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PharmNOTES

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

Date: 08/09/2021

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NEWS

DRUG ISSUE	DATE	DETAILS
FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy	07/20/2021	The FDA is requesting that statin manufacturers remove its strongest warning against using cholesterol-lowering statin medicines in pregnant patients as part of FDA's ongoing effort to update the pregnancy and breastfeeding information for all prescription medicines. The FDA continues to advise that most pregnant patients stop taking statins. In addition, breastfeeding is not recommended in patients who require statins. Additional information can be found at Drug Safety and Availability.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
KERENDIA (FINERENONE) TABLETS	BAYER HEALTHCARE PHARMACEUTICALS, INC.	07/09/2021

THERAPEUTIC CLASS
Endocrine and metabolic agent

FDA-APPROVED INDICATION(S)
KERENDIA is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

DOSAGE AND ADMINISTRATION
The recommended starting dosage is 10mg or 20mg orally once daily based on eGFR and serum potassium thresholds.

Increase dosage after 4 weeks to the target dose of 20mg once daily, based on eGFR and serum potassium thresholds.

Tablets may be taken with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 10mg and 20mg

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Concomitant use with strong CYP3A4 inhibitors
- Patients with adrenal insufficiency

WARNINGS AND PRECAUTIONS
- Hyperkalemia
- Patients with decreased kidney function and higher baseline potassium levels
- Monitor serum potassium levels and adjust dose as needed

ADVERSE REACTIONS
Most common adverse reactions are hyperkalemia, hypotension and hyponatremia.

DRUG INTERACTIONS
- Strong CYP3A4 inhibitors (use is contraindicated)
- Grapefruit or grapefruit juice (avoid concomitant use)
- Moderate or weak CYP3A4 inhibitors (monitor serum potassium during drug initiation or dosage adjustment of either KERENDIA or the moderate CYP3A4 inhibitor, and adjust KERENDIA dosage as appropriate)
- Strong or moderate CYP3A4 inducers (avoid concomitant use)

USE IN SPECIFIC POPULATIONS
- Pregnancy: There are no available data on KERENDIA use in pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.
- Lactation: Avoid breastfeeding during treatment and 1 day after treatment
- Pediatric use: The safety and efficacy of KERENDIA have not been established in patients below 18 years of age.
- Hepatic impairment: Avoid use in patients with severe hepatic impairment (Child Pugh C) and consider additional serum potassium monitoring with moderate hepatic impairment (Child Pugh B)

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
FEXINIDAZOLE TABLETS	DRUGS FOR NEGLECTED DISEASES INITIATIVE; DISTRIBUTED BY SANOFI-AVENTIS	07/16/2021

THERAPEUTIC CLASS
Antimicrobial agent

FDA-APPROVED INDICATION(S)
FEXINIDAZOLE is a nitroimidazole antimicrobial indicated for the treatment of both first-stage (hemolymphatic) and second-stage (meningoencephalitic) human African Trypanosomiasis (HAT) due to *Trypanosoma brucei gambiense* in patients 6 years of age and older and weighing at least 20 kg.

DOSAGE AND ADMINISTRATION
The recommended dose is based on the patient's weight:
- ≥35 Kg (LD-1,800mg x 4 days, MD-1,200mg x 6 days)
- ≥20 Kg ≤35 Kg (LD-1,200mg x 4 days, MD-600mg x 6 days)

DOSAGE FORMS AND STRENGTHS
Tablets: 600 mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to FEXINIDAZOLE, and/or nitroimidazole drugs
- Hepatic impairment

WARNINGS AND PRECAUTIONS
- Decreased efficacy in severe Human African Trypanosomiasis Caused by *Trypanosoma brucei gambiense*
- QT Interval Prolongation
- Neuropsychiatric Adverse Reactions
- Neutropenia
- Potential for Hepatotoxicity
- Disulfiram-like Reaction

ADVERSE REACTIONS
Most common adverse reactions with an incidence >10% are headache, vomiting, insomnia, nausea, asthenia, tremor, decreased appetite, dizziness, hypocalcemia, dyspepsia, back pain, upper abdominal pain, and hyperkalemia.

