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PharmNOTES

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

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 12/08/2021

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NEWS

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

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
BESREMI™ (ROPEGINTERFERON ALFA-2B-NJFT)	PHARMAESSENIA CORP.	11/12/2021

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Besremi™ is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera.

DOSAGE AND ADMINISTRATION
The recommended starting dose is 100mcg by subcutaneous injection every 2 weeks (500mcg if receiving hydroxyurea). Increase the dose by 50mcg every 2 weeks (up to maximum of 500mcg) until hematological parameters are stabilized.

DOSAGE FORMS AND STRENGTHS
Injection: 500mcg/mL solution in a single-dose prefilled syringe

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation or suicide attempt
- Hypersensitivity to interferon or to any component of Besremi™
- Hepatic impairment (Child-Pugh B or C)
- History or presence of active serious or untreated autoimmune disease
- Immunosuppressed transplant recipients

WARNINGS AND PRECAUTIONS
- Depression and Suicide: Monitor closely for symptoms and need for treatment.
- Endocrine Toxicity: Discontinue if endocrine disorders occur that cannot be medically managed.
- Cardiovascular Toxicity: Avoid use in patients with severe, acute or unstable cardiovascular disease. Monitor patients with history of cardiovascular disorders more frequently.
- Decreased Peripheral Blood Counts: Perform blood counts at baseline, every 2 weeks during titration, and at least every 3-6 months during maintenance treatment.
- Hypersensitivity Reactions: Stop treatment and immediately manage reaction.

WARNING AND PRECAUTIONS (cont.)
- Pancreatitis: Consider discontinuation if confirmed pancreatitis.
- Colitis: Discontinue if signs or symptoms of colitis
- Pulmonary Toxicity: Discontinue if pulmonary infiltrates or pulmonary function impairment.
- Ophthalmologic Toxicity: Advise patients to have eye examinations before and during treatment. Evaluate eye symptoms promptly and discontinue if new or worsening eye disorders.
- Hyperlipidemia: Monitor serum triglycerides before treatment and intermittently during therapy and manage when elevated.
- Hepatotoxicity: Monitor liver enzymes and hepatic function at baseline and during treatment. Reduce dose or discontinue depending on severity.
- Renal Toxicity: Monitor serum creatinine at baseline and during therapy. Discontinue if severe renal impairment develops.
- Dental and Periodontal Toxicity: Advise patients on good oral hygiene and to have regular dental examinations.
- Dermatologic Toxicity: Consider discontinuing if clinically significant dermatologic toxicity.
- Driving and Operating Machinery: Advise patients to avoid driving or using machinery if they experience dizziness, somnolence, or hallucination.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

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DOSAGE FORMS AND STRENGTHS
Injection: 500mcg/mL solution in a single-dose prefilled syringe

Orphan status: Orphan

SAFETY PROFILE

ADVERSE REACTIONS
- The most common adverse reactions reported in > 40% of patients were influenza-like illness, arthralgia, fatigue, pruritus, nasopharyngitis, and musculoskeletal pain.

DRUG INTERACTIONS
- Monitor patients taking CYP450 substrates with a narrow therapeutic index for adverse reactions to inform the need for dose adjustment of the concomitant drug.
- Avoid use with myelosuppressive agents and monitor patients receiving the combination for effects of excessive myelosuppression.
- Avoid use with narcotics, hypnotics or sedatives. Monitor patients receiving the combination for excessive central nervous system toxicity.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Besremi™ may cause fetal harm and should be assumed to have abortifacient potential when administered to a pregnant woman.
- Lactation: Advise women not to breastfed during treatment and for 8 weeks after the final dose.
- Females and males of reproductive potential: Pregnancy testing prior to Besremi™ treatment is recommended for females of reproductive potential. Advise female patients of reproductive potential to use effective contraception during treatment and for at least 8 weeks after the final dose.

USE IN SPECIFIC POPULATIONS (cont.)
- Pediatric use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric use: Clinical studies did not include enough subjects aged 65 years and over to determine whether they respond differently from younger subjects.
- Renal impairment: No dose adjustment is necessary in patients with estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73m^2. Avoid use in patients with eGFR <30 mL/min/1.73m^2.
- Hepatic impairment: Besremi™ is contraindicated in patients with hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VOXZOGO™ (VOSORITIDE)	BIOMARIN PHARMACEUTICAL INC.	11/19/2021

THERAPEUTIC CLASS
Endocrine and metabolic agents

FDA-APPROVED INDICATION(S)
Voxzogo™ is a C type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses.

