pak™ since it has been reported in patients receiving clarithromycin tablets.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

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Carton of 14 daily administration packs for morning and evening dosing, each containing the following three drug products:
- Tablets: Vonoprazan 20mg
- Tablets: Clarithromycin 500mg
- Capsules: Amoxicillin 500mg

Orphan status: No

SAFETY PROFILE

ADVERSE REACTIONS
- Most common adverse reactions (≥ 2%) were dysgeusia, diarrhea, vulvovaginal candidiasis, headache, abdominal pain, and hypertension.

DRUG INTERACTIONS
- Clarithromycin (a component of Voquezna Triple Pak™) is a strong CYP3A inhibitor. Concomitant use of Voquezna Triple Pak™ with a drug(s) primarily metabolized by CYP3A may cause elevations in CYP3A substrate drug's concentrations that could increase or prolong both therapeutic and adverse effects of the concomitant drug.
- Strong or moderate CYP3A inducers: avoid concomitant use with Voquezna Triple Pak™ as the inducers may decrease vonoprazan exposure.
- Allopurinol: Discontinue allopurinol at the first appearance of skin rash when used concomitantly allopurinol with Voquezna Triple Pak™ as this combination may increase the incidence of rash.
- Atazanavir and nelfinavir: avoid concomitant use with Voquezna Triple Pak™ as vonoprazan may alter the absorption of antiretrovirals drugs.

USE IN SPECIFIC POPULATIONS
- Pregnancy (vonoprazan component): Available data from pharmacovigilance reports with vonoprazan use in pregnant women are not sufficient to evaluate for a drug-associated risk for major birth defects, miscarriage or other adverse maternal or fetal outcomes.
- Lactation (vonoprazan component): Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, a woman should pump and discard human milk for the duration of Voquezna Triple Pak™ therapy, and for 2 days after therapy ends, and feed her infant stored human milk (collected prior to therapy) or formula.
- Males of reproductive potential: Based on animal fertility study findings for clarithromycin, Voquezna Triple Pak™ may impair fertility in males of reproductive potential
- Pediatric use: Safety and effectiveness of Voquezna Triple Pak™ in pediatric patients have not been established.
- Geriatric use (vonoprazan component): No overall differences in safety or effectiveness were observed between these patients and younger adult patients.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

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FDA-APPROVED INDICATION(S)
Treatment of *Helicobacter pylori (H. pylori)* infection in adults

DOSAGE AND ADMINISTRATION
The recommended dosage regimen is vonoprazan 20mg plus amoxicillin 1,000mg plus clarithromycin 500mg each given twice daily (morning and evening, 12 hours apart) with or without food for 14 days.

DOSAGE FORMS AND STRENGTHS
Carton of 14 daily administration packs for morning and evening dosing, each containing the following three drug products:
- Tablets: Vonoprazan 20mg
- Tablets: Clarithromycin 500mg
- Capsules: Amoxicillin 500mg

Orphan status: No

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS (cont.)
- Renal impairment: No dosage adjustment of Voquezna Triple Pak™ is recommended in patients with mild to moderate renal impairment. Avoid the use of Voquezna Triple Pak™ in patients with severe renal impairment.
- Hepatic impairment: No dosage adjustment of Voquezna Triple Pak™ is recommended in patients with mild hepatic impairment. Avoid the use of Voquezna Triple Pak™ in patients with moderate to severe hepatic impairment.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VOQUEZNA DUAL PAK™ (VONOPRAZAN TABLETS; AMOXICILLIN CAPSULES) FOR ORAL USE	PHANTOM PHARMACEUTICALS, INC.	5/3/2022

THERAPEUTIC CLASS
Potassium-competitive acid blocker (PCAB) and penicillin class antibacterial

FDA-APPROVED INDICATION(S)
Treatment of *Helicobacter pylori (H. pylori)* infection in adults

DOSAGE AND ADMINISTRATION
The recommended dosage regimen is vonoprazan 20mg twice daily (morning and evening, 12 hours apart) plus amoxicillin 1,000mg three times a day (morning, mid-day, and evening), with or without food for 14 days.

