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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
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NEWS .....

- No new drug safety communication other that recalls published during November 2020.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Zokinvy™ (lonafarnib) Capsules, for oral use	Eiger BioPharmaceuticals, Inc.	11/20/2020

THERAPEUTIC CLASS
Farnesyltransferase inhibitor (FTI)

FDA-APPROVE INDICATION(S)
Zokinvy™ is a farnesyltransferase inhibitor indicated in patients 12 months of age and older with a body surface area of 0.39 m2 and above:

- To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome
- For treatment of processing-deficient Progeroid Laminopathies with either:
  - Heterozygous LMNA mutation with progerin-like protein accumulation
  - Homozygous or compound heterozygous ZMPSTE24 mutations

DOSAGE AND ADMINISTRATION
The recommended starting dose is 115 mg/m2 twice daily with morning and evening meals to reduce the risk of gastrointestinal adverse reactions. After 4 months of treatment, increase the dosage to 150 mg/m2 twice daily with morning and evening meal.

DOSAGE FORMS AND STRENGTHS
Capsules: 50 mg and 75 mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS

- Strong or moderate CYP3A inhibitors or inducers
- Midazolam
- Lovastatin, simvastatin, and atorvastatin

WARNINGS AND PRECAUTIONS

- Risk of reduced efficacy or adverse reactions due to drug interactions
- Laboratory abnormalities
- Nephrotoxicity
- Retinal toxicity
- Impaired fertility
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: vomiting, diarrhea, infection, nausea, decreased appetite, fatigue, upper respiratory tract infection, abdominal pain, musculoskeletal pain, electrolyte abnormalities, decreased weight, headache, myelosuppression, increased aspartate aminotransferase, decreased blood bicarbonate, cough, hypertension, and increased alanine aminotransferase.

DRUG INTERACTIONS

- Effect of other drugs on Zokinvy™: Refer to full prescribing information for details regarding clinically significant drug interactions with drugs that affect Zokinvy™.
- Zokinvy's effect on other drugs: Refer to full prescribing information for details regarding clinically significant drug interactions with drugs affected by Zokinvy™.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Can cause embryo-fetal toxicity.
- Females and males of reproductive potential: Advise females of reproductive potential to use appropriate effective contraception during treatment. May reduce fertility in females and males of reproductive potential.
- Pediatric use: Safety and effectiveness in pediatric patients less than 12 months of age have not been established.

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New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Oxlumo™ (lumasiran) Injection, for subcutaneous use	Alnylam Pharmaceuticals, Inc.	11/23/2020

THERAPEUTIC CLASS
Renal-urologic agent

FDA-APPROVE INDICATION(S)
Oxlumo™ is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients.

DOSAGE AND ADMINISTRATION
The recommended dose is based on body weight, with loading doses monthly for 3 doses followed by maintenance doses once monthly or quarterly depending on patient weight. Oxlumo™ is intended for subcutaneous use and should be administered by a healthcare professional. Refer to full prescribing information for additional details.

DOSAGE FORMS AND STRENGTHS
Injection: 94.5 mg/0.5 mL in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
None.

ADVERSE REACTIONS
Most common adverse reactions: injection site reactions.

DRUG INTERACTIONS
- No clinical studies evaluating the drug interaction potential of lumasiran have been conducted.
- In vitro studies indicate that lumasiran is not a substrate or an inhibitor of cytochrome CYP) enzymes. Lumasiran is not expected to induce CYP enzymes or modulate the activities of drug transporters.

USE IN SPECIFIC POPULATIONS
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.
- Hepatic impairment: No dose adjustment is recommended for patients with or moderate hepatic impairment. Has not been studied in patients with severe hepatic impairment.
- Renal impairment: No dose adjustment is necessary in patients with an eGFR of ≥30 mL/min/1.73 m2. Has not been studied in patients with an eGFR <30 mL/min/1.73 m2 or patients on dialysis.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Imcivree™ (setmelanotide) Injection, for subcutaneous use	Rhythm Pharmaceuticals, Inc.	11/25/2020

THERAPEUTIC CLASS
Melanocortin 4 (MC4) receptor agonist

FDA-APPROVE INDICATION(S)
Imcivree™ is a MC4 receptor agonist indicated for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).

