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PharmNOTES

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

urac ACCREDITED
Pharmacy Benefit Management
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NEWS

DRUG ISSUE	DATE	DETAILS
FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain	01/12/2022	The U.S. Food and Drug Administration (FDA) is warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues. The FDA is requiring a new warning about the risk of dental problems be added to the prescribing information and the patient Medication Guide for all buprenorphine-containing medicines dissolved in the mouth.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
QUVIVIQ™ (DARIDOREXANT) TABLETS	IDORSIA PHARMACEUTICALS LTD.	01/07/2022

THERAPEUTIC CLASS
Hypnotics/sedatives/sleep disorder agents

FDA-APPROVED INDICATION(S)
Quviviq™ is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

DOSAGE AND ADMINISTRATION
The recommended dosage is 25mg to 50mg once per night, taken orally within 30 minutes before going to bed, with at least 7 hours remaining prior to planned awakening.

DOSAGE FORMS AND STRENGTHS
Tablets: 25mg, 50mg

Orphan status: N/A
Controlled substance: Schedule pending

SAFETY PROFILE

CONTRAINDICATIONS
- Patients with narcolepsy.

WARNINGS AND PRECAUTIONS
- CNS-Depressant Effects and Daytime Impairment: Impairs alertness and motor coordination including morning impairment. Risk increases when used with other central nervous system (CNS) depressants. For patients taking Quviviq™, caution against next-day driving and other activities requiring complete mental alertness.
- Worsening of Depression/Suicidal Ideation: Worsening of depression or suicidal thinking may occur.
- Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms: May occur with use of Quviviq™.
- Complex Sleep Behaviors: Behaviors including sleepwalking, sleep-driving, and engaging in other activities while not fully awake may occur. Discontinue immediately if complex sleep behavior occurs.
- Compromised Respiratory Function: Effect on respiratory function should be considered.
- Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days.

ADVERSE REACTIONS
- The most common adverse reactions (reported in ≥ 5% of patients treated with Quviviq™ and at an incidence ≥ than placebo) were headache and somnolence or fatigue.

DRUG INTERACTIONS
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- Moderate CYP3A4 inhibitors: Maximum recommended dose is 25 mg.
- Moderate or Strong CYP3A4 inducers: Avoid concomitant use.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Quviviq™ during pregnancy.
- Lactation: There are no data on the presence of daridorexant in human milk, the effects on the breastfed infant, or the effects on milk production.
- Pediatric use: The safety and effectiveness of Quviviq™ have not been established in pediatric patients.
- Geriatric use: No dose adjustment is required in patients over the age of 65 years. Because Quviviq™ can increase somnolence and drowsiness, patients, particularly the elderly, are at higher risk of falls.
- Hepatic impairment: Quviviq™ has not been studied in patients with severe hepatic impairment. Use in this population is not recommended.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
CIBINQO™ (ABROCITINIB) TABLET	PFIZER	01/14/2022

THERAPEUTIC CLASS
Analgesics – Anti-inflammatory

FDA-APPROVED INDICATION(S)
Cibinqo™ is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately or when use of those therapies is advisable.

DOSAGE AND ADMINISTRATION
The recommended dosage is 100 mg orally once daily. 200 mg orally once daily is recommended for those patients who are not responding to 100 mg once daily.

DOSAGE FORMS AND STRENGTHS
Tablets: 50mg, 100mg, 200mg

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Antiplatelet therapies except for low-dose aspirin (≤81mg daily), during the first 3 months of treatment.

WARNINGS AND PRECAUTIONS
- Laboratory Abnormalities: Laboratory monitoring is recommended due to potential changes in platelets, lymphocytes, and lipids.
- Immunizations: Avoid use of live vaccines prior to, during, and immediately after Cibinqo™ treatment.

ADVERSE REACTIONS
- Most common adverse reactions (≥1%) in subjects receiving 100 mg and 200 mg include: nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, gastroenteritis.
- Most common adverse reactions (≥1%) in subjects receiving either 100 mg or 200 mg also include: impetigo, hypertension, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia.

DRUG INTERACTIONS
- Strong inhibitors of CYP2C19: The recommended dose is 50 mg daily or 100 mg once daily for those patients who are not responding to 50 mg once daily.
- Moderate to strong inhibitors of both CYP2C19 and CYP2C9, or strong CYP2C19 or CYP2C9 inducers: Avoid concomitant use.
- P-gp substrate where small concentration changes may lead to serious or life-threatening toxicities: Monitor or titrate dosage of P-gp substrate.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Cibinqo™ during pregnancy.
- Lactation: There are no data on the presence of abrocitinib in human milk, the effects on the breast-fed infant, or the effects on milk production.
- Females and Males of Reproductive Potential: Based on the findings in rats, oral administration of Cibinqo™ may impair female fertility. Impaired fertility in female rats was reversible 1 month after cessation of abrocitinib oral administration.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

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Cibinqo™ is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately or when use of those therapies is advisable.

