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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

Drug issue	Date	Details
Belviq, Belviq XR (lorcaserin): FDA Requests Withdrawal of Weight-Loss Drug	02/13/2020	[Update to safety communication published in January 2020] The FDA has requested that the manufacturer of Belviq, Belviq XR (lorcaserin) voluntarily withdraw the weight-loss drug from the US market because a safety clinical trial shows an increased occurrence of cancer. The drug manufacturer, Eisai Inc.,. has submitted a request to voluntarily withdraw the drug. Recommendations for healthcare professionals: • Stop prescribing and dispensing lorcaserin to patients. • Contact patients currently taking lorcaserin, inform them of the increased occurrence of cancer seen in the clinical trial, and ask them to stop taking the medicine. • Discuss alternative weight-loss medicines or strategies with your patients.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Pizensy™ (lactitol) solution, for oral use	Braintree labs	02/12/2020

THERAPEUTIC CLASS
Gastrointestinal agent; Laxative

FDA-APPROVE INDICATION(S)
Pizensy™ is an osmotic laxative indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

DOSAGE AND ADMINISTRATION
The recommended dose is 20 grams orally once Most common adverse reactions (≥ 3%) are upper respiratory daily, preferably with meals. Dose is to be reduced to 10 grams once daily for persistent phosphokinase, abdominal distension, and increased blood loose stools

DOSAGE FORMS AND STRENGTHS
Powder for oral solution:
- 280 grams of lactitol in multi-dose bottles
- 560 grams of lactitol in multi-dose bottles
- 10 grams of lactitol in unit-dose packets

SAFETY PROFILE

CONTRAINDICATIONS
- Mechanical gastrointestinal obstruction.
- Galactosemia.

ADVERSE REACTIONS
Most common adverse reactions: upper respiratory tract infection, flatulence, diarrhea, increased blood creatinine phosphokinase, abdominal distension, and increased blood pressure.

DRUG INTERACTIONS
- Other oral medications: Pizensy™ may reduce the absorption of concomitantly administered oral medications. Administer oral medications at least 2 hours before or 2 hours after Pizensy™.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or effectiveness observed between geriatric and younger patients.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Vyepti™ (eptinezumab-jjmr) Injection, for intravenous use	Lundbeck Seattle BioPharmaceuticals, Inc.	02/21/2020

THERAPEUTIC CLASS
Antimigraine; Calcitonin gene-related peptide (CGRP) antagonist

FDA-APPROVE INDICATION(S)
Vyepti™ is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults.

DOSAGE AND ADMINISTRATION
The recommended dose is 100 mg as an intravenous infusion over approximately 30 minutes every 3 months. Some patients may benefit from a dosage of 300 mg. Of note, must be diluted before use.

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

SAFETY PROFILE

CONTRAINDICATIONS
- Serious hypersensitivity to eptinezumab-jjmr or to any of the excipients.

WARNINGS AND PRECAUTIONS
- Hypersensitivity reactions: Have occurred. If a hypersensitivity reaction occurs, consider discontinuing and initiate appropriate therapy.

ADVERSE REACTIONS
Most common adverse reactions: nasopharyngitis and hypersensitivity.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Nexletol™ (bempedoic acid) Tablets, for oral use	Esperion Therapeutics, Inc.	02/21/2020

THERAPEUTIC CLASS
Antihyperlipidemic; Cardiovascular agent

FDA-APPROVE INDICATION(S)
Nexletol™ is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

DOSAGE AND ADMINISTRATION
The recommended dose is 180 mg orally once daily with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 180 mg.

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Hyperuricemia: Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.
- Tendon rupture: Tendon rupture has occurred. Discontinue at the first sign of tendon rupture. Avoid in patients who have a history of tendon disorders or tendon rupture.

ADVERSE REACTIONS
Most common adverse reactions: upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.

DRUG INTERACTIONS
- Simvastatin: Concomitant use causes an increase in simvastatin concentration and may increase the risk of simvastatin-related myopathy. Avoid concomitant use of Nexletol™ with simvastatin greater than 20 mg.