DOSAGE AND ADMINISTRATION
The recommended starting dose varies per patient population, and includes once daily doses injected subcutaneously for 2 weeks. If tolerated, the dose is increased. Dose adjustments are recommended to manage gastrointestinal (GI) adverse reactions. Refer to full prescribing information for additional details.

DOSAGE FORMS AND STRENGTHS
Injection: 10 mg/mL solution in a 1 mL multiple-dose vial .

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Disturbance in sexual arousal
- Depression and suicidal ideation
- Skin pigmentation and darkening of pre-existing nevi
- Risk of serious adverse reactions due to benzyl alcohol preservative in neonates and low birth weight infants

ADVERSE REACTIONS
Most common adverse reactions: injection site reactions, skin hyperpigmentation, nausea, headache, diarrhea, abdominal pain, back pain, fatigue, vomiting, depression, upper respiratory tract infection, and spontaneous penile erection.

DRUG INTERACTIONS
- Setmelanotide has low potential for pharmacokinetic drug-drug interactions related to CYP, transporters and plasma protein binding.
- No clinical studies evaluating the drug-drug interaction potential of setmelanotide have been conducted.

USE IN SPECIFIC POPULATIONS
- Lactation: Not recommended when breastfeeding.
- Pediatric use: Safety and effectiveness have not been established in pediatric patients younger than 6 years old.
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.
- Renal impairment: Population pharmacokinetic analysis suggests decreased clearance in patients with renal impairment. No dose adjustments for patients with mild renal impairment are needed. Is not recommended for use in patients with moderate and severe renal impairment and end stage renal disease.

(continuation) – IF APPLY

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Danyelza™ (naxitamab-gqgk) Injection, for intravenous use	Y-mAbs Therapeutics, Inc.	11/25/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Danyelza™ is a GD2-binding monoclonal antibody indicated, in combination with granulocyte-macrophage colony-stimulating factor (GMCSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.

DOSAGE AND ADMINISTRATION
The recommended dose is s 3 mg/kg/day (up to 150 mg/day), administered as an intravenous infusion after dilution on Days 1, 3, and 5 of each treatment cycle. Treatment cycles are repeated every 4 weeks until complete response or partial response, followed by 5 additional cycles every 4 weeks. Subsequent cycles may be repeated every 8 weeks.

DOSAGE FORMS AND STRENGTHS
Injection: 40 mg/10 mL (4 mg/mL) in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- History of severe hypersensitivity reaction to naxitamab-gqgk.

WARNINGS AND PRECAUTIONS
- Boxed warning: Serious infusion-related reactions and neurotoxicity
- Neurotoxicity
- Hypertension
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: infusion-related reaction, pain, tachycardia, vomiting, cough, nausea, diarrhea, decreased appetite, hypertension, fatigue, erythema multiforme, peripheral neuropathy, urticaria, pyrexia, headache, injection site reaction, edema, anxiety, localized edema, and irritability.

Most common Grade 3 or 4 laboratory abnormalities: decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased platelet count, decreased potassium, increased alanine aminotransferase, decreased glucose, decreased calcium, decreased albumin, decreased sodium, and decreased phosphate.

DRUG INTERACTIONS

USE IN SPECIFIC POPULATIONS
- Pregnancy: May cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating.
- Females of reproductive potential: Advise to use effective contraception during treatment and for 2 months after the final dose.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established in pediatric patients younger than 1 year of age.
- Geriatric use: Neuroblastoma is largely a disease of pediatric and young adult Clinical studies did not include patients 65 years of age and older.

