A REVIEW OF NEW DRUGS

Clark Kebodeaux, Pharm.D., BCACP
Assistant Professor of Pharmacy Practice
St. Louis College of Pharmacy

Learning Objectives

- At the conclusion of the program, participants should be able to:
  - Identify new molecular and biological entities, with the exception of diagnostic compounds, that entered the U.S. drug market in the past year
  - Describe each agent’s mechanism of action, dosage, adverse reactions, contraindications, and drug interaction profile
  - Compare new medicines with other agents used for the same indications
  - List special patient instruction and monitoring parameters for each of these agents
  - Compare and contrast new agents to current therapies as they pertain to a patient case.

FDA News/Approvals

- 35 New Molecular entities (NMEs) in September 2014
- 27 NMEs approved in 2013
- 5 to date in 2015
**Suvorexant (Belsomra™)**
*Merck*
- Orexin Receptor antagonist indicated for the treatment of insomnia (sleep onset and/or sleep maintenance)
  - OX1R
  - OX2R
- Schedule IV controlled substance
- **Dosing**
  - 10 mg within 30 minutes of going to bed and 7 hours prior to time of awakening
- Available as a 5mg, 10mg, 15mg, 20mg

**Suvorexant (Belsomra™)**
*Merck*
- **Adverse Reactions**
  - Somnolence
  - Contraindicated in Narcolepsy
- **Precautions**
  - Nighttime, complex sleep behaviors
  - Depression
  - Respiratory function (COPD, Sleep Apnea)
- **Drug Interactions**
  - 5 mg with moderate CYP3A inhibitors
  - Titrated to 10 mg QD

**Empagliflozin (Jardiance™)**
*Boehringer Ingelheim*
- Approved in 2014
- **3rd SGLT2 Inhibitor**
  - Inhibits the transporter responsible for reabsorbing the majority of glucose in the kidneys and increases the amount of glucose excreted through the urine
- Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
  - Similar Profile to Canagliflozin, Dapagliflozin
Empagliflozin (Jardiance™)
Boehringer Ingelheim

- Dosing
  - 10 mg once daily
  - Titrate to 25 mg daily

- Renal Function
  - D/C if GFR < 45 ml/min

- Adverse effects
  - Hypoglycemia
  - UTI
  - Increase LDL
  - Hypotension

Albiglutide (Tanzeum™)
GSK

- GLP-1 receptor agonist

- Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

- NOT
  - Recommended as a first line therapy
  - Treatment for type 1
  - Hx of GI Disease

- Dosing
  - 30 mg SC once weekly
  - Increased to 50 mg once weekly
  - Available as a single dose pen

- Adverse events/CI similar to other contraindications
  - Hx of Thyroid Cancer
  - N/V/D
  - Renal function
Dulaglutide (Trulicity™)
Lilly
- GLP-1 receptor agonist
- Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
  - NOT
  - Recommended as a first line therapy
  - Treatment for type 1 or DKA
  - Hx of GI Disease or hx of pancreatitis
- Not been studied in combination with basal insulin
- Dosing
  - 0.75 mg SC once weekly
  - Increased to 1.5 mg once weekly
  - Available as a pen

Vorapaxar (Zontivity™)
Merck
- Newest Oral Antiplatelet Drug
- Protease-activated receptor-1 antagonist (PAR-