DOSAGE AND ADMINISTRATION
The recommended dosage is based on the patient's actual body weight and the concentration of reconstituted Voxzogo™ is 0.8mg/mL or 2mg/mL depending on the vial. It is administered by subcutaneous injection once daily.

DOSAGE FORMS AND STRENGTHS
For injection: 0.4 mg, 0.56 mg, or 1.2 mg lyophilized powder in a single-dose vial for reconstitution.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Risk of low blood pressure: Transient decreases in blood pressure have been reported.

ADVERSE REACTIONS
- Most common adverse reactions (>10%) are injection site erythema, injection site swelling, vomiting, injection site urticaria, arthralgia, decreased blood pressure, and gastroenteritis.

DRUG INTERACTIONS
- None

USE IN SPECIFIC POPULATIONS
- Pregnancy: In animal reproduction studies, there was no evidence of embryo-fetal toxicity or congenital malformations.
- Lactation: There is no information regarding the presence of vosoritide in human milk, the effects on the breastfed infant, or the effects on milk production.
- Pediatric use: Safety and effectiveness of VOXZOGO have been established in pediatric patients aged 5 years and older for the improvement in linear growth in patients with achondroplasia.

USE IN SPECIFIC POPULATIONS (cont.)
- Renal impairment: The influence of renal impairment on has not been evaluated. No dosage adjustment is needed for patients with eGFR ≥ 60mL/min/1.73 m2. Voxzogo™ is not recommended for patients with eGFR < 60 mL/min/1.73 m^2.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LIVTENCITY™ (MARIBAVIR)	TAKEDA PHARMS USA	11/23/2021

THERAPEUTIC CLASS
Antivirals

FDA-APPROVED INDICATION(S)
Livtencity™ is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

DOSAGE AND ADMINISTRATION
The recommended dosage is 400mg (two 200mg tablets) orally twice daily with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 200mg of maribavir

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Livtencity™ may antagonize the antiviral activity of ganciclovir and valganciclovir. Coadministration is not recommended.
- Virologic failure can occur during and after treatment with Livtencity™. Monitor CMV DNA levels and check for resistance if patient does not respond to treatment. Some maribavir pUL97 resistance-associated substitutions confer cross-resistance to ganciclovir and valganciclovir.
- The concomitant use of Livtencity™ and certain drugs may result in potentially significant drug interactions, some of which may lead to reduced therapeutic effect of Livtencity™ or adverse reactions of concomitant drugs.
- Livtencity™ has the potential to increase the drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-gp substrates where minimal concentration changes may lead to serious adverse events (including tacrolimus, cyclosporine, sirolimus and everolimus). Frequently monitor immunosuppressant drug levels throughout treatment with Livtencity™, especially following initiation and after discontinuation of Livtencity™ and adjust the dose, as needed.

ADVERSE REACTIONS
- The most common adverse events (all grades, >10%) in subjects treated with Livtencity™ were taste disturbance, nausea, diarrhea, vomiting, and fatigue.

DRUG INTERACTIONS
- Livtencity™ is not recommended to be coadministered with valganciclovir/ganciclovir (vGCV/GCV). Livtencity™ may antagonize the antiviral activity of ganciclovir and valganciclovir by inhibiting human CMV pUL97 kinase, which is required for activation/phosphorylation of ganciclovir and valganciclovir.
- Maribavir is a substrate of CYP3A4. Coadministration of Livtencity™ with strong inducers of CYP3A4 is not recommended, except for selected anticonvulsants.
- Maribavir is a weak inhibitor of CYP3A4, and an inhibitor of P-gp and breast cancer resistance protein (BCRP). Co-administration of Livtencity™ with drugs that are sensitive substrates of CYP3A, P-gp and BCRP may result in a clinically relevant increase in plasma concentrations of these substrates.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
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THERAPEUTIC CLASS
Antivirals

FDA-APPROVED INDICATION(S)
Livtencity™ is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

DOSAGE AND ADMINISTRATION
The recommended dosage is 400mg (two 200mg tablets) orally twice daily with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 200mg of maribavir