DOSAGE FORMS AND STRENGTHS
Carton of 14 daily administration packs for morning, mid-day and evening dosing, each containing the following two drug products:
- Tablets: Vonoprazan 20mg
- Capsules: Amoxicillin 500mg

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to vonoprazan, amoxicillin, or any other beta-lactams or any component of Voquezna Dual Pak™.
- Rilpivirine-containing products

WARNINGS AND PRECAUTIONS
- Hypersensitivity reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of Voquezna Dual Pak™.
- Severe Cutaneous Adverse Reactions (SCAR): Discontinue Voquezna Dual Pak™ at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation.
- Clostridioides difficile-associated diarrhea (CDAD): Evaluate if diarrhea occurs with Voquezna Dual Pak™.

ADVERSE REACTIONS
- Most common adverse reactions (≥ 2%) were diarrhea, abdominal pain, vulvovaginal candidiasis and nasopharyngitis.

DRUG INTERACTIONS
- Strong or moderate CYP3A inducers: avoid concomitant use with Voquezna Dual Pak™ as the inducers may decrease vonoprazan exposure.
- Allopurinol: Discontinue allopurinol at the first appearance of skin rash when used concomitantly allopurinol with Voquezna Dual Pak™ as this combination may increase the incidence of rash.
- Atazanavir and nelfinavir: avoid concomitant use with Voquezna Dual Pak™ as vonoprazan may alter the absorption of antiretrovirals drugs.

USE IN SPECIFIC POPULATIONS
- Pregnancy (vonoprazan component): Available data from pharmacovigilance reports with vonoprazan use in pregnant women are not sufficient to evaluate for a drug-associated risk for major birth defects, miscarriage or other adverse maternal or fetal outcomes.
- Lactation (vonoprazan component): Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, a woman should pump and discard human milk for the duration of Voquezna Dual Pak™ therapy, and for 2 days after therapy ends, and feed her infant stored human milk (collected prior to therapy) or formula.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VOQUEZNA DUAL PAK™ (VONOPRAZAN TABLETS; AMOXICILLIN CAPSULES) FOR ORAL USE	PHANTOM PHARMACEUTICALS, INC.	5/3/2022

THERAPEUTIC CLASS
Potassium-competitive acid blocker (PCAB) and penicillin class antibacterial

FDA-APPROVED INDICATION(S)
Treatment of *Helicobacter pylori (H. pylori)* infection in adults

DOSAGE AND ADMINISTRATION
The recommended dosage regimen is vonoprazan 20mg twice daily (morning and evening, 12 hours apart) plus amoxicillin 1,000mg three times a day (morning, mid-day, and evening), with or without food for 14 days.

DOSAGE FORMS AND STRENGTHS
Carton of 14 daily administration packs for morning, mid-day and evening dosing, each containing the following two drug products:
- Tablets: Vonoprazan 20mg
- Capsules: Amoxicillin 500mg

Orphan status: No

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS (cont.)
- Pediatric use: Safety and effectiveness of Voquezna Dual Pak™ in pediatric patients have not been established.
- Geriatric use (vonoprazan component): No overall differences in safety or effectiveness were observed between these patients and younger adult patients.
- Renal impairment: No dosage adjustment of Voquezna Dual Pak™ is recommended in patients with mild to moderate renal impairment. Avoid the use of Voquezna Dual Pak™ in patients with severe renal impairment.
- Hepatic impairment: No dosage adjustment of Voquezna Dual Pak™ is recommended in patients with mild hepatic impairment. Avoid the use of Voquezna Dual Pak™ in patients with moderate to severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
MOUNJARO™ (TIRZEPATIDE) INJECTION	ELI LILLY AND CO.	5/13/2022

THERAPEUTIC CLASS
Antidiabetics

FDA-APPROVED INDICATION(S)
As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

DOSAGE AND ADMINISTRATION
The recommended dosage starting dosage is 2.5mg injected subcutaneously once weekly. After 4 weeks, increase to 5mg injected subcutaneously once weekly. If additional glycemic control is needed, increase the dosage in 2.5mg increments after at last 4 weeks on the current dose. The maximum dosage is 15mg subcutaneously once weekly.

