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PharmNOTES

Summary of New FDA-Approved Products,
New Indications, First-Time Generics,
and WHAT'S IN THE PIPELINE
For: **OCTOBER 2021**

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

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NEWS

- No drug safety communication, excluding recalls, published during the month of October.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TAVNEOS™ (AVACOPAN) CAPSULES	CHEMOCENTRYX	10/07/2021

THERAPEUTIC CLASS
Hematological agent

FDA-APPROVED INDICATION(S)
Tavneos™ is a complement 5a receptor (C5aR) antagonist indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids.

DOSAGE AND ADMINISTRATION
The recommended dosage is 30mg (three 10mg capsules) twice daily, with food.

DOSAGE FORMS AND STRENGTHS
Capsules: 10mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Serious hypersensitivity to avacopan or to any of the excipients

WARNINGS AND PRECAUTIONS
- Hepatotoxicity: Increase in liver function tests occurred in clinical trials. Obtain liver function tests before initiation of therapy and monitor as clinically indicated.
- Serious Hypersensitivity Reactions: Cases of angioedema occurred in a clinical trial. Observe for signs and symptoms of angioedema and manage accordingly.
- Hepatitis B Virus (HBV) Reactivation: Cases of HBV reactivation occurred in a clinical trial. Withhold Tavneos™ and institute appropriate anti-infective therapy.
- Serious Infections: Avoid use of Tavneos™ in patients with active, serious infection, including localized infections.

ADVERSE REACTIONS
- The most common adverse reactions (≥5%) are nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.

DRUG INTERACTIONS
- Strong and moderate CYP3A4 enzyme inducers: Avoid use.
- Strong CYP3A4 enzyme inhibitors: Reduce avacopan dose to 30 mg once daily.
- Sensitive CYP3A4 substrates: Monitor for adverse reactions and consider dose reduction of sensitive CYP3A4 substrates with narrow therapeutic window.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There are no adequate and well-controlled studies with Tavneos™ in pregnant women to inform a drug-associated risk.
- Lactation: There are no available data on the effects of avacopan on the breastfed child or on milk production. It is unknown whether avacopan is secreted in human milk.
- Pediatric Use: The safety and effectiveness of Tavneos™ in pediatric patients have not been established.
- Geriatric Use: No overall differences in safety or effectiveness were observed between geriatric patients and younger patients.

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DOSAGE FORMS AND STRENGTHS
Capsules: 10mg

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USE IN SPECIFIC POPULATIONS

- Renal Impairment: No dosage adjustment is required for patients with mild, moderate, or severe renal impairment.
- Hepatic Impairment: No dosage adjustment is recommended for patients with mild or moderate (as indicated by the Child-Pugh method) hepatic. Tavneos™ has not been studied in patients with severe hepatic impairment (Child-Pugh Class C).

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
SCEMBLIX™ (ASCIMINIB) TABLET	NOVARTIS PHARMS CORP	10/29/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVED INDICATION(S)
Scemblix™ is a kinase inhibitor indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). It is also indicated for Ph+ CML in CP with the T315I mutation.

DOSAGE AND ADMINISTRATION
Recommended dosage in Ph+ CML in CP: 80mg orally once daily or 40mg twice daily

Recommended dosage in Ph+ CML with the T315I mutation: 200mg orally twice daily

DOSAGE FORMS AND STRENGTHS
Film-coated tablets: 20mg and 40mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Myelosuppression: Severe thrombocytopenia and neutropenia events may occur. Monitor complete blood counts regularly during therapy and manage by treatment interruption or dose reduction.
- Pancreatic Toxicity: Monitor serum lipase and amylase. Interrupt, then resume at reduced dose or discontinue Scemblix™ based on severity. Evaluate for pancreatitis when lipase elevation is accompanied by abdominal symptoms.
- Hypertension: Monitor blood pressure and manage hypertension as clinically indicated. Interrupt, dose reduce, or stop Scemblix™ if hypertension is not medically controlled.
- Hypersensitivity: May cause hypersensitivity reactions. Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated.
- Cardiovascular Toxicity: Cardiovascular toxicity may occur. Monitor patients with history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS
- Most common adverse reactions (≥ 20%) are upper respiratory tract infections, musculoskeletal pain, fatigue, nausea, rash, and diarrhea. Most common laboratory abnormalities (≥ 20%) are platelet count decreased, triglycerides increased, neutrophil count decreased, hemoglobin decreased, creatine kinase increased, alanine aminotransferase increased, lipase increased, and amylase increased.

DRUG INTERACTIONS
- Strong CYP3A4 Inhibitors: Closely monitor for adverse reactions during concomitant use of Scemblix™ at 200 mg twice daily.
- Itraconazole Oral Solution Containing Hydroxypropyl-β-cyclodextrin: Avoid concomitant use of Scemblix™ at all recommended doses.
- Certain Substrates of CYP3A4: Closely monitor for adverse reactions during concomitant use of Scemblix™ at 80 mg total daily dose. Avoid use of Scemblix™ at 200 mg twice daily.