DOSAGE AND ADMINISTRATION
The recommended dosage is 100 mg orally once daily. 200 mg orally once daily is recommended for those patients who are not responding to 100 mg once daily.

DOSAGE FORMS AND STRENGTHS
Tablets: 50mg, 100mg, 200mg

Orphan status: N/A

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Pediatric use: The safety and effectiveness of Cibinqo™ have not been established in pediatric patients.
- Geriatric use: . Clinical trials of Cibinqo™ did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.
- Renal impairment: Cibinqo™ is not recommended for use in patients with severe renal impairment and ESRD including those on renal replacement. Cibinqo™ has not been studied in patients on renal replacement therapy.
- Hepatic impairment: Avoid use of Cibinqo™ in patients with severe (Child Pugh C) hepatic impairment.
- CYP2C19 poor metabolizers: Dosage reduction of Cibinqo™ is recommended in patients who are known or suspected to be CYP2C19 poor metabolizers based on genotype or previous history/experience with other CYP2C19 substrates.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
KIMMTRAK™ (TEBENTAFUSP-TEBN) INJECTION	IMMUNOCORE LTD.	01/25/2022

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Kimmtrak™ is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

DOSAGE AND ADMINISTRATION
The recommended dosage is 20mcg intravenously on Day 1, 30mcg intravenously on Day 8, 68mcg intravenously on Day 15, and 68mcg intravenously once every week thereafter.

DOSAGE FORMS AND STRENGTHS
Injection: 100mcg/0.5mL solution in a single-dose vial

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Skin reactions: Rash, pruritus, and cutaneous edema occurred in patients treated with Kimmtrak™. If skin reactions occur, treat based on persistence and severity of symptoms.
- Elevated liver enzymes: Elevations in liver enzymes occurred in patients treated with Kimmtrak™. Monitor ALT, AST, and total bilirubin.
- Embryo-Fetal toxicity: May cause fetal harm. Advise patients of reproductive potential of the potential risk to the fetus and to use effective contraception.

ADVERSE REACTIONS
- The most common adverse reactions (occurring in ≥ 30%) are cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache and vomiting.
- The most common laboratory abnormalities (occurring in ≥50%) are decreased lymphocyte count, increased creatinine, increased glucose, increased aspartate aminotransferase, increased alanine aminotransferase, decreased hemoglobin, and decreased phosphate.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on the mechanism of action, Kimmtrak™ may cause fetal harm when administered to a pregnant woman.
- Lactation: There are no data on the presence of tebentafusp-tebn in human milk, the effect on the breastfed child, or the effects on milk production. Because tebentafusp-tebn may be excreted in human milk and because of the potential for serious adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with Kimmtrak™ and for at least 1 week after the last dose.
- Females and males of reproductive potential: Kimmtrak™ may cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating Kimmtrak™ treatment. Advise female of reproductive potential to use effective contraception during treatment and for 1 week following the last dose of Kimmtrak™.
- Pediatric use: Safety and efficacy of Kimmtrak™ have not been established in pediatric patients.
- Geriatric use: No overall differences in safety or efficacy were observed between patients ≥ 65 years of age compared to younger adult patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VABYSMO™ (FARICIMAB-SVOA) INJECTION	GENENTECH INC.	01/28/2022

THERAPEUTIC CLASS
Ophthalmic agents

FDA-APPROVED INDICATION(S)
Vabysmo™ is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME).

DOSAGE AND ADMINISTRATION
nAMD: 6 mg administered by intravitreal injection every 4 weeks for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44.
DME: One of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks for at least 4 doses OR 2) 6 mg can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks.

DOSAGE FORMS AND STRENGTHS
Injection: 120 mg/mL solution in a single-dose vial

SAFETY PROFILE

CONTRAINDICATIONS
- Ocular or periocular infection
- Active intraocular inflammation
- Hypersensitivity

WARNINGS AND PRECAUTIONS
- Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management.
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.
- There is a potential risk of arterial thromboembolic events (ATEs) associated with VEGF inhibition.

ADVERSE REACTIONS
- The most common adverse reaction (≥ 5%) reported in patients receiving VABYSMO was conjunctival hemorrhage (7%).

