

# New Drug Update 2019

Natalea Braden-Suchy, PharmD, BCACP  
OSU College of Pharmacy

0

## Conflict of Interest

- I have no conflict of interest to declare

1

## Objectives

- Discuss new pharmacotherapy choices
- Describe indications, mechanism of action, common adverse effects and significant drug interactions for these products
- Highlight safety concerns with selected new choices
- Compare selected new choices with established therapies

OREGON STATE UNIVERSITY 2

2

## Assessment Question

1. Which of the following medications is a novel drug for postpartum depression?
  - a) Zulresso
  - b) Xolair
  - c) Zirabev

OREGON STATE UNIVERSITY 3

3

## Assessment Question

2. What is the indication for Wakix?
- a) Skin and skin structure infections
  - b) Hypoactive sexual desire disorder
  - c) Excessive daytime sleepiness

OREGON STATE UNIVERSITY 4

4

## Assessment Question

3. Which of the following medications has a black box warning for serious infections, malignancies and thrombosis?
- a) Yupelri
  - b) Rinvoq
  - c) Motegrity

OREGON STATE UNIVERSITY 5

5

## Assessment Question

4. Which of the following is/are purported benefit(s) of Jatenzo?
- a) Oral dosing
  - b) No inadvertent testosterone exposure
  - c) All of the above

OREGON STATE UNIVERSITY 6

6

## Our Agenda

- Novel agents
- New formulations and rebranding
- Biosimilars
- New combinations

OREGON STATE UNIVERSITY 7

7

# NOVEL AGENTS

8

## Yupelri (revefenacin)

- Indications: COPD
- Mechanism of action: Long-acting muscarinic antagonist
- Adverse effects: Nasopharyngitis, upper respiratory tract infection, headache, back pain

OREGON STATE UNIVERSITY 9

9

## Yupelri (revefenacin)

- Warnings/precautions:
  - Not for acute episodes
  - Paradoxical bronchospasm
  - Worsening of narrow-angle glaucoma
  - Worsening of urinary retention
  - Immediate hypersensitivity
- Drug interactions:
  - Anticholinergics
  - OATP1B1 and OATP1B3 inhibitors

OREGON STATE UNIVERSITY 10

10

## Motegrity (prucalopride)

- Indications: Chronic idiopathic constipation
- Mechanism of action: Serotonin-4 receptor agonist
- Contraindications
  - Hypersensitivity
  - Intestinal perforation or obstruction

OREGON STATE UNIVERSITY 11

11

## Motegrity (prucalopride)

- Warnings: Suicidal ideation
- Adverse effects: Headache, abdominal pain, nausea, diarrhea, distension, dizziness, vomiting, flatulence, fatigue
- Drug interactions: CYP3A4 inhibitors

OREGON STATE UNIVERSITY 12

12

## Sunosi (solriamfetol)

- Indications: Excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea
- Mechanism of action: Believed to be its activity as a dopamine and norepinephrine reuptake inhibitor
- Adverse effects: Decreased appetite, insomnia, anxiety, headache, palpitations, nausea, dry mouth, constipation

OREGON STATE UNIVERSITY 13

13

## Sunosi (solriamfetol)

- Warnings/precautions:
  - Increased blood pressure and heart rate
  - Psychiatric symptoms
- Drug interactions:
  - MAOIs
  - Dopaminergic drugs
  - Drugs that increase HR or BP

OREGON STATE UNIVERSITY 14

14

## Wakix (pitolisant)

- Indications: Excessive daytime sleepiness due to narcolepsy
- Mechanism of action: Possibly mediated by histamine-3 receptor antagonist activity
- 
- Adverse effects: Headache, insomnia, nausea, upper respiratory infections, musculoskeletal pain, anxiety, increased heart rate, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, rash

OREGON STATE UNIVERSITY 15

15



## Wakix (pitolisant)

- Warnings/precautions:
  - QT prolongation
- Drug interactions:
  - Strong CYP2D6 inhibitors
  - Strong CYP3A4 inducers
  - H1 blockers
  - Other medications that can increase QT intervals

OREGON STATE UNIVERSITY 16

16

## Skyrizi (risankizumab-rzaa)

- Indications: Moderate to severe plaque psoriasis
- Mechanism of action: Antibody that binds IL-23
- Adverse effects: Upper respiratory infections, headache, fatigue, injection site reactions, tinea infections

OREGON STATE UNIVERSITY 17

17

## Skyrizi (risankizumab-rzaa)

- Warnings/precautions: Infections
- Drug interactions: None reported

OREGON STATE UNIVERSITY 18

18

## Nourianz (istradefylline)

- Indications: Adjunct to levodopa/carbidopa for “off” episodes
- Mechanism of action: Unclear, but it is an adenosine A<sub>2a</sub> receptor antagonist
- Adverse effects: Dyskinesia, dizziness, constipation, nausea, diarrhea, hallucinations, insomnia, decreased appetite, upper respiratory infections, rash

OREGON STATE UNIVERSITY 19

19

## Nourianz (istradefylline)

- Warnings/precautions:
  - Dyskinesia
  - Psychiatric symptoms
- Drug interactions:
  - CYP3A4 inducers and inhibitors
  - P-gp substrates