DRUG INTERACTIONS
- Herbal Medicines and Supplements: Avoid concomitant use of herbal medicines and supplements during treatment with Fexinidazole Tablets.
- Avoid concomitant use of drugs known to block potassium channels (e.g., antiarrhythmics, neuroleptics, fluoroquinolones, imidazole and triazole antifungals, pentamidine) prolong the QT interval (e.g., antimalarials, phenothiazines, tricyclic antidepressants, terfenadine and astemizole, IV erythromycin, and quinolone antibacterial drugs) and/or induce bradycardia (such as β-blockers)

USE IN SPECIFIC POPULATIONS
- Pregnancy: Insufficient data to evaluate drug-associated risk of major birth defects or miscarriage.
- Females and males of reproductive potential: No effect on fertility parameters and no evidence of impairment of reproductive performance up to the dose of 600 mg/kg/day seen in animal studies.
- Lactation: There are no reports of adverse effects to the breastfed child associated with fexinidazole exposure through breastmilk based on a limited number of reported cases.
- Pediatric use: Safety and efficacy have been established in pediatric patients weighing at least 20 kg supported by evidence from an adequate and well-controlled trial in pediatric patients aged 6 years and older.
- Geriatric use: Insufficient number of elderly subjects to detect differences in safety and/or effectiveness between elderly and younger adult patients
- Hepatic impairment: Contraindicated in patients with hepatic impairment due to unknown pharmacokinetics in this population.
- Renal impairment: No dosage adjustment is needed for patients with mild to moderate renal impairment with estimated glomerular filtration rates (eGFR) from 30 mL/min/1.73 m2 to less than or equal to 89 mL/min/1.73 m2. Unknown effect on patients with severe renal impairment; avoid the use in these patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VAXNEUVANCE (PNEUMOCOCCAL 15-VALENT CONJUGATE VACCINE) INJECTION	MERCK	07/16/2021

THERAPEUTIC CLASS
Inactivated bacterial vaccine

FDA-APPROVED INDICATION(S)
VAXNEUVANCE is a vaccine indicated for the active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older

DOSAGE AND ADMINISTRATION
Single 0.5mL dose, for intramuscular use only

DOSAGE FORMS AND STRENGTHS
Suspension for injection (0.5ml dose), supplied as a single-dose prefilled syringe

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Severe allergic reaction (e.g., anaphylaxis) to any component of VAXNEUVANCE or to diphtheria toxoid

WARNINGS AND PRECAUTIONS
- Individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to VAXNEUVANCE

ADVERSE REACTIONS
- In individuals 18 through 49 years of age the most common adverse reactions were: injection-site pain, fatigue, myalgia, headache, injection-site swelling, injection-site erythema and arthralgia.
- In individuals 50 years of age and older the most common adverse reactions were: injection-site pain, myalgia, fatigue, headache, injection-site swelling, injection-site erythema and arthralgia.

DRUG INTERACTIONS
- Immunosuppressive therapies may reduce the immune response to this vaccine

USE IN SPECIFIC POPULATIONS
- Pregnancy: Available data on VAXNEUVANCE administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- Lactation: Human data are not available to assess the impact of VAXNEUVANCE on milk production, its presence in breast milk, or its effects on the breastfed child.
- Pediatric use: The safety and effectiveness of VAXNEUVANCE in individuals younger than 18 years of age have not been established.
- Geriatric use: No clinically meaningful differences in the safety profile or immune responses observed in older individuals when compared to younger individuals.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
REZUROCK (BELUMOSUDIL) TABLETS	KADMON HOLDINGS, INC.	07/16/2021

THERAPEUTIC CLASS
Immunosuppressive agent

FDA-APPROVED INDICATION(S)
REZUROCK is a kinase inhibitor indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

DOSAGE AND ADMINISTRATION
200mg taken orally once daily with food

DOSAGE FORMS AND STRENGTHS
Tablets: 200mg

Orphan status: Orphan

SAFETY PROFILE

WARNINGS AND PRECAUTIONS
- Embryo-fetal toxicity: can cause fetal harm

ADVERSE REACTIONS
Most common adverse reactions are infections, asthenia, nausea, diarrhea, dyspnea, cough, edema, hemorrhage, abdominal pain, musculoskeletal pain, headache, phosphate decreased, gamma glutamyl transferase increased, lymphocytes decreased and hypertension.

