



**PHARMACY
VISION
20/20**

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Disneyland
RESORT

NEW DRUGS – PART 2

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DISCLOSURE

Doris Kao and Susan Lee declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

LEARNING OBJECTIVES

At the completion of this activity, the **pharmacist** will be able to:

1. Describe selected new drug approvals and trends at the Food and Drug Administration (FDA) in 2019 and 2020.
2. Differentiate between the four new drugs approved to treat migraines.
3. Understand the role in therapy of recently approved infectious disease agents.

At the completion of this activity, the **pharmacy technician** will be able to:

1. List four or more new drug approvals by the FDA in 2019 and 2020.
2. Name two new drugs approved to treat complicated urinary tract infections.
3. Name two new drugs approved to treat Parkinson's Disease.

U.S. APPROVAL PATHWAYS FOR DRUGS & BIOLOGICS

Food Drug & Cosmetic Act (FDC)

Traditional Drugs

NDA

505(b) of FDC Act

- Phase 1, 2, 3 studies
- Phase 3 for each new indication

Generics

abbreviated

aNDA

505(j) of FDC Act

- Bioequivalence data

Public Health Service Act (PHS)

Biologics

BLA

351(a) of PHS Act

- Phase 1, 2, 3 studies
- Phase 3 for each new indication

Biosimilars

abbreviated

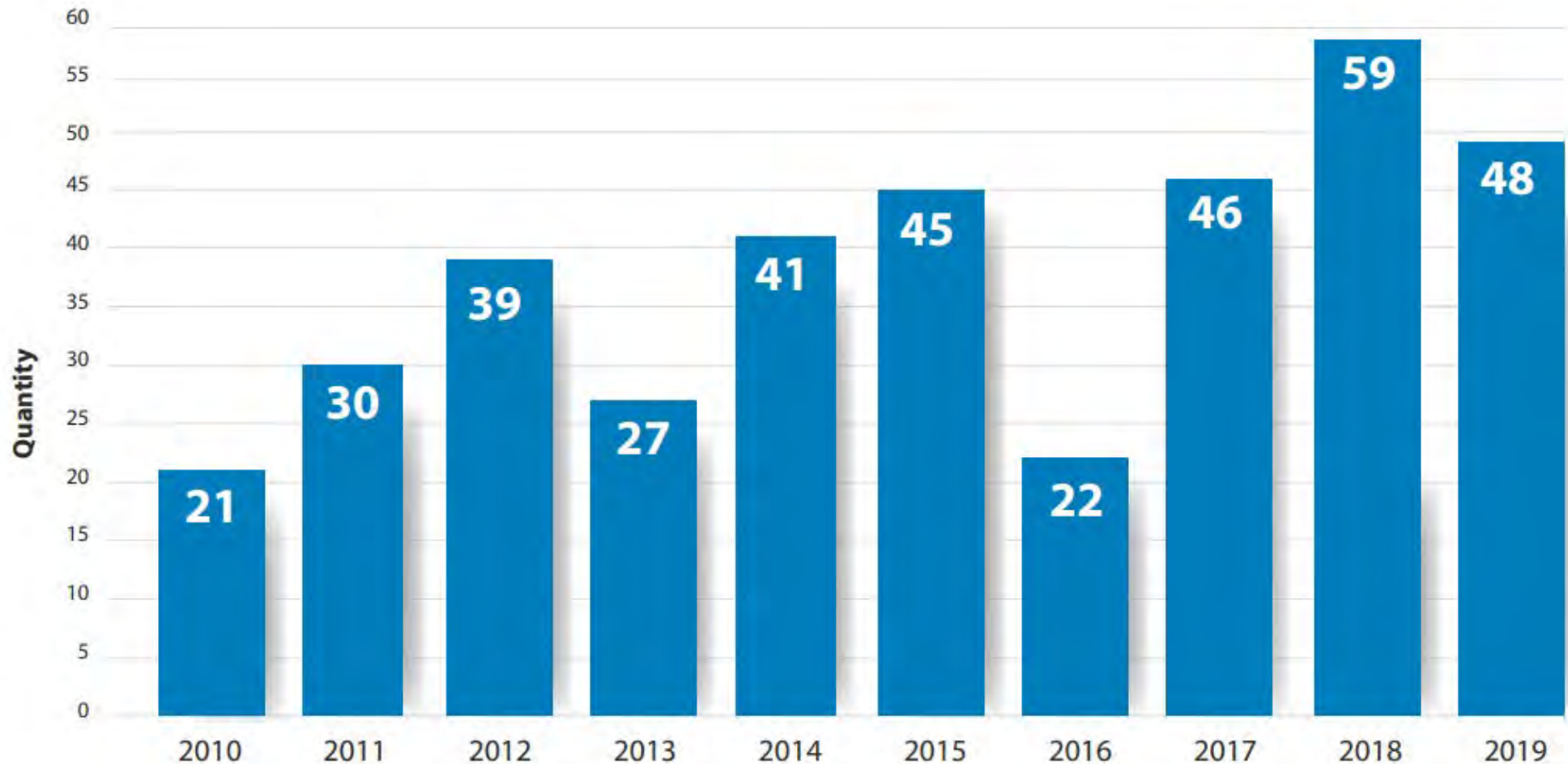
aBLA

351(k) of PHS Act

- Analytical studies
- Animal studies
- Clinical trials

NDA = New Drug Application, BLA = Biologics License Application

ANNUAL NOVEL DRUG APPROVALS: 2010 – 2019



EXPEDITED FDA APPROVAL PATHWAYS

60% of novel drugs had ≥ 1 method of expedited approval in 2019



Fast Track

35% – Drugs to treat serious conditions and **fill an unmet medical need**



Accelerated Approval

19% – Drugs for serious conditions that fill an unmet medical need; Approval **based on surrogate endpoints**



Priority Review

58% – Drugs with significant improvements over available therapies; FDA action on application **within 6 months**



Breakthrough Therapy

27% – Drugs which may **demonstrate substantial improvement** over available therapies



NOVEL DRUG APPROVALS

DRUGS TO BE COVERED (BY THERAPEUTIC CLASS)

Cardiology

bempedoic acid (Nexletol)

Infectious Diseases

artesunate (Artesunate)

cefiderocol (Fetroja)

imipenem, cilastatin,

and relebactam (Recarbrio)

lefamulin (Xenleta)

pretomanid (Pretomanid)

Endocrinology

osilodrostat (Isturisa)

Neurology