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DOSAGE AND ADMINISTRATION
Recommended dosage in Ph+ CML in CP: 80mg orally once daily or 40mg twice daily

Recommended dosage in Ph+ CML with the T315I mutation: 200mg orally twice daily

DOSAGE FORMS AND STRENGTHS
Film-coated tablets: 20mg and 40mg

Orphan status: Orphan

SAFETY PROFILE

DRUG INTERACTIONS (continuation)
- Substrates of CYP2C9: Avoid concomitant use of Scemblix™ at all recommended doses.
  - 80 mg total daily dose: If unavoidable, reduce the CYP2C9 substrate dosage as necessary.
  - 200 mg twice daily: If unavoidable, consider alternative therapy with non-CYP2C9 substrate.
- Certain P-gp Substrates: Closely monitor for adverse reactions during concomitant use of Scemblix™ at all recommended doses.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on findings from animal studies and the mechanism of action, Scemblix™ can cause embryo-fetal harm when administered to a pregnant woman.
- Lactation: Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with Scemblix™ and for 1 week after the last dose.
- Females and males of reproductive potential: Verify the pregnancy status of females of reproductive potential prior to starting treatment with Scemblix™. Females of reproductive potential should use effective contraception during treatment with Scemblix™ and for 1 week after the last dose.

USE IN SPECIFIC POPULATIONS (continuation)
- Pediatric Use: The safety and efficacy of Scemblix™ in pediatric patients have not been established.
- Geriatric Use: Overall, no differences in safety or efficacy of Scemblix™ were observed between patients 65 years of age or older compared to younger patients.
- Renal Impairment: No dose adjustment is required for patients with mild to severe renal impairment and not requiring dialysis receiving Scemblix™.
- Hepatic Impairment: No dose adjustment is required for patients with mild to severe hepatic impairment receiving Scemblix™.

NEW BIOSMILAR PRODUCTS

- No biosimilar product approved during the month of October.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
SERTRALINE HYDROCHLORIDE CAPSULES / ALMATICA	Antidepressant	Treatment of major depressive disorder (MDD) in adults and treatment of obsessive-compulsive disorder (OCD) in adults and pediatric patients 6 years and older	10/04/2021	This new dosage form of sertraline hydrochloride should not be used as an initial treatment for MDD or OCD. It is recommended to use another sertraline product for initial dosage, titration, and dosages below 150mg once daily.
ZIMHI™ (NALOXONE HYDROCHLORIDE) INJECTION FOR INTRAMUSCULAR OR SUBCUTANEOUS USE / ADAMIS PHARMACEUTICALS CORPORATION	Opioid antagonist	Emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression	10/15/2021	Zimhi™ provides a 5-mg dose of naloxone in a prefilled syringe. The higher dose of naloxone is intended to counteract the rise in use of more potent and/or longer-acting synthetic opioids.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
SEGLENTIS™ (CELECOXIB AND TRAMADOL HYDROCHLORIDE) TABLETS FOR ORAL USE / ESTEVE	Analgesic	Management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate	10/15/2021	Seglentis™ is a new analgesic designed for acute pain management in a multimodal treatment approach targeting four complementary pain relief mechanisms. It offers a new treatment option for acute pain management aligned with multimodal analgesia now considered standard of care.
TYRVAYA™ (VARENICLINE) NASAL SPRAY / OYSTER POINT PHARMA, INC.	Ophthalmic agent	Treatment of dry eye disease	10/18/2021	Tyrvaya™ nasal spray is a highly selective cholinergic agonist delivered twice daily as an aqueous nasal spray into each nostril to activate basal tear production. Nasal spray administration provides a new way to treat dry eye disease without administering medication onto an already irritated ocular surface. In addition, nasal delivery may allow some patients who have difficulty independently administering topical eye drops to administer independently their prescribed dry eye disease therapy.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
SUSVIMO™ (RANIBIZUMAB INJECTION) FOR INTRAVITREAL USE / GENENTECH	Ophthalmic agent	Treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor	10/22/2021	Susvimo™ delivers ranibizumab continuously, offering people living with wet AMD an alternative to anti-VEGF eye injections needed as often as once a month. The implant is surgically inserted into the eye during a one-time, outpatient procedure and refilled every six months. If necessary, supplemental ranibizumab treatment can be given to the affected eye while the Susvimo implant is in place.
XIPERE™ (TRIAMCINOLONE ACETONIDE INJECTABLE SUSPENSION) FOR SUPRACHOROIDAL USE / CLEARSIDE BIOMEDICAL, INC.	Corticosteroid	Treatment of macular edema associated with uveitis	10/25/2021	Xipere™ (triamcinolone acetonide suprachoroidal injectable suspension), formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye for the treatment of macular edema associated with uveitis. Clearside's patented technology is designed to deliver drug to the suprachoroidal space located between the choroid and the outer protective layer of the eye, known as the sclera. Suprachoroidal injection enables the rapid dispersion of medicine to the back of the eye, offering the potential for the medicine to act longer and minimize harm to the surrounding healthy parts of the eye.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
VUITY™ (PILOCARPINE HYDROCHLORIDE) OPHTHALMIC SOLUTION	Ophthalmic agent	Treatment of presbyopia in adults	10/29/2021	Vuity™ is the first and only eye drop to treat presbyopia (age-related blurry near vision). Phase 3 clinical studies demonstrated Vuity™ works in as early as 15 minutes and lasts for up to 6 hours, as measured on day 30, to improve near and intermediate vision without impacting distance vision.
DILTIAZEM HYDROCHLORIDE IN DEXTROSE INJECTION / EXELA PHARMA	Calcium channel blocker	Temporary control of rapid ventricular rate in atrial fibrillation or atrial flutter, and rapid conversion of paroxysmal supraventricular tachycardias (PSVT) to sinus rhythm	10/29/2021	The new formulation of diltiazem hydrochloride was approved following the 505(b)(2) drug approval pathway.