DRUG INTERACTIONS
- Strong CYP3A4 inducers: increase REZUROCK dosage to 200mg twice daily
- Proton pump inhibitors: increase REZUROCK dosage to 200mg twice daily

USE IN SPECIFIC POPULATIONS
- Pregnancy: REZUROCK can cause fetal harm when administered to pregnant women.
- Females and males of reproductive potential: Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for at least one week after the last dose.
- Lactation: Advise lactating women not to breastfeed during treatment with REZUROCK and for at least one week after the last dose
- Geriatric use: No clinically meaningful differences in the safety profile or immune responses observed in older individuals when compared to younger individuals.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
BYLVAY (ODEVIXIBAT) CAPSULES, ORAL PELLETS	ALBIREO PHARMA	07/20/2021

THERAPEUTIC CLASS
Gastrointestinal agent; ileal bile acid transporter inhibitor

FDA-APPROVED INDICATION(S)
BYLVAY is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

DOSAGE AND ADMINISTRATION
The recommended dose is based on patient's weight: 40 mcg/kg once daily in the morning with a meal. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg.

DOSAGE FORMS AND STRENGTHS
Oral Pellets: 200 mcg, 600 mcg (3)
Capsules: 400 mcg, 1200 mcg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Liver Test Abnormalities
- Diarrhea
- Fat-Soluble Vitamin (FSV) Deficiency

ADVERSE REACTIONS
Most common adverse reactions: (>2%) are liver test abnormalities, diarrhea, abdominal pain, vomiting, and fat-soluble vitamin deficiency.

DRUG INTERACTIONS
- Bile acid binding resins (e.g., cholestyramine, colesevelam, or colestipol) may bind BYLVAY in the gut, which may reduce BYLVAY efficacy. Administer at least 4 hours before or 4 hours after administration of BYLVAY.

USE IN SPECIFIC POPULATIONS
- Pregnancy: No human data on BYLVAY use in pregnant persons to establish a drug-associated risk of major birth defects, miscarriage, or adverse developmental outcomes. Cardiac malformations founds in animal studies.
- Females and males of reproductive potential: No human data. No effects on fertility or reproductive function in male and female rats at oral doses of up to 1000 mg/kg/day.

USE IN SPECIFIC POPULATIONS *(cont.)*

- Lactation: Low absorption following oral administration, and breastfeeding is not expected to result in exposure of the infant to BYLVAY at the recommended dose. There are no data on the presence of BYLVAY in human milk, the effects on the breastfed infant, or the effects on milk production.
- Pediatric use: The safety and effectiveness of BYLVAY have been established in pediatric patients 3 months to 17 years of age for the treatment of pruritus in PFIC.
- Geriatric use: Safety and efficacy have not been established.
- Hepatic impairment: No dose adjustment is required for patients with mild or moderate hepatic impairment. The efficacy and safety in PFIC patients with clinically significant portal hypertension and in patients with decompensated cirrhosis have not been established.
- Renal impairment: No dose adjustment is required for patients with mild or moderate renal impairment. There are no available clinical data for the use of BYLVAY patients with moderate or severe renal impairment or end-stage renal disease (ESRD) requiring haemodialysis.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
SAPHNELO (ANIFROLUMAB-FNIA) INJECTION	ASTRAZENECA	07/30/2021

THERAPEUTIC CLASS
First-in-class type I interferon receptor antibody

FDA-APPROVED INDICATION(S)
SAPHNELO is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.
Limitations of Use: The efficacy of SAPHNELO has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of SAPHNELO is not recommended in these situations

DOSAGE AND ADMINISTRATION
The recommended dosage is 300 mg as an intravenous infusion over a 30-minute period every 4 weeks.