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Sesquient™ (fosphenytoin sodium) for Injection / Sedor Pharmaceuticals, LLC	Antiepileptic	• Treatment of generalized tonic-clonic status epilepticus in adult patients • Prevention and treatment of seizures occurring during neurosurgery in adult patients • Short-term substitution for oral phenytoin in patients 2 years of age and older	11/05/2020	Sesquient™ is a new room-temperature stable formulation of fosphenytoin sodium. Fosphenytoin sodium was already available as an injectable formulation (in generic and branded), with similar indications as Sesquient™. However, Sesquient™ is the only FDA-approved room-temperature stable formulation of fosphenytoin sodium, allowing point-of-care storage, as well as fast and efficient administration in emergency rooms, intensive care units, first responder vehicles, and long-term care facilities, where serial seizures such as status epilepticus are most commonly treated. Orphan status: N/A
Sutab™ (sodium sulfate, magnesium sulfate, and potassium chloride) Tablets / Sebela Pharmaceuticals, Inc.	Laxative	Cleansing of the colon in preparation for colonoscopy in adults	11/10/2020	Sutab™ is an osmotic laxative containing sodium sulfate, magnesium sulfate, and potassium chloride in a new tablet formulation, giving patients and physicians an alternative to liquid-based colonoscopy preparations. Other similar osmotic laxative that was already available is SUPREP™ Bowel Prep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution, with the same indication as Sutab™. Orphan status: N/A

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments

Xofluza™ (baloxavir marboxil) Granules for Oral Suspension / **Genentech, Inc.**	Anti-infective agent; Antiviral	• Treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are:
		  • otherwise healthy, or
		  • at high risk of developing influenza-related complications
		• Post-exposure prophylaxis of influenza in patients 12 years of age and older following contact with an individual who has influenza
			11/23/2020	Xofluza™ was initially approved in a tablet formulation for the treatment of influenza. Now, a new formulation in granules for oral suspension has been approved together with a new indication for post-exposure prophylaxis of influenza.
				
				Orphan status: N/A

Thyquidity™ (levothyroxine sodium) Oral Solution / **Reguliance LLC**	Thyroid agent	• Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism • Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer	11/30/2020	Orphan status: N/A

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Brilinta™ (ticagrelor) Tablets / AstraZeneca	Platelet aggregation inhibitor; P2Y12 platelet inhibitor	• To reduce the risk of cardiovascular (CV) death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI. For at least the first 12 months following ACS, it is superior to clopidogrel. Brilinta also reduces the risk of stent thrombosis in patients who have been stented for treatment of ACS. • To reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. While use is not limited to this setting, the efficacy of Brilinta was established in a population with type 2 diabetes mellitus (T2DM).	To reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤5) or high-risk transient ischemic attack (TIA).	11/05/2020
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent	Treatment of melanoma, non-small cell lung cancer, 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.	In combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test.	11/13/2020
Vimpat (lacosamide) Tablets, Injection, Oral Solution / UCB	Anti-convulsant	Treatment of partial-onset seizures.	As an adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older	11/16/2020

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Xofluza™ (baloxavir marboxil) Granules for Oral Suspension / Genentech, Inc.	Anti-infective agent; Antiviral	Treatment of influenza.	Post-exposure prophylaxis of influenza in people 12 years of age and older.	11/23/2020

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Indication(s)	Generic for:	Date
Gemmily (ethinyl estradiol and norethindrone acetate) Capsules 0.02 mg / 1 mg / Chemo Research SL	Contraceptive	Contraception	Taytulla	11/09/2020
Brinzolamide Ophthalmic Suspension 1% / Watson Laboratories Inc.	Ophthalmic agent	• Glaucoma • Ocular hypertension	Azopt	11/27/2020
Nitazoxanide Tablets 500 mg / Rising Pharma Holdings Inc.	Anti-infective agent; Antiprotozoal	• Giardiasis • Cryptosporidiosis	Alinia	11/27/2020

PIPELINE .....

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Pegcetacoplan / Apellis Pharmaceuticals, Inc.	11/16/2020	Treatment for: Paroxysmal Nocturnal Hemoglobinuria	Pegcetacoplan is an investigational, targeted C3 inhibitor in development for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). FDA accepted NDA for pegcetacoplan and granted orphan drug designation.	High High

References

- Food and Drug Administration (www.fda.gov)
- Drugs.com (www.drugs.com)
- IBM Micromedex® (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)