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
OXYMETAZOLINE HYDROCHLORIDE TOPICAL CREAM 1% / TARO PHARMACEUTICALS U.SA., INC.	Dermatological, rosacea agents	Treatment of rosacea	Rhofade™	10/04/2021
CARGLUMIC ACID TABLETS FOR ORAL SUSPENSION 200MG / NOVITIUM PHARMA LLC	Endocrine and metabolic agent	Treatment of hyperammonemia	Carbaglu™	10/13/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

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DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
TECARTUS™ (BREXUCABTAGENE AUTOLEUCEL) SUSPENSION FOR INTRAVENOUS INFUSION / KITE	Antineoplastic agent	Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)	Treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia	10/01/2021
BIKTARVY™ (BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE) TABLETS / GILEAD SCIENCES, INC.	Antiviral agent	Treatment of HIV-1 infection in adult patients who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per ML) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy™	Treatment of HIV-1 infection in pediatric patients weighing at least 14kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per ML) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy™	10/07/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
DEXTENZA™ (DEXAMETHASONE) OPHTHALMIC INSERT / OCULAR THERAPEUTIX, INC.	Ophthalmic agent	Treatment of ocular inflammation and pain following ophthalmic surgery	Treatment of ocular itching associated with allergic conjunctivitis	10/07/2021
KEYTRUDA™ (PEMBROLIZUMAB) INJECTION FOR INTRAVENOUS USE / 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 (MSI-H) or mismatch repair deficient (dMMR) 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 (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer	Treatment of patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (combined positive score [CPS] ≥ 1), as determined by an FDA-approved test, in combination with chemotherapy, with or without bevacizumab	10/13/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
VERZENIO™ (ABEMACICLIB) TABLETS / ELI LILLY	Antineoplastic agent	Treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy in combination with fulvestrant As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting	Adjuvant treatment of adult patients with HR-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score ≥20% as determined by an FDA-approved test	10/13/2021
TECENTRIQ™ (ATEZOLIZUMAB) INJECTION FOR INTRAVENOUS USE / GENENTECH	Antineoplastic agent	Treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), small cell lung cancer (SCLC), hepatocellular carcinoma and melanoma	Adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥1% of tumor cells as determined by an FDA-approved test	10/15/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
DUPIXENT™ (DUPILUMAB) INJECTION FOR SUBCUTANEOUS USE / REGENERON PHARMACEUTICALS, INC. AND SANOFI	Dermatological and anti-asthmatic agent	Treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)	As an add-on maintenance treatment of patients aged 6 to 11 years with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma	10/20/2021

PIPELINE

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
ARQ-151 (ROFLUMILAST) CREAM / ARCUTIS BIOTHERAPEUTICS, INC.	10/04/2021	Treatment of mild-to-severe plaque psoriasis	ARQ-151 is a once-daily topical formulation of roflumilast, a highly potent and selective inhibitor of phosphodiesterase type 4 (PDE4), an enzyme that drives overactive immune responses. In clinical trials, roflumilast cream demonstrated robust efficacy coupled with favorable safety and tolerability that, if approved, would enable chronic use across the body, without many of the local tolerability issues associated with alternative treatments. NDA submitted.	Moderate
TEBIPENEM HYDROBROMIDE TABLETS / SPERO THERAPEUTICS, INC.	10/28/2021	Treatment of complicated urinary tract infections (cUTI), including pyelonephritis	Tebipenem is an oral carbapenem antibiotic that could decrease the use of intravenous therapy for cUTI, The avoidance of IV administration could lead to reduced healthcare resource utilization. NDA submitted.	Moderate

REFERENCES

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