DOSAGE FORMS AND STRENGTHS
Injection: 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg or 15mg per 0.5mL in single-dose pen

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2.
- Known serious hypersensitivity to tirzepatide or any of the excipients in Mounjaro™.

WARNINGS AND PRECAUTIONS
- Pancreatitis: Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected.
- Hypoglycemia with concomitant use of insulin secretagogues or insulin: Concomitant use with an insulin secretagogue or insulin may increase the risk of hypoglycemia, including severe hypoglycemia. Reducing dose of insulin secretagogue or insulin may be necessary.
- Hypersensitivity reactions: Hypersensitivity reactions have been reported. Discontinue Mounjaro™ if suspected.
- Acute kidney injury: Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions.
- Severe gastrointestinal disease: Use may be associated with gastrointestinal adverse reactions, sometimes severe. Has not been studied in patients with severe gastrointestinal disease and is not recommended in these patients.

WARNINGS AND PRECAUTIONS (cont.)
- Diabetic retinopathy complications in patients with a history of diabetic retinopathy: Has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Monitor patients with a history of diabetic retinopathy for progression
- Acute gallbladder disease: Has occurred in clinical trials. If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated.

ADVERSE REACTIONS
- The most common adverse reactions, reported in ≥5% of patients treated with Mounjaro™ are: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain.

DRUG INTERACTIONS
- Mounjaro™ delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Mounjaro™.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
MOUNJARO™ (TIRZEPATIDE) INJECTION	ELI LILLY AND CO.	5/13/2022

THERAPEUTIC CLASS
Antidiabetics

FDA-APPROVED INDICATION(S)
As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

DOSAGE AND ADMINISTRATION
The recommended dosage starting dosage is 2.5mg injected subcutaneously once weekly. After 4 weeks, increase to 5mg injected subcutaneously once weekly. If additional glycemic control is needed, increase the dosage in 2.5mg increments after at last 4 weeks on the current dose. The maximum dosage is 15mg subcutaneously once weekly.

DOSAGE FORMS AND STRENGTHS
Injection: 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg or 15mg per 0.5mL in single-dose pen

Orphan status: No

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide during pregnancy. Mounjaro™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Lactation: There are no data on the presence of tirzepatide in animal or human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Mounjaro™ and any potential adverse effects on the breastfed infant from Mounjaro™ or from the underlying maternal condition.
- Females and males of reproductive potential: Use of Mounjaro™ may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with Mounjaro™.
- Pediatric use: Safety and effectiveness of Mounjaro™ have not been established in pediatric patients (younger than 18 years of age).

USE IN SPECIFIC POPULATIONS (cont.)

- Geriatric use: No overall differences in safety or efficacy were detected between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
- Renal impairment: No dosage adjustment of Mounjaro™ is recommended for patients with renal impairment.
- Hepatic impairment: No dosage adjustment of Mounjaro™ is recommended for patients with hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VTAMA™ (TAPINAROF) CREAM	DERMAVANT SCIENCES INC.	5/23/2022

THERAPEUTIC CLASS
Dermatologicals

FDA-APPROVED INDICATION(S)
Treatment of plaque psoriasis in adults

DOSAGE AND ADMINISTRATION
Apply a thin layer of cream topically to affected areas once daily.

DOSAGE FORMS AND STRENGTHS
Cream: 1%, each gram of Vtama™ cream contains 10mg of tapinarof.

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- None.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥ 1%) in subjects treated with Vtama™ cream were folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza.

DRUG INTERACTIONS
- None.