cenobamate (Xcopri)

eptinezumab (Vyepi)

golodirsen (Vyondys 53)

istradefylline (Nourianz)

lasmiditan (Reyvow)

opicapone (Ongentys)

ozanimod (Zeposia)

pitolisant (Wakix)

rimegepant (Nurtec ODT)

ubrogepant (Ubrelvy)

Gastroenterology

amisulpride (Barhemsys)

lactitol (Pizensy)

Ophthalmology

teprotumumab (Tepezza)

Psychiatry

lemborexant (Dayvigo)

lumateperone tosylate (Caplyta)

Rheumatology

upadacitinib (Rinvoq)

PITOLISANT (WAKIX)

4.45 MG AND 17.8 MG ORAL TABLETS

- **Indication:** Treatment of **excessive daytime sleepiness (EDS)** in adult patients with narcolepsy
- **Drug class:** Histamine-3 (H3) receptor antagonist/inverse agonist
- **Dose:** 17.8 mg to 35.6 mg once daily, administered in the morning upon awakening
 - Dose adjustment for hepatic and renal impairment, and poor metabolizers of CYP2D6
 - May take up to 8 weeks to achieve a clinical response
- **Contraindications:** Severe hepatic impairment
- **Warnings:** QT interval prolongation
- **Adverse drug events (ADEs):** Insomnia, nausea, anxiety

LEMBOREXANT (DAYVIGO)

5 AND 10 MG ORAL TABLETS

- **Indication:** Treatment of adult patients with **insomnia**, characterized by difficulties with sleep onset and/or sleep maintenance
- **Drug class:** Orexin receptor antagonist
- **Dose:** 5 mg taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening
 - Maximum recommended dose is 10 mg once daily
- **Contraindications:** Narcolepsy
- **Warnings:** Central nervous system depressant effects and daytime impairment; sleep paralysis, hypnagogic/hypnopompic hallucinations, cataplexy-like symptoms; complex sleep behaviors; compromised respiratory function; worsening of depression/suicidal ideation; need to evaluate for comorbid diagnoses
- **ADEs:** Somnolence

LUMATEPERONE (CAPLYTA)

42 MG ORAL CAPSULES

- **Indication:** Treatment of **schizophrenia** in adults
- **Drug class:** Atypical antipsychotic
- **Dose:** 42 mg once daily with food (no dose titration required)
- **Boxed warnings:** Increased mortality in elderly patients with dementia-related psychosis
- **Warnings:** Cerebrovascular adverse reactions in elderly patients with dementia-related psychosis; neuroleptic malignant syndrome; tardive dyskinesia; metabolic changes; leukopenia, neutropenia, agranulocytosis; orthostatic hypotension and syncope; seizures; potential for cognitive and motor impairment
- **ADEs:** Somnolence/sedation, dry mouth

QUESTION 1

Which of the following is FALSE?