DRUG INTERACTIONS (continuation)
- Pravastatin: Concomitant use causes an increase in pravastatin concentration and may increase the risk of pravastatin-related myopathy. Avoid concomitant use of Nexletol™ with pravastatin greater than 40 mg.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on mechanism of action, may cause fetal harm. Discontinue Nexletol™ when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus.
- Lactation: Breastfeeding is not recommended.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or effectiveness observed between geriatric and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.
- Renal impairment: No dose adjustment necessary in for mild or moderate renal impairment. There is limited experience with severe renal impairment and Nexletol™ has not been studied in patients with end-stage renal disease (ESRD) receiving dialysis.
- Hepatic impairment: No dose adjustment necessary for mild or moderate hepatic impairment. Nexletol™ has not been studied in patients with severe hepatic impairment.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Nexlizet™ (bempedoic acid and ezetimibe) tablets, for oral use	Esperion Therapeutics, Inc.	02/26/2020

THERAPEUTIC CLASS
Antihyperlipidemic; Cardiovascular agent

FDA-APPROVE INDICATION(S)
Nexlizet™ is a combination of an adenosine triphosphate-citrate lyase (ACL) inhibitor and a cholesterol absorption inhibitor, indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

DOSAGE AND ADMINISTRATION
The recommended dose is one tablet (180 mg bempedoic acid and 10 mg ezetimibe) orally once daily with or without food. Note: If co-administered with bile acid sequestrants (BAS), administer at least 2 hours before or at least 4 hours after BAS.

DOSAGE FORMS AND STRENGTHS
Tablets: 180 mg bempedoic acid/10 mg ezetimibe.

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Hyperuricemia: Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.
- Tendon rupture: Tendon rupture has occurred. Discontinue at the first sign of tendon rupture. Avoid in patients who have a history of tendon disorders or tendon rupture.

ADVERSE REACTIONS
Most common adverse reactions: upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes, diarrhea, arthralgia, sinusitis, fatigue, and influenza.

DRUG INTERACTIONS
- Simvastatin: Concomitant use causes an increase in simvastatin concentration and may increase the risk of simvastatin-related myopathy. Avoid concomitant use of Nexlizet™ with simvastatin greater than 20 mg.

DRUG INTERACTIONS (continuation)
- Pravastatin: Concomitant use causes an increase in pravastatin concentration and may increase the risk of pravastatin-related myopathy. Avoid concomitant use of Nexlizet™ with pravastatin greater than 40 mg.
- Cyclosporine: Concomitant use increases ezetimibe and cyclosporine concentrations. Monitor cyclosporine concentrations.
- Fibrates: Both fenofibrate and ezetimibe may increase cholesterol excretion into the bile, leading to cholelithiasis. Co-administration of Nexlizet™ with fibrates other than fenofibrate is not recommended. If cholelithiasis is suspected in a patient receiving Nexlizet™ and fenofibrate, consider alternative lipid-lowering therapy.
- Cholestyramine: Concomitant use decreases ezetimibe
- concentration. This may result in a reduction of efficacy. Administer Nexlizet™ either at least 2 hours before or at least 4 hours after BAS.

USE IN SPECIFIC POPULATIONS
Same precautions as with Nexletol™ (bempedoic acid). See page 6).

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Barhemsys™ (amisulpride) injection, for intravenous use	Acacia Pharma LTD	02/26/2020

THERAPEUTIC CLASS
Dopaminergic agent

FDA-APPROVE INDICATION(S)
Barhemsys™ is a dopamine-2 (D2) antagonist indicated in adults for:

- Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class.
- Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.

DOSAGE AND ADMINISTRATION

- For prevention: 5 mg as a single intravenous dose infused over 1 to 2 minutes at the time of induction of anesthesia.
- For treatment: 10 mg as a single intravenous dose infused over 1 to 2 minutes in the event of nausea and/or vomiting after a surgical procedure.

DOSAGE FORMS AND STRENGTHS
Injection: 5 mg/2 mL (2.5 mg/mL) in a single-dose vial.

SAFETY PROFILE

CONTRAINDICATIONS

- Known hypersensitivity to amisulpride.

WARNINGS AND PRECAUTIONS

- QT prolonation.

ADVERSE REACTIONS
Most common adverse reactions: increased blood prolactin concentrations, chills, hypokalemia, procedural hypotension, abdominal distension, and infusion site pain.

DRUG INTERACTIONS

- Dopamine agonists: Reciprocal antagonism of effects occurs between dopamine agonists (e.g. levodopa) and Barhemsys™. Avoid using levodopa with Barhemsys™.
- Drugs Prolonging the QT Interval: Barhemsys™ causes dose- and concentration-dependent QT prolongation. To avoid potential additive effects, avoid use in patients taking droperidol. ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval.