DOSAGE FORMS AND STRENGTHS
Injection: 300 mg/2 mL (150 mg/mL) in a single-dose vial.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- History of anaphylaxis with anifrolumab-fnia.

WARNINGS AND PRECAUTIONS
- Serious Infections: respiratory infections and herpes zoster
- Hypersensitivity Reactions including anaphylaxis and angioedema
- Malignancy
- Immunization: Avoid use of live or live-attenuated vaccines
- Not Recommended for Use with Other Biologic Therapies

ADVERSE REACTIONS
Most common adverse reactions: (incidence ≥5%) are nasopharyngitis, upper respiratory tract infections, bronchitis, infusion related reactions, herpes zoster and cough.

DRUG INTERACTIONS
- No formal drug interaction studies have been conducted.

USE IN SPECIFIC POPULATIONS
- Pregnancy: The limited human data with SAPHNELO use in pregnant women are insufficient to inform on drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcome.
- Females and males of reproductive potential: Not evaluated in human.
- Lactation: No data are available regarding the presence of SAPHNELO in human milk.
- Pediatric use: Safety and efficacy have not been established in pediatric patients less than 18 years of age.
- Geriatric use: Safety and efficacy have not been established.
- Hepatic impairment: No clinical studies have been conducted in this population.
- Renal impairment: No clinical studies have been conducted in this population.

NEW BIOSMILAR PRODUCTS

- No new biosimilar product approved during July 2021

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
TWYNEO (TRETINOIN AND BENZOYL PEROXIDE) CREAM / SOL-GEL TECHNOLOGIES, LTD.	Keratolytics; antiacne agents	Treatment of acne vulgaris in adults and pediatric patients 9 years and older	07/26/2021	Twyneo is a topical cream containing a fixed-dose combination of tretinoin, 0.1%, and benzoyl peroxide, 3%, for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older. The formulation uses silica core shell structures to separately micro-encapsulate tretinoin crystals and benzoyl peroxide crystals enabling inclusion of the two active ingredients in the cream. Orphan status: N/A
UPTRAVI (SELEXIPAG) FOR INJECTION, FOR INTRAVENOUS USE / JANSSEN PHARMACEUTICAL	Peripheral Vasodilator	Treatment of pulmonary arterial hypertension (PAH)	7/29/2021	The FDA has approved Uptravi (selexipag) injection for intravenous (IV) use for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) in adult patients with WHO functional class (FC) II–III, who are temporarily unable to take oral therapy. Uptravi IV is a therapeutic option that will allow patients to avoid short-term treatment interruptions and stay on Uptravi therapy, as uninterrupted treatment is considered key for individuals with PAH. Uptravi tablets were first approved by the FDA in 2015 to delay disease progression and reduce the risk of hospitalization for PAH Orphan status: Orphan