- A) Pitolisant (Wakix) is approved for treatment of excessive daytime sleepiness in patients with narcolepsy.
- B) Lemborexant (Dayvigo) is approved for the treatment of narcolepsy.
- C) Lumateperone (Caplyta) is approved for the treatment of schizophrenia in adults.

QUESTION 1

Which of the following is FALSE?

- A) Pitolisant (Wakix) is approved for treatment of excessive daytime sleepiness in patients with narcolepsy.
- B) Lemborexant (Dayvigo) is approved for the treatment of narcolepsy.
- C) Lumateperone (Caplyta) is approved for the treatment of schizophrenia in adults.

Lemborexant

Indication: Treatment of adult patients with **insomnia**, characterized by difficulties with sleep onset and/or sleep maintenance

Contraindications: Narcolepsy

LASMIDITAN (REYVOW)

50 MG AND 100 MG ORAL TABLETS, SCHEDULE V CONTROLLED SUBSTANCE (CV)

- **Indication:** **Acute** treatment of **migraine** with or without aura in adults
 - Limitations of use: Not indicated for the preventive treatment of migraine
- **Drug class:** Serotonin (5-HT) 1F receptor agonist
- **Dose:** 50 mg, 100 mg, or 200 mg, as needed
 - No more than 1 dose in 24 hours
 - Safety of treating more than 4 migraines in a 30-day period has not been established
- **Warnings:** Driving impairment (patients should not drive or operate machinery for at least 8 hours after a dose), central nervous system depression, serotonin syndrome, medication overuse headache
- **ADEs:** Dizziness, fatigue, paresthesia, sedation

UBROGEPANT (UBRELVY)

50 MG AND 100 MG ORAL TABLETS

- **Indication:** **Acute** treatment of **migraine** with or without aura in adults
 - Limitations of use: Not indicated for the preventive treatment of migraine
- **Drug class:** Calcitonin gene-related peptide (CGRP) receptor antagonist
- **Dose:** 50 mg or 100 mg, as needed
 - If needed, a second dose may be administered at least 2 hours after the initial dose
 - Maximum dose in a 24-hour period is 200 mg
 - Safety of treating more than 8 migraines in a 30-day period has not been established
- **Contraindications:** Concomitant use with strong CYP3A4 inhibitors
- **Interactions:** Avoid use with strong CYP3A4 inducers, end-stage renal disease
- **ADEs:** Nausea and somnolence

RIMEGEPANT (NURTEC ODT)

75 MG ORALLY DISINTEGRATING TABLETS

- **Indication:** **Acute** treatment of **migraine** with or without aura in adults
 - Limitations of use: Not indicated for the preventive treatment of migraine
- **Drug class:** CGRP receptor antagonist
- **Dose:** 75 mg, as needed
 - No more than 1 dose in 24 hours
 - Safety of treating more than 15 migraines in a 30-day period has not been established
- **Contraindications/warnings:** Hypersensitivity reactions
- **Interactions:** Avoid use with strong or moderate CYP3A4 inhibitors, strong or moderate CYP3A4 inducers, inhibitors of P-gp or BCRP, severe hepatic impairment, or end-stage renal disease
- **ADEs:** Nausea

EPTINEZUMAB (VYEPTI)

100 MG/ML IN SINGLE-DOSE VIAL

- **Indication:** **Preventive** treatment of **migraine** in adults
- **Drug class:** CGRP receptor antagonist
- **Dose:** 100 mg as an IV infusion over 30 minutes every 3 months
 - Some patients may benefit from a 300 mg dose every 3 months
- **Contraindications:** Hypersensitivity to eptinezumab or to any of the excipients
 - Reactions have included angioedema
- **Warnings:** Hypersensitivity reactions
- **ADEs:** Nasopharyngitis and hypersensitivity reactions

QUESTION 2

Which of the following is TRUE for the migraine treatment drugs?