OREGON STATE UNIVERSITY 20

20

## Rinvoq (upadacitinib)

- Indications: Moderate to severe rheumatoid arthritis who have tried methotrexate
- Mechanism of action: It is a Janus kinase inhibitor which affects the activation of Signal Transducers and Activators of Transcription
- Adverse effects: Upper respiratory infections, cough, pyrexia

OREGON STATE UNIVERSITY 21

21

## Rinvoq (upadacitinib)

- Warnings/precautions:
  - *Infections*
  - *Malignancy*
  - *Thrombosis*
  - GI perforation
  - Lab monitoring
  - Embryo-fetal toxicity
- Drug interactions: Strong CYP 3A4 inducers and inhibitors

OREGON STATE UNIVERSITY 22

22

## Accrufer (ferric maltol)

- Indications: Replacement in iron deficiency
- Contraindications:
  - Hypersensitivity
  - Hemochromatosis or other iron overload issues
  - Repeated blood transfusions
- Adverse effects: Gastrointestinal

OREGON STATE UNIVERSITY 23

23

## Accrufer (ferric maltol)

- Warnings/precautions:
  - Iron overload/poisoning
  - IBD flare
- Drug interactions:
  - Dimercaprol
  - No empirical data on any other medications

OREGON STATE UNIVERSITY 24

24

## Vyleesi (bremelanotide)

- Indications: Treatment of hypoactive sexual desire disorder in premenopausal women
- Mechanism of action: It is a melanocortin receptor agonist and there is expression of the receptors in the nervous system. However, how it has therapeutic effects is unknown

OREGON STATE UNIVERSITY 25

25

## Vyleesi (bremelanotide)

- Adverse effects: Nausea, flushing, injection site reactions, headache, vomiting, cough, fatigue, hot flush, paresthesia, dizziness, nasal congestion
- Warnings/precautions:
  - Increase in blood pressure and decrease in heart rate
  - Focal hyperpigmentation
  - Nausea

OREGON STATE UNIVERSITY 26

26

## Vyleesi (bremelanotide)

- Drug interactions:
  - May decrease gastric emptying
  - Naltrexone

OREGON STATE UNIVERSITY 27

27

## Xofluza (baloxavir marboxil)

- Indications: Acute uncomplicated influenza in those 12+ years of age
- Mechanism of action: Inhibits polymerase acidic protein which ultimately inhibits viral replication
- Adverse effects: Diarrhea, bronchitis, nausea, nasopharyngitis, headache

OREGON STATE UNIVERSITY 28

28

## Xofluza (baloxavir marboxil)

- Warnings/precautions: Bacterial infections
- Drug interactions:
  - Polyvalent cations
  - Vaccines

OREGON STATE UNIVERSITY 29

29

## Seysara (sarecycline)

- Indications: Non-nodular moderate to severe acne vulgaris in those 9 years or older
- Mechanism of action: Unknown
- Adverse Effects: Nausea, vulvovaginal infections

OREGON STATE UNIVERSITY 30

30

## Seysara (sarecycline)

- Warnings/precautions:
  - Discoloration of teeth
  - *Clostridium difficile*
  - CNS side effects
  - Intracranial hypertension
  - Photosensitivity

OREGON STATE UNIVERSITY 31

31



## Seysara (sarecycline)

- Drug interactions:
  - Oral retinoids
  - Antacids and iron
  - Penicillin
  - Anticoagulants
  - P-gp substrates

OREGON STATE UNIVERSITY 32

32

## Xenleta (lefamulin)

- Indications: Community acquired bacterial pneumonia in adults
- Mechanism of action: Binds to the 50S subunit to prevent replication
- Contraindications:
  - Hypersensitivity
  - Coadministration with CYP3A substrates that cause QT prolongation

OREGON STATE UNIVERSITY 33

33

## Xenleta (lefamulin)

- Warnings/precautions:
  - QT prolongation
  - Embryo-fetal toxicity
  - *Clostridium difficile*
- Adverse effects: Diarrhea, nausea, vomiting, elevations of hepatic enzymes

OREGON STATE UNIVERSITY 34

34

## Xenleta (lefamulin)

- Drug interactions
  - Moderate or strong inhibitors and inducers of CYP3A
  - Substrates of CYP3A
  - Moderate or strong inhibitors and inducers of P-gp

OREGON STATE UNIVERSITY 35

35

## Nuzyra (omadacycline)

- Indications: Community acquired bacterial pneumonia or acute bacterial skin/skin structure infections
- Contraindication: Hypersensitivity to tetracycline medications
- Mechanism of action: Binds 30S ribosomal subunit to prevent protein synthesis
- Adverse events: Increased liver enzymes, hypertension, insomnia, vomiting, constipation, nausea, headache

OREGON STATE UNIVERSITY 36

36

## Nuzyra (omadacycline)

- Warnings/precautions:
  - Mortality imbalance in CABP patients
  - Tooth discoloration and enamel hypoplasia
  - Inhibition of bone growth
  - *Clostridium difficile*
- Drug interactions:
  - Anticoagulants
  - Antacids and iron