NEW FIRST-TIME GENERIC APPROVALS

- No new first-time generic approved during July 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
PROGRAF (TACROLIMUS) CAPSULES, FOR ORAL USE PROGRAF (TACROLIMUS) INJECTION, FOR INTRAVENOUS USE PROGRAF GRANULES (TACROLIMUS FOR ORAL SUSPENSION) / ASTELLAS	Immunosuppressive agent	Prophylaxis of organ rejection in adult and pediatric patients receiving allogeneic liver, kidney, heart, in combination with other immunosuppressants	Prevention of organ rejection in adult and pediatric lung transplant recipients	7/16/2021
OCTAGAM 10% [IMMUNE GLOBULIN INTRAVENOUS (HUMAN)] LIQUID SOLUTION FOR INTRAVENOUS ADMINISTRATION / OCTAPHARMA	Immune globulins	Treatment of primary humoral immunodeficiency, chronic immune thrombocytopenic purpura (ITP)	Treatment of adult dermatomyositis	7/20/2021
BYDUREON BCISE (EXENATIDE) EXTENDED-RELEASE INJECTABLE SUSPENSION / ASTRAZENECA	Antidiabetic agent	Treatment of type 2 diabetes in patients 18 years and older	Treatment of type 2 diabetes in pediatric patient ages 10 years and older	7/22/2021
DALVANCE (DALBAVANCIN) INJECTION / ALLERGAN PHARMACEUTICALS	Anti-infective agent	Treatment of acute bacterial skin and skin structure infections in adult patients	Treatment of acute bacterial skin and skin structure infections in pediatric patients	7/23/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
SHINGRIX (ZOSTER VACCINE RECOMBINANT, ADJUVANTED) INJECTION / GLAXOSMITHKLINE (GSK)	Viral vaccine	Treatment for the prevention of shingles (herpes zoster) in adults 50 years of age or older	Treatment for the prevention of shingles in adults aged 18 years and older who are or who will be at increased risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy	7/26/2021
KEYTRUDA (PEMBROLIZUMAB) FOR INJECTION / MERCK	Antineoplastic agent	Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer	(1) Treatment of patients with locally advanced cutaneous squamous cell carcinoma (cSCC) that is not curable by surgry or radiation; (2) Treatment of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) with disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation in combination with Lenvima (lenvatinib); (3) Treatment of patients with high-risk early-stage triple-negative breast cancer in combination with chemotherapy as neoadjuvant treatment, then continued as single agent as adjuvant treatment after surgery	07/01/2021; 07/22/2021; 07/26/2021
NUCALA (MEPOLIZUMAB) INJECTION / GLAXOSMITHKLINE (GSK)	Antiasthmatic and bronchodilator agent	Treatment of asthma, eosinophilic granulomatosis with polyangiitis (including relapsing or refractory), hypereosinophilic syndrome	Treatment of chronic rhinosinusitis with nasal polyps in adults	07/29/2021

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
SURUFATINIB / HUTCHISON CHINA MEDITECH LIMITED	7/1/2021	Neuroendocrine carcinoma	Surufatinib is a novel, oral angio-immuno kinase inhibitor in development for the treatment of pancreatic and non-pancreatic neuroendocrine tumors ("NET"). FDA accepted NDA.	High
LIBERVANT (DIAZEPAM) / AQUESTIVE THERAPEUTICS, INC.	7/19/2021	Seizure clusters	Libervant (diazepam) is a buccal film formulation of the approved benzodiazepine diazepam in development for the management of seizure clusters. NDA resubmitted.	Moderate
BRIXADI (BUPRENORPHINE) EXTENDED-RELEASE INJECTION / BRAEBURN, INC.	07/26/2021	Moderate to severe opioid use disorder	Brixadi (buprenorphine) is a long-acting partial opioid agonist injection formulation in development for the treatment of opioid use disorder. NDA resubmitted.	Moderate
LV-101 (CARBETOCIN) / LEVO THERAPEUTICS, INC.	7/27/2021	Prader-Willi syndrome	LV-101 (carbetocin intranasal) is an oxytocin analog in development as a treatment for hyperphagia and behavioral distress associated with Prader-Willi syndrome (PWS). NDA priority review.	High High
FARICIMAB / GENENTECH	07/28/2021	Wet age-related macular degeneration (AMD) and diabetic macular edema (DME)	Faricimab is a bispecific antibody targeting the vascular endothelial growth factor (VEGF) and angiopoietin 2 (Ang-2) pathways in development for the treatment of wet, or neovascular, age-related macular degeneration (AMD) and diabetic macular edema (DME). BLA accepted.	High
OTESECONAZOLE / MYCOVIA PHARMACEUTICALS, INC.	07/28/2021	Recurrent vulvovaginal candidiasis	Oteseconazole (VT-1161) is an investigational oral antifungal in development for the treatment of recurrent vulvovaginal candidiasis (RVVC). NDA accepted.	Moderate

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)