- A) Lasmiditan is a Schedule IV controlled substance.
- B) A second dose of ubrogepant or rimegepant may be taken 2 hours after the initial dose if patients do not experience sufficient pain relief.
- C) Eptinezumab and ubrogepant are CGRP inhibitors for the acute treatment of migraine.
- D) Rimegepant is available as an orally disintegrating tablet.

QUESTION 2

Which of the following is TRUE for the migraine treatment drugs?

A) Lasmiditan is a Schedule IV controlled substance.

Lasmiditan is a *Schedule V* controlled substance

B) A second dose of ubrogepant or rimegepant may be taken 2 hours after the initial dose if patients do not experience sufficient pain relief.

A second dose is only allowed for *ubrogepant*

C) Eptinezumab and ubrogepant are CGRP inhibitors for the acute treatment of migraine.

Eptinezumab is for the *preventive* treatment of migraine

D) Rimegepant is available as an orally disintegrating tablet.

LEFAMULIN (XENLETA)

600 MG TABLETS; 150 MG/15 ML IN SINGLE-DOSE VIAL

- **Indication:** Treatment of adults with **community-acquired bacterial pneumonia (CABP)** caused by susceptible microorganisms
- **Drug class:** Semi-synthetic pleuromutilin antibacterial
- **Dose:** 150 mg every 12 hours by IV infusion over 60 mins* for 5-7 days or 600 mg PO every 12 hours x 5 days
 - *Option to switch to oral treatment after 3 days of IV
 - Take at least 1 hour before a meal or 2 hours after a meal
- **Warnings:** QT prolongation, embryo-fetal toxicity, *Clostridium difficile*-associated diarrhea
- **ADEs:** Site reactions, hepatic enzyme elevation, diarrhea, nausea, hypokalemia, insomnia, headache, vomiting

CEFIDEROCOL (FETROJA)

1 GRAM IN SINGLE-DOSE VIAL

- **Indication:** **Complicated urinary tract infections (cUTI)**, including pyelonephritis caused by susceptible Gram-negative microorganisms in patients ≥ 18 years who have limited or no alternative treatment options
- **Drug class:** Novel siderophore cephalosporin antibacterial
- **Dose:** 2 grams every 8 hours by IV infusion over 3 hours
 - Dose adjustments required for $CL_{cr} < 60$ mL/min and for $CL_{cr} \geq 120$ mL/min
- **Warnings:** Increase in all-cause mortality in patients with carbapenem-resistant gram-negative bacterial infection, hypersensitivity reactions, *Clostridioides difficile*-associated diarrhea, seizures and other central nervous system (CNS) adverse reactions
- **ADEs:** Diarrhea, infusion site reactions, constipation, rash, candidiasis, cough, elevations in liver tests, headache, hypokalemia, nausea, and vomiting

IMIPENEM, CILASTATIN, AND RELEBACTAM (RECARBRIO)

1.25 GRAMS IN SINGLE-DOSE VIAL (IMIPENEM 500 MG, CILASTATIN 500 MG, RELEBACTAM 250 MG)

- **Indication:** Patients ≥ 18 years for the treatment of the following infections caused by susceptible gram-negative microorganisms:
 - **Hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia (HABP/VABP)**
 - **cUTI**, including pyelonephritis, and **complicated intra-abdominal infections (cIAI)**, in patients who have limited or no alternative treatment options
- **Dose:** 1.25 grams IV infusion over 30 mins every 6 hrs with $CL_{cr} \geq 90$ mL/min; adjust dose for renal impairment
- **Warnings:** Hypersensitivity reactions, seizures and CNS adverse reactions, \uparrow seizure potential due to interaction w/valproic acid, *Clostridium difficile*-associated diarrhea
- **ADEs (selected):** \uparrow alanine aminotransferase, \uparrow aspartate aminotransferase, diarrhea

QUESTION 3

True/False:

Cefiderocol (Fetroja) and imipenem, cilastatin, and relebactam (Recarbrio) are both IV infusions with FDA-approved indications for treating complicated urinary tract infections (cUTIs).

QUESTION 3

True/False:

Cefiderocol (Fetroja) and imipenem, cilastatin, and relebactam (Recarbrio) are both IV infusions with FDA-approved indications for treating complicated urinary tract infections (cUTIs).