USE IN SPECIFIC POPULATIONS
- Pregnancy: There are no adequate and well-controlled studies of Vabysmo™ administration in pregnant women.
- Lactation: There is no information regarding the presence of faricimab in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production.
- Females and males of reproductive potential: Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment and for at least 3 months following the last dose of Vabysmo™. No studies on the effects of faricimab on human fertility have been conducted and it is not known whether faricimab can affect reproduction capacity. Based on the mechanism of action, treatment with Vabysmo™ may pose a risk to reproductive capacity.
- Pediatric use: The safety and efficacy of Vabysmo™ in pediatric patients have not been established.
- Geriatric use: No significant differences in efficacy or safety of faricimab were seen with increasing age in these studies. No dose adjustment is required in patients 65 years and above.

Orphan status: N/A

NEW BIOSMILAR PRODUCTS

- No new biosimilar product approved during the month of January.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
RYALTRIS™ (OLOPATIDINE HYDROCHLORIDE AND MOMETASONE FUROATE MONOHYDRATE) NASAL SPRAY / GLENMARK SPECIALTY	Nasal agents – systemic and topical	Treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older	1/13/2022	Ryaltris™ is a metered, fixed-dose, aqueous suspension, prescription drug product nasal spray. It contains 665mcg of olopatadine hydrochloride and 25mcg of mometasone furoate. Orphan: N/A
DAPZURA RT™ (DAPTOMYCIN) INJECTION / BAXTER HEALTHCARE CORP.	Anti-infective agents	Treatment of complicated skin and skin structure infections (cSSSI) in adult and pediatric patients (1 to 17 years of age), *Staphylococcus aureus* bloodstream infections (bacteremia) in adult patients including those with right-sided infective endocarditis, *Staphylococcus aureus* bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age)	1/25/2022	Dapzura RT™ is a new formulation of daptomycin that differs from other formulations of daptomycin in terms of storage, reconstitution and shelf life. This formulation needs to be reconstituted with either sterile water or bacteriostatic water for injection to avoid a hyperosmotic solution that may result in infusion site reactions. Dapzura RT™'s un-reconstituted vials can be stored at room temperature in comparison to Cubicin™ and generic daptomycin that have to be stored in refrigerated conditions. Orphan: N/A
CITALOPRAM HYDROBROMIDE CAPSULES / ALMATICA	Antidepressants	Treatment of major depressive disorder (MDD) in adults	1/31/2022	Citalopram hydrobromide capsules are not recommended for initial treatment. This new dosage form is recommended for patients that require 30mg daily of citalopram. Orphan: N/A

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
PIRFENIDONE CAPSULES 267MG / AMNEAL PHARMACEUTICALS, LLC.	Respiratory agents	Idiopathic pulmonary fibrosis	Esbriet™	1/3/2022
SOFOSBUVIR TABLETS 400MG / TEVA PHARMACEUTICALS USA, INC.	Antivirals	Hepatitis C	Sovaldi™	1/27/2022
BRIMONIDINE TARTRATE OPHTHALMIC SOLUTION 0.15% / APOTEX INC.	Ophthalmic agents	Glaucoma	Alphagan P™	1/31/2022

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
RINVOQ™ (UPADACITNIB) EXTENDED-RELEASE TABLETS / ABBVIE INC.	Analgesics – Anti-inflammatory	(1) Treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers, (2) Treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers	Treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable	1/14/2022
SKYRIZI™ (RISANKIZUMAB-RZAA) INJECTION / ABBVIE INC.	Dermatologicals	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	Treatment of active psoriatic arthritis in adults	1/21/2022
VEKLURY™ (REMDESIVIR) INJECTION / GILEAD SCIENCES INC.	Antivirals	Treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are hospitalized	Treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.	1/21/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
VONVENDI™ [VON WILLEBRAND FACTOR (RECOMBINANT)] LYOPHILIZED POWDER FOR SOLUTION / BAXALTA US INC.	Hematological agents	Adults (age 18 and older) diagnosed with von Willebrand disease(VWD) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding	adults (age 18 and older) diagnosed with von Willebrand disease(VWD) for: • Routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease receiving on-demand therapy	1/24/2022

PIPELINE

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
OMAVELOXOLONE / REATA PHARMACEUTICALS, INC.	1/31/2022	Treatment of patients with Friedreich's ataxia	Reata Pharmaceuticals, Inc. initiated a rolling submission of a NDA to the FDA for omaveloxolone for the treatment of patients with Friedreich's ataxia. This is a rare, genetic, life-shortening, debilitating, and degenerative neuromuscular disorder. Omaveloxolone will be the first therapy for this disease. The rolling submission allows Reata to submit portions of the regulatory application to the FDA for review on an ongoing basis. The company expects to complete the submission of the NDA by the end of the first quarter of 2022. NDA submitted.	High high

REFERENCES

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