USE IN SPECIFIC POPULATIONS
- Pregnancy: The available data on Vtama™ cream use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.
- Lactation: No data are available regarding the presence of tapinarof in human milk or the effects of tapinarof on the breastfed infant, or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Vtama™ cream and any potential adverse effects on the breastfed infant from Vtama™ cream or from the underlying maternal condition.

USE IN SPECIFIC POPULATIONS (cont.)
- Pediatric use: Safety and efficacy of Vtama™ cream have not been established in pediatric subjects with psoriasis under 18 years of age.
- Geriatric use: No overall differences in efficacy, safety, or tolerability were observed between elderly subjects and younger adult subjects in clinical trials.

NEW BIOSMILAR PRODUCTS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
FYLNETRA™ (PEGFILGRASTIM-PBBK) INJECTION / KASHIV BIOSCIENCES LLC. AND AMNEAL PHARMACEUTICALS, INC.	Hematopoietic agents	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	5/26/2022	Reference product: Neulasta™ Fylnetra™ marks the fifth biosimilar of Neulasta™ and the third biosimilar from Amneal to receive FDA approval. Orphan: No.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
RADICAVA ORS™ (EDAVARONE) ORAL SUSPENSION / MITSUBISHI TANABE PHARMA CORPORATION	Neuromuscular agents	Treatment of amyotrophic lateral sclerosis (ALS)	5/12/2022	Radicava ORS™ offers a flexible administration option (taken orally or via feeding tube) for patients with ALS. It has demonstrated to have the same efficacy as the intravenous formulation (Radicava™). Orphan: Yes
TPOXX™ (TECOVIRIMAT) INJECTION / SIGA TECHNOLOGIES, INC.	Antivirals	Treatment of human smallpox disease caused by variola virus in adults and pediatric patients weighing at least 3kg	5/18/2022	This new formulation of TPOXX™ provides an alternative for those patients unable to swallow the oral capsules of TPOXX™. The FDA approval of TPOXX™ is based on results from adequate and well-controlled animal efficacy studies of nonhuman primates and rabbits infected with nonvariola orthopoxviruses. Orphan: Yes
TYVASO DPI™ (TREPROSTINIL) INHLATION POWDER / UNITED THERAPEUTICS CORP.	Cardiovascular agents – Prostaglandin vasodilators	Treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability; treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability	5/23/2022	Tyvaso DPI™ is a new formulation and inhalation device for inhaled treprostinil and is the only dry powder inhaler approved by the FDA for use in PAH and PH-ILD. Orphan: Yes

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
ESTRADIOL AND PROGESTERONE CAPSULES 1MG-100MG / AMNEAL PHARMACEUTICALS LLC.	Estrogens	Vasomotor symptoms due to menopause	Bijuva™	5/16/2022
IODIXANOL INJECTION 55% AND 65.2% / JIANGSU HENGRUI PHARMACEUTICALS CO., LTD.	Diagnostic products	Radiographic procedures	Visipaque™ 270™ and Visipaque™ 320	5/19/2022
LACOSAMIDE ORAL SOLUTION 10MG/ML / ALKEM LABORATORIES LTD.	Anticonvulsants	Seizures	Vimpat™	5/19/2022
PEMETREXED DISODIUM INJECTION 100MG/VIAL AND 500MG/VIAL / ACCORD HEALTHCARE, INC.; APOTEX CORP.; DR. REDDYS LABORATORIES INC.; EUGIA PHARMA SPECIALITIES LIMITED; FRESENIUS KABI USA LLC; HOSPIRA, INC.; JIANGSU HANSOH PHARMACEUTICAL GROUP CO., LTD.; NANG KUANG PHARMACEUTICAL CO., LTD.; QILU PHARMACEUTICAL CO., LTD.; WAVERLEY PHARMA INC.; ZYDUS PHARMACEUTICALS (USA) INC.	Antineoplastics and adjunctive therapies	Non-small cell lung cancer	Alimta™	5/25/2022