Orphan status: Orphan

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Pregnancy: No significant toxicological effects on embryo-fetal growth or development were observed in rabbits when maribavir was administered at oral doses up to 100 mg/kg/day at exposures approximately half the human exposure.
- Lactation: It is not known whether maribavir or its metabolites are present in human or animal milk, affect milk production, or have effects on the breastfed infant.
- Pediatric use: The recommended dosing regimen in pediatric patients 12 years of age and older and weighing at least 35 kg is the same as that in adults. The safety and effectiveness of LIVTENCITY have not been established in children younger than 12 years of age.
- Geriatric use: No dosage adjustment is required for patients over 65 years of age based on the results from population pharmacokinetics analysis.
- Renal impairment: No dose adjustment of Livtencity™ is needed for patients with mild, moderate, or severe renal impairment. Administration of Livtencity™ in patients with end stage renal disease (ESRD), including patients on dialysis, has not been studied.
- Hepatic impairment: No dose adjustment of Livtencity™ is needed for patients with mild or moderate hepatic impairment. Administration of Livtencity™ in patients with severe hepatic impairment has not been studied.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
CYTALUX™ (PAFOLACIANINE)	GRAND RIVER ASEPTIC MANUFACTURING	11/29/2021

THERAPEUTIC CLASS
Optical imaging agent

FDA-APPROVED INDICATION(S)
Cytalux™ is an optical imaging agent indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions.

DOSAGE AND ADMINISTRATION
The recommended dosage is 0.025 mg/kg administered intravenously over 60 minutes 1 hour to 9 hours prior to surgery

DOSAGE FORMS AND STRENGTHS
Injection: 3.2 mg/1.6 mL (2 mg/mL) of pafolacianine in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNING AND PRECAUTIONS
- Infusion-related reactions: Interrupt the infusion and treat as necessary with antihistamines and/or nausea medications.
- Risk of misinterpretation: Non-fluorescing tissue in the surgical field does not rule out the presence of tumor. Fluorescence may be seen in non-cancerous tissues.
- Embryo-fetal toxicity: Cytalux™ may cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus.
- Risk of pafolacianine aggregation and infusion reactions: Use only 5% Dextrose Injection for dilution. Do not use other diluents.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥1%) are nausea, vomiting, abdominal pain, flushing, dyspepsia, chest discomfort, pruritus and hypersensitivity.

DRUG INTERACTIONS
- Use of folate, folic acid, or folate-containing supplements may reduce binding of pafolacianine to folate receptors overexpressed on ovarian cancer cells and could reduce the detection of malignant lesions with Cytalux™. Avoid administration of folate, folic acid, or folate-containing supplements within 48 hours before administration of Cytalux™.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on its mechanism of action, pafolacianine may cause fetal harm when administered to a pregnant woman.
- Lactation: There are no data on the presence of pafolacianine in either human or animal milk, the effects on the breastfed infant, or the effects on milk production.
- Females and males of reproductive potential: Obtain a pregnancy test in females of reproductive potential and verify the absence of pregnancy prior to administration of Cytalux™.
- Pediatric use: Safety and effectiveness of Cytalux™ in pediatric patients have not been established.
- Geriatric use: No overall differences in safety, effectiveness or pharmacokinetics were observed between these patients and younger patients.

NEW BIOSMILAR PRODUCTS

- No biosimilar product approved during the month of November.

BIOSMILAR PRODUCT: SEMGLEE™

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
SEMGLEE™ (INSULIN GLARGINE-YFGN) / VIATRIS	Antidiabetics	Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus	11/16/2021	Biocon Biologics and Viatris launched both branded and unbranded versions of the interchangeable biosimilar version of Semglee™ in the United States. With this launch, both the branded product, Semglee™ (insulin glargine-yfgn) injection, and unbranded insulin glargine (insulin glargine-yfgn) injection, are both available for substitution at pharmacies for the reference product, Sanofi's Lantus™ (insulin glargine). The non-interchangeable Semglee™ that has been marketed prior to this launch is anticipated to be phased out by the end of the 2021 calendar year.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
DYANAVEL™ XR (AMPHETAMINE) EXTENDED-RELEASE ORAL TABLETS / TRIS PHARMA INC	Amphetamines	Treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older	11/04/2021	In a clinical study in healthy adults, Dyanavel™ XR extended-release tablets were deemed to be equivalent to Dyanavel™ XR extended-release oral suspension.
EPRONTIA™ (TOPIRAMATE) ORAL SOLUTION / AZURITY	Anticonvulsants	Epilepsy: Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older Preventive treatment of migraine in patients 12 years of age and older	11/05/2021	Eprontia™ provides a ready to use liquid medication for patients who have trouble swallowing pills. Caregivers may benefit from the ease of administering the medication.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
DHIVY™ (CARBIDOPA AND LEVODOPA) TABLETS / AVION PHARMS	Antiparkinson and related therapy agents	Treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication	11/12/2021	Dhivy™ was shown to be bioequivalent to an immediate-release carbidopa/levodopa 25/100mg tablet.
LYVISPAH™ (BACLOFEN) ORAL GRANULES / SAOL THERAPEUTICS, INC.	Musculoskeletal therapy agents	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity	11/22/2021	Pharmacokinetics studies in healthy adult subjects under fasting conditions at 20mg dose level demonstrated similar bioavailability for baclofen oral granules and oral tablets.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
FYARRO™ (SIROLIMUS ALBUMIN-BOUND NANOPARTICLES) FOR INJECTABLE SUSPENSION / AADI BIOSCIENCE INC.	Antineoplastics and adjunctive therapies	Treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)	11/22/2021	Fyarro™ is the first FDA-approved treatment for this indication, which is an ultra-rate and aggressive form of sarcoma that is most often diagnosed in women.