USE IN SPECIFIC POPULATIONS

- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or effectiveness observed between geriatric and younger patients. However, greater sensitivity of some older individuals cannot be ruled out. Amisulpride is known to be substantially excreted by the kidneys, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function.
- Renal impairment: No dose adjustment necessary for mild to moderate renal impairment. Avoid in patients with severe renal impairment.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Nurtec™ ODT (rimegepant) Orally Disintegrating Tablets, for sublingual or oral use	Biohaven Pharmaceutical Holding Company Ltd.	02/27/2020

THERAPEUTIC CLASS
Antimigraine; Calcitonin gene-related peptide (CGRP) antagonist

FDA-APPROVE INDICATION(S)
Nurtec™ ODT T is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults.

DOSAGE AND ADMINISTRATION
The recommended dose is 75 mg taken orally, as needed. The maximum dose in a 24-hour period is 75 mg. The safety of treating more than 15 migraines in a 30-day period has not been established.

DOSAGE FORMS AND STRENGTHS
Orally disintegrating tablets: 75 mg.

SAFETY PROFILE

CONTRAINDICATIONS
- History of hypersensitivity reaction to rimegepant, or to any of the components of Nurtec™ ODT.

WARNINGS AND PRECAUTIONS
- Hypersensitivity reactions: If a serious hypersensitivity reaction occurs, discontinue and initiate appropriate therapy. Severe hypersensitivity reactions have included dyspnea and rash, and can occur days after administration.

ADVERSE REACTIONS
Most common adverse reactions: nausea.

DRUG INTERACTIONS
- Strong CYP3A4 inhibitors: Concomitant administration results in a significant increase in rimegepant exposure. Avoid concomitant administration.
- Moderate CYP3A4 inhibitors: Concomitant administration may result in increased exposure of rimegepant. Avoid another dose within 48 hours when administered with a moderate CYP3A4 inhibitor.

DRUG INTERACTIONS
- Strong and Moderate CYP3A inducers: Concomitant administration can result in a significant reduction in rimegepant exposure, which may lead to loss of efficacy of Nurtec™ ODT. Avoid concomitant administration.
- Inhibitors of P-gp or BCRP: Concomitant administration may result in a significant increase in rimegepant

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: Clinical studies of did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Pemfexy™ (pemetrexed) Injection / Eagle Pharmaceuticals, Inc.	Antineoplastic agent; Folate analog metabolic inhibitor	• in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC). • as a single agent for the maintenance treatment of patients with locally advanced or metastatic non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. • as a single agent for the treatment of patients with recurrent, metastatic non-squamous NSCLC after prior chemotherapy (Limitations of use: Not indicated for the treatment of patients with squamous cell NSCLC). • in combination with cisplatin for the initial treatment, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.	02/08/2020	Pemfexy™ is a new formulation of pemetrexed that is ready-to-dilute, and comes to be a branded alternative to Alimta™. • Alimta™ is available as a lyophilized powder for injection that must be reconstituted and further dilution is required prior administration. • Pemfexy™ shares the same indications with Alimta™, as well as the limitations of use. Of note, Pemfexy™ received tentative approval in 2017, reflecting FDA's conclusion that the product met all required quality, safety and efficacy standards, but at the time was not eligible for marketing in the US because of existing patent protections.

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Twirla™ (ethinyl estradiol and levonorgestrel) Transdermal System / Agile Therapeutics, Inc.	Contraceptive	Contraception for use in women of reproductive potential with a BMI < 30 kg/m2 for whom a combined hormonal contraceptive is appropriate	02/14/2020	Twirla™ is a new dosage form of ethinyl estradiol and levonorgestrel. Specifically, Twirla™ is a transdermal system (TDS) designed to be used in a 28-days (4-weeks) cycle, with a new TDS applied and worn for 7 days for 3 consecutive weeks. No TDS is worn during week 4 (the TDS-free week).
Procysbi™ (cysteamine bitartrate) delayed-release granules / Horizon Pharma USA	Genitourinary agent	Treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older	02/14/2020	Procysbi™ is a new formulation of cysteamine bitartrate in delayed-release granules. Procysbi™ was already available as a delayed-release oral capsule formulation. • The granules and capsules share the same indication. Orphan status: Orphan.
Anjeso™ (meloxicam) Injection / Baudax Bio, Inc.	Analgesic	Management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics	02/20/2020	Anjeso™ is a new dosage form of meloxicam for intravenous (IV) use. Of note, Anjeso™ is the first IV formulation of meloxicam. Meloxicam was already available as a generic oral tablet and suspension, branded oral capsule (Vivlodex™), and branded orally disintegrating tablet (Qmiiz™ ODT). • The tablet, suspension, and Qmiiz™ ODT are approved for osteoarthritis (OA), rheumatoid arthritis (RA), and juvenile RA. • Vivlodex™ is only approved for OA.
Advil Dual Action (ibuprofen and acetaminophen) Tablets / Pfizer Inc.	Analgesic	Pain relief	02/28/2020	Advil Dual Action is an over-the-counter (OTC) fixed-dose combination of ibuprofen (the nonsteroidal anti-inflammatory drug (NSAID) contained in Advil) and acetaminophen (the active ingredient in Tylenol) for the relief of pain.

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date	Comments
Nerlynx™ (neratinib) Tablets / Puma Biotechnology, Inc.	Antineoplastic agent	Extended adjuvant treatment of early-stage, HER2-positive breast cancer	In combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting	02/25/2020	The approval was based on results of the Phase III NALA trial assessing progression-free survival (PFS) and overall survival (OS). Treatment with neratinib in combination with capecitabine resulted in a statistically significant improvement in PFS (HR: 0.76; 95% CI: 0.63, 0.93; p-value =0.0059) compared to treatment with lapatinib plus capecitabine. The PFS rate at 12 months was 29% (95% CI: 23, 35) for patients who received neratinib plus capecitabine versus 15% (95% CI: 10, 20) for patients who received lapatinib plus capecitabine; the PFS rate at 24 months was 12% (95% CI: 7, 18) versus 3% (95% CI: 1, 8), respectively. Median OS was 21 months (95% CI: 17.7, 23.8) for patients who received neratinib in combination with capecitabine compared to 18.7 months (95% CI: 15.5, 21.2) for patients who received lapatinib in combination plus capecitabine (HR: 0.88; 95% CI: 0.72, 1.07; p-value =0.2086).

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Date	Generic for:
Olopatadine Hydrochloride Ophthalmic Solution 0.7% (base) / Watson Laboratories, Inc.	Antihistamine	02/19/2020	Pazeo
Albuterol Sulfate Inhalation Aerosol 90 mcg/actuation / Perrigo Pharmaceuticals Company	Antiasthma	02/24/2020	ProAir HFA
Pyrimethamine Tablets, 25 mg / Cerovene, Inc.	Anti-infective agent	02/28/2020	Daraprim

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Viltolarsen / Nippon Shinyaku Co., Ltd.	02/07/2020	Treatment for: Duchenne Muscular Dystrophy	Viltolarsen is an antisense oliogonucleotide in development for the treatment of patients with Duchenne muscular dystrophy who are amenable to exon 53 skipping therapy. FDA granted priority review to NDA of viltolarsen and orphan drug designation.	High
Olinvo (oliceridine) Injection / Trevena, Inc.	02/10/2020	Treatment for: Pain	Olinvo (oliceridine) is a G protein biased ligand of the mu opioid receptor, a new class of opioid receptor modulator in development for the treatment of moderate-to-severe acute pain. NDA was re-submitted to the FDA.	Moderate
Ripretinib / Deciphera Pharmaceuticals, Inc.	02/12/2020	Treatment for: Gastrointestinal Stromal Tumor	Ripretinib is an investigational broad-spectrum KIT and PDGFRα inhibitor in development for the treatment of patients with advanced gastrointestinal stromal tumors (GIST). FDA granted priority review to NDA of ripretinib.	High
Lisocabtagene maraleucel / Bristol-Myers Squibb Company	02/13/2020	Treatment for: Large B-Cell Lymphoma	Lisocabtagene maraleucel (liso-cel) is an investigational chimeric antigen receptor (CAR) T-cell therapy in development for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL). FDA granted priority review to BLA of lisocabtagene maraleucel.	High
Lurbinectedin / PharmaMar and Jazz Pharmaceuticals plc	02/17/2020	Treatment for: Small Cell Lung Cancer	Lurbinectedin is a selective inhibitor of oncogenic transcription in development for the treatment of relapsed small cell lung cancer. FDA granted priority review to NDA of lurbinectedin.	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)