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
ENHERTU™ (FAM-TRASTUZUMAB DERUXTECAN-NXKI) FOR INJECTION / DAICCHI SANKYO, INC. AND ASTRAZENECA	Antineoplastics and adjunctive therapies	Treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen	Treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either: • In the metastatic setting, or • In the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy	5/4/2022
OLUMIANT™ (BARICITINIB) TABLETS / ELI LILLY AND CO.	Analgesics – anti-inflammatory	Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers	Treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO	5/10/2022
DUPIXENT™ (DUPILUMAB) INJECTION / REGENERON PHARMACEUTICALS	Dermatologicals	Treatment of atopic dermatitis, asthma and chronic rhinosinusitis with nasal polypsis	Treatment of adult and pediatric patients aged 12 years and older, weighing at least 40kg, with eosinophilic esophagitis (EoE)	5/20/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
TIBSOVO™ (IVOSIDENIB) TABLETS / SERVIER PHARMACEUTICALS LLC.	Antineoplastics and adjunctive therapies	Treatment of relapsed or refractory acute myeloid leukemia (AML), newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy, and locally advanced or metastatic cholangiocarcinoma in patients with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test	In combination with azacitidine for the treatment of newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy	5/25/2022
BEOVU™ (BROLUCIZUMAB-DBLL) INJECTION / NOVARTIS PHARMACEUTICALS CORP.	Ophthalmic agents	Treatment of neovascular age-related macular degeneration	Treatment of diabetic macular edema	5/27/2022
EVRYSDI™ (RISDIPLAM) FOR ORAL SOLUTION / GENENTECH, INC.	Neuromuscular agents	Treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older	Treatment of spinal muscular atrophy (SMA) in pediatric and adult patients	5/27/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
KYMRIAH™ (TISAGENLECLEUCEL) SUSPENSION / NOVARTIS PHARMACEUTICALS CORP.	Antineoplastics and adjunctive therapies	Treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse, adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy	Treatment of adult patients with r/r follicular lymphoma (FL) after two or more lines of systemic therapy	5/27/2022
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 carcinoma	Treatment of patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy; treatment of patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with ipilimumab	5/27/2022

PIPELINE

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
ZURANOLONE / SAGE THERAPEUTICS, INC. AND BIOGEN, INC.	5/2/2022	Treatment of major depressive disorder (MDD) and postpartum depression (PPD)	Zuranolone is an investigational two-week, once-daily oral neuroactive steroid (NAS) GABA-A receptor positive allosteric modulator. It has been granted Fast Track and Breakthrough Therapy Designation for MDD and Fast Track Designation for PPD by the U.S. FDA. NDA submitted.	Moderate
LECANEMAB / EISAI CO., LTD. AND BIOGEN, INC.	5/9/2022	Treatment of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD with confirmed presence of amyloid pathology in the brain	Lecanemab is an investigational anti-amyloid beta (Aβ) protofibril antibody. Lecanemab was granted Breakthrough Therapy and Fast Track designations by the FDA in June and December 2021, respectively. BLA submitted.	Moderate
FUROSCIX™ (FUROSEMIDE) / SCPHARMACEUTICALS, INC.	5/16/2022	Treatment of congestion due to fluid overload in adult patients with New York Heart Association (NYHA) Class II and III chronic heart failure who display reduced responsiveness to oral diuretics and who do not require hospitalization	In April 2022 scPharmaceuticals, Inc. had resubmitted the NDA and it has now been accepted for filing by the FDA. Furoscix™ has the potential of providing a new treatment option and generate significant healthcare system cost savings. NDA accepted.	Moderate
SPARSENTAN / TRAVERE THERAPEUTICS, INC.	5/16/2022	Treatment of IgA nephropathy	Sparsentan, a dual endothelin angiotensin receptor antagonist (DEARA), is a novel investigational product candidate selectively targeting the endothelin A receptor (ETAR) and the angiotensin II subtype 1 receptor (AT1R). The FDA granted Priority Review of its NDA for accelerated approval. NDA accepted.	Moderate

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