ARTESUNATE

110 MG POWDER IN SINGLE-DOSE VIAL

- **Indication:** Initial treatment of **severe malaria** in adult and pediatric patients
 - Should always be followed by a complete treatment course of an appropriate oral antimalarial regimen
 - Limitations of use
 - Will not prevent relapses of malaria due to *Plasmodium vivax* or *ovale*
 - Concomitant therapy with antimalarial necessary for treatment of severe malaria due to *P. vivax* or *P. ovale*
- **Dose:** 2.4 mg/kg administered IV (as slow bolus over 1-2 mins) at 0 hrs, 12 hrs, and 24 hrs, and then once daily until patient able to tolerate oral antimalarial therapy
- **Warnings:** Post-treatment hemolysis, hypersensitivity
- **ADEs:** Acute renal failure requiring dialysis, hemoglobinuria, jaundice

PRETOMANID

200 MG ORAL TABLETS

- **Indication:** As part of a combination regimen with bedaquiline and linezolid for treatment of adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) **tuberculosis**
 - Approval based on limited clinical safety and efficacy data; for use in a limited and specific population of patients. Limitations of use: See package insert.
 - Approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs
- **Dose:** 200 mg PO once daily for 26 weeks with bedaquiline and linezolid (with food)
- **Warnings:** Hepatic adverse reactions, myelosuppression, peripheral and optic neuropathy, QT prolongation, reproductive effects, lactic acidosis
- **ADEs (selected):** Peripheral neuropathy, acne, anemia, nausea, vomiting, headache, ↑ transaminases

ISTRADEFYLLINE (NOURIANZ)

20 AND 40 MG ORAL TABLETS

- **Indication:** **Adjunctive** treatment to levodopa/carbidopa in adult patients with **Parkinson's disease (PD)** experiencing “off” episodes
- **Drug class:** Adenosine A_{2A} receptor antagonist
- **Dose:** 20 mg once daily with or without food
 - Maximum: 40 mg once daily
 - Patients who smoke ≥ 20 cigarettes/day or equivalent: 40 mg
 - Patients with hepatic impairment: 20 mg
- **Warnings:** Dyskinesia, hallucinations/psychotic behavior, impulse control/compulsive behaviors
- **ADEs:** Dyskinesia, dizziness, constipation, nausea, hallucination, and insomnia

OPICAPONE (ONGENTYS)

25 MG AND 50 MG ORAL TABLETS

- **Indication:** **Adjunctive** treatment to levodopa/carbidopa in patients with **PD** experiencing “off” episodes
- **Drug class:** Catechol-O-methyltransferase (COMT) inhibitor
- **Dose:** 50 mg once daily at bedtime
 - No food for 1 hour before and for at least 1 hour after taking opicapone
- **Contraindications:** Concomitant use of non-selective MAO inhibitors; history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms
- **Warnings:** Cardiovascular effects with concomitant use of drugs metabolized by COMT, falling asleep during activities of daily living, hypotension/syncope, dyskinesia, hallucinations/psychosis, impulse control/compulsive disorders, withdrawal-emergent hyperpyrexia and confusion
- **ADEs:** Dyskinesia, constipation, blood creatine kinase increased, hypotension/syncope, and weight decreased

OZANIMOD (ZEPOSIA)

0.23 MG, 0.46 MG, AND 0.92 MG ORAL TABLETS

- **Indication:** Treatment of **relapsing forms of multiple sclerosis (MS)**, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- **Drug class:** Sphingosine 1-phosphate receptor modulator
- **Dose:** 0.92 mg once daily; requires a 7-day titration period
- **Contraindications:** In the last 6 months, myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure (HF) requiring hospitalization, or Class III or IV HF; presence of Mobitz type II second- or third-degree AV block, sick sinus syndrome, or sino-atrial block; severe untreated sleep apnea; concomitant use of a MAO inhibitor
- **Warnings:** Infections, bradyarrhythmia and atrioventricular conduction delays, liver injury, fetal risk, increased blood pressure, respiratory effects, macular edema
- **ADEs:** Upper respiratory infection, hepatic transaminase elevation, orthostatic hypotension, urinary tract infection, back pain, and hypertension

QUESTION 4

Which of the following is TRUE?

- A) Istradefylline is an adenosine receptor antagonist approved for Parkinson's disease
- B) Ozanimod is a COMT inhibitor approved for Parkinson's disease
- C) Opicapone is a sphingosine 1-phosphate receptor modulator approved for multiple sclerosis
- D) Pitolisant is a histamine-3 receptor antagonist/inverse agonist approved for multiple sclerosis

QUESTION 4

Which of the following is TRUE?

- A) Istradefylline is an adenosine receptor antagonist approved for Parkinson's disease
- B) Ozanimod is a COMT inhibitor approved for Parkinson's disease
- C) Opicapone is a sphingosine 1-phosphate receptor modulator approved for multiple sclerosis
- D) Pitolisant is a histamine-3 receptor antagonist/inverse agonist approved for multiple sclerosis

BEMPEDOIC ACID (NEXLETOL)

180 MG ORAL TABLETS

- **Indication:** Adjunct to diet and maximally tolerated statin therapy for treatment of adults with **heterozygous familial hypercholesterolemia** or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C
 - Limitations of use: Effect on cardiovascular morbidity/mortality has not been determined
- **Drug class:** First-in-class adenosine triphosphate (ATP)-citrate lyase inhibitor that inhibits cholesterol synthesis in liver
- **Dose:** 180 mg orally once daily with or without food
- **Warnings:** Hyperuricemia, tendon rupture
- **ADEs:** Upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes
- **Interactions:** Avoid concomitant use with simvastatin > 20 mg or pravastatin > 40 mg

OSILODROSTAT (ISTURISA)

1 MG, 5 MG, 10 MG ORAL TABLETS

- **Indication:** Treatment of adult patients with **Cushing's disease** for whom pituitary surgery is not an option or has not been curative
- **Drug class:** Inhibits 11-beta-hydroxylase enzyme to prevent cortisol synthesis
- **Dose:** Initiate at 2 mg PO BID; titrate by 1 to 2 mg BID, no more frequently than every 2 weeks based on rate of cortisol changes, individual tolerability and improvement in signs and symptoms. Max recommended dosage is 30 mg BID.
 - Correct hypokalemia and hypomagnesemia, and obtain baseline electrocardiogram prior to therapy initiation
- **Warnings:** Hypocortisolism, QTc prolongation, elevations in adrenal hormone precursors and androgens
- **ADEs:** Adrenal insufficiency, fatigue, nausea, headache, edema

TEPROTUMUMAB (TEPEZZA)

500 MG LYOPHILIZED POWDER IN SINGLE-DOSE VIAL

- **Indication:** Treatment of **thyroid eye disease**
- **Drug class:** Insulin-like growth factor-1 receptor inhibitor
- **Dose:** 10 mg/kg for first IV infusion, followed by 20 mg/kg every 3 weeks for 7 additional IV infusions
 - Administer IV infusion over 60-90 mins
- **Warnings:** Infusion reactions, exacerbation of preexisting inflammatory bowel disease, hyperglycemia
- **ADEs:** Muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dry skin, dysgeusia, and headache

UPADACITINIB (RINVOQ)

15 MG EXTENDED-RELEASE ORAL TABLETS

- **Indication:** Treatment of adults with **moderately to severely active rheumatoid arthritis** who have had an inadequate response or intolerance to methotrexate
 - Limitations of use: Use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants is not recommended
- **Drug class:** Janus kinase (JAK) inhibitor
- **Dose:** 15 mg once daily with or without food
 - May be used as monotherapy or in combination with methotrexate or other nonbiologic DMARDs
- **Boxed warnings:** Serious infections, malignancy, and thrombosis
- **Warnings:** Serious infections, malignancy, thrombosis, GI perforations, lab monitoring (lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids), embryo-fetal toxicity, avoid live vaccines
- **ADEs:** Upper respiratory tract infections, nausea, cough, and pyrexia

QUESTION 5

Which of the following is FALSE?

- A) Concomitant statin use should be assessed with bempedoic acid.

- B) Upadacitinib should be considered before methotrexate for rheumatoid arthritis.

QUESTION 5

Which of the following is FALSE?

A) Concomitant statin use should be assessed with bempedoic acid.

DDIs: Avoid concomitant use with simvastatin > 20 mg or pravastatin > 40 mg

B) Upadacitinib should be considered before methotrexate for rheumatoid arthritis.

Indication: Treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate

LACTITOL (PIZENSY)

280 GRAMS, 560 GRAMS (MULTI-DOSE BOTTLES), 10 GRAMS (UNIT-DOSE PACKETS)
FOR ORAL SOLUTION

- **Indication:** Treatment of **chronic idiopathic constipation (CIC)** in adults
- **Drug class:** Osmotic laxative; simple monosaccharide sugar alcohol
- **Dose:** 20 grams orally once daily, preferably with meals; reduce to 10 grams once daily for persistent loose stools
 - Administer oral medications at least 2 hours before or 2 hours after lactitol
- **Contraindications:** Mechanical gastrointestinal obstruction, galactosemia
- **ADEs:** Upper respiratory tract infection, flatulence, diarrhea, ↑ blood creatinine phosphokinase, abdominal distention, ↑ blood pressure

AMISULPRIDE (BARHEMSYS)

5 MG/2 ML (2.5 MG/ML) IN SINGLE-DOSE VIAL

- **Indication:** In adults for **prevention of postoperative nausea and vomiting (PONV)**, either alone or in combination with an antiemetic of a different class, and **treatment of PONV** in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis
- **Drug class:** Dopamine-2 (D2) antagonist
- **Dose:** PONV prevention: 5 mg as a single IV dose infused over 1 to 2 mins at the time of induction of anesthesia; PONV treatment: 10 mg as a single IV dose infused over 1 to 2 mins in the event of nausea and/or vomiting after a surgical procedure
- **Warnings:** QT prolongation
- **ADEs:** PONV prevention: increased blood prolactin concentrations, chills, hypokalemia, procedural hypotension, and abdominal distension; PONV treatment: infusion site pain

GOLODIRSEN (VYONDYS 53)

100 MG/2 ML (50 MG/ML) IN SINGLE-DOSE VIAL

- **Indication:** Treatment of **Duchenne muscular dystrophy (DMD)** in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping (*accelerated approval* based on increase in dystrophin production in skeletal muscle observed)
 - Continued approval may be contingent upon verification of a clinical benefit in confirmatory trials
- **Drug class:** Antisense oligonucleotide
- **Dose:** 30 milligrams per kilogram once weekly as IV infusion over 35 to 60 minutes
- **Warnings:** Hypersensitivity reactions, renal toxicity
- **ADEs:** Headache, pyrexia, fall, abdominal pain, nasopharyngitis, cough, vomiting, and nausea

CENOBAMATE (XCOPRI)

12.5 MG, 25 MG, 50 MG, 100 MG, 150 MG, AND 200 MG ORAL TABLETS, CV

- **Indication:** Treatment of **partial-onset seizures** in adult patients
- **Drug class:** Broad-spectrum anticonvulsant - Primary effects through inhibition of voltage-gated sodium currents and positive modulation of GABA_A ion channels
- **Dose:** Initially 12.5 mg once daily, titrated to maintenance dose of 200 mg once daily
 - Maximum dose is 400 mg once daily
- **Contraindications:** Hypersensitivity to cenobamate, familial short QT syndrome
- **Warnings:** Drug reaction with eosinophilia and systemic symptoms (DRESS)/multi-organ hypersensitivity, QT shortening, suicidal behavior and ideation, neurological adverse reactions, withdrawal of antiepileptic drugs
- **ADEs:** Somnolence, dizziness, fatigue, diplopia, and headache

DRUGS COVERED (BY THERAPEUTIC CLASS)

Cardiology

bempedoic acid (Nexletol)

Infectious Diseases

artesunate (Artesunate)

cefiderocol (Fetroja)

imipenem, cilastatin,

and relebactam (Recarbrio)

lefamulin (Xenleta)

pretomanid (Pretomanid)

Endocrinology

osilodrostat (Isturisa)

Neurology

cenobamate (Xcopri)

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golodirsen (Vyondys 53)

istradefylline (Nourianz)

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opicapone (Ongentys)

ozanimod (Zeposia)

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Gastroenterology

amisulpride (Barhemsys)

lactitol (Pizensy)

Ophthalmology

teprotumumab (Tepezza)

Psychiatry

lemborexant (Dayvigo)

lumateperone tosylate (Caplyta)

Rheumatology

upadacitinib (Rinvoq)

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**SESSION
CODE:**



**PHARMACY
VISION
20/20**

CSHP SEMINAR 20 • OCTOBER 21-25
Disneyland
RESORT