OREGON STATE UNIVERSITY 37

37

## Other Interesting Approvals

- Infectious disease
  - Aemcolo (rifamycin) for traveler's diarrhea caused by non-invasive strains of *E. coli*
  - Pretomanid in combination with linezolid and bedaquiline for MDR tuberculosis
- Mental Health
  - Zulresso (brexanolone) injection for postpartum depression
  - Spravato (esketamine) nasal spray for treatment resistant depression

OREGON STATE UNIVERSITY 38

38

## Cancer Agents

- Vitakvi (larotrectinib sulfate): NTRK\*gene fusion positive solid tumors
- Xospata (gilteritinib fumarate): Acute myeloid leukemia with FLT3 mutations
- Daurismo (glasdegib maleate): Acute myeloid leukemia
- Lobrena (loratinib): Metastatic non-small cell lung cancer (ALK+)
- Piqray (alpelisib): Advanced or metastatic breast cancer (HR+, HER2-, PIK3CA mutated)

OREGON STATE UNIVERSITY 39

39

## Cancer Agents

- Zykadia (ceritinib): Metastatic non-small cell lung cancer (ALK+)
- Balversa (erdafatinib): Locally advanced or metastatic urothelial carcinoma
- Talzenna (talazoparib): Locally advanced or metastatic breast CA (HER2- and abnormal BRCA gene)
- Xpovio (selinexor): Relapsed or refractory multiple myeloma
- Nubeqa (darolutamide): Non-metastatic castration-resistant prostate cancer

OREGON STATE UNIVERSITY 40

40

## Cancer agents

- Turalio (pexidartinib): Tenosynovial giant cell tumor
- Rozlytrek (entrectinib): Non-small cell lung cancer (ROS1+) or solid tumors with NTRK fusion

OREGON STATE UNIVERSITY 41

41

# NEW FORMULATIONS

42

## New Formulations

- Sympazan: Clobazam oral film
- Bryhalinda: Halobetasol proprionate
- Nayzilam: Nasal midazolam
- Slynd: Drospirenone
- Tolsura: Itraconazole- SUBA
- Ezallor: Rosuvastatin sprinkles
- Licart: Diclofenac epolamine patch
- Inbrija: Levodopa inhaled

OREGON STATE UNIVERSITY 43

43

## New Formulations

- Tosymra: Sumatriptan nasal
- Gloperba: Colchicine oral solution
- Jatenzo: Testosterone undecanoate capsule
- Avaclyr: Acyclovir ointment
- Lotemax SM: Loteprednol etabonate
- Qmiiz ODT: Meloxicam
- Ortikos: Budesonide ER
- Katerzia: Amlodipine suspension

OREGON STATE UNIVERSITY 44

44

## New formulations

- Baqsimi: Glucagon nasal powder
- Harvoni: Ledipasvir/sofosbuvir pellets
- Sovaldi: Sofosbuvir pellets
- Riomet ER: Metformin ER suspension

OREGON STATE UNIVERSITY 45

45

## Mental Health Reformulations

- Brixadi: Buprenorphine weekly/monthly injections
- Evekeo ODT: Amphetamine sulfate
- Adhansia XR: Methylphenidate
- Drizalma: Duloxetine sprinkles

OREGON STATE UNIVERSITY 46

46

# BIOSIMILARS

47



## Biosimilar Approvals

- Truxima (rituximab-abbs)
- Ruxience (rituximab-pvvr)
- Herzuma (trastuzumab-pkrb)
- Ontruzant (trastuzumab-dttb)
- Trazimera (trastuzumab-qyyp)
- Kanjinti (trastuzumab-anns)
- Eticovo (etanercept-ykro)
- Zirabev (bevacizumab-bvzr)
- Hadlima (adalimumab-bwwd)

OREGON STATE UNIVERSITY 48

48

NEW COMBINATIONS

49

## New Combinations

- Qternmet XR: dapagliflozin, metformin, saxagliptin
- Rocklatan: latanoprost, netarsudil dimesylate
- Duaklir pressair: acclidinium bromide, formoterol fumarate
- Dovato: dolutegravir sodium, lamivudine
- Duobrii: halobetasol proprionate, tazarotene
- Bijuva: estradiol, progesterone

OREGON STATE UNIVERSITY 50

50

## Assessment Question

1. Which of the following medications is a novel medication for postpartum depression?
  - a) **Zulresso**
  - b) Xolair
  - c) Zirabev

OREGON STATE UNIVERSITY 51

51

## Assessment Question

2. What is the indication for Wakix?
- a) Skin and skin structure infections
  - b) Hypoactive sexual desire disorder
  - c) Excessive daytime sleepiness

OREGON STATE UNIVERSITY 52

52

## Assessment Question

3. Which of the following medications has a black box warning for serious infections, malignancies and thrombosis?
- a) Yupelri
  - b) Rinvoq
  - c) Motegrity

OREGON STATE UNIVERSITY 53

53

## Assessment Question

4. Which of the following is purported benefit of Jatenzo?
- a) Oral dosing
  - b) No inadvertent testosterone exposure
  - c) All of the above