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
VALSARTAN ORAL SOLUTION 20MG/5ML / NOVITIUM PHARMA LLC	Antihypertensives	Hypertension; heart failure	Prexxartan™	11/02/2021
NELARABINE INJECTION 250MG/50ML / ZYDUS PHARMACEUTICALS INC.	Antineoplastics	Acute lymphoblastic leukemia; lymphoblastic lymphoma	Arranon™	11/17/2021
DASATINIB TABLETS 80 MG AND 140 MG / APOTEX CORP.	Antineoplastics	Philadelphia-positive chronic myeloid leukemia; Philadelphia-positive acute lymphoblastic leukemia	Sprycel™	11/23/2021
BETAINE FOR ORAL SOLUTION 1GM / NOVITIUM PHARMA LLC	Endocrine and metabolic agents	Homocystinuria	Cystadane™	11/23/2021

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
KEYTRUDA™ (PEMBROLIZUMAB) INJECTION / MERCK SHARP DOHME	Antineoplastics	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	Adjuvant treatment of patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions	11/17/2021

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PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
MAXIGESIC IV (PARACETAMOL AND IBUPROFEN) SOLUTION FOR INFUSION / HYLORIS PHARMACEUTICALS SA	11/01/2021	Treatment of postoperative pain	Maxigesic IV is a novel, unique combination of 1000mg paracetamol and 300mg ibuprofen solution. A few studies have shown that it has a faster onset of action and offers higher pain relief when compared to ibuprofen IV or paracetamol IV alone in the same doses. Studies have shown that this combination allows for a reduction in opioid usage. NDA accepted.	Moderate
PARSACLISIB / INCYTE	11/01/2021	Treatment of patients with relapsed or refractory follicular lymphoma (FL), marginal zone lymphoma (MZL) and mantle cell lymphoma (MCL)	Parsaclisib is an investigational novel potent, highly selective, next-generation oral inhibitor of phosphatidylinositol 3-kinase delta. It has been granted Priority Review by the FDA. NDA accepted.	Moderate
AMX0035 (SODIUM PHENYLBUTYRATE AND TAURURSODIOL	11/02/2021	Treatment of amyotrophic lateral sclerosis (ALS)	The NDA submission to the FDA is based on data from the CENTAUR trial, a placebo-controlled study evaluating 137 people with ALS. In this study, participants receiving AMX0035 had statistically significant slowing of functional decline at the end of the 6-month randomized phase as measured by the Revised ALS Functional Rating Scale (ALSFRS-R), the most commonly used scale in clinics worldwide to measure function in ALS. NDA accepted.	Moderate

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
HTX-019 (APREPITANT) / HERON THERAPEUTICS, INC.	11/18/2021	Prevention of postoperative nausea and vomiting	HTX-019 is an intravenous injectable emulsion formulation designed to directly deliver aprepitant, the active ingredient in Emend™. NDA submitted.	Moderate
BULEVIRTIDE / GILEAD SCIENCES, INC.	11/19/2021	Treatment of chronic hepatitis D virus infection in adults with compensated liver disease	Bulevirtide is a potential first-in-class antiviral medicine. It has been granted Breakthrough Therapy and Orphan Drug designations by the FDA. BLA submitted.	High high
LINZAGOLIX / OBSEVA SA	11/22/2021	Management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women	Linzagolix, if approved, would be the first and only gonadotropin-releasing hormone receptor antagonist with flexible dosing options for uterine fibroids, including a low dose option to address the needs of women who cannot or do not want to take hormones. NDA accepted.	Moderate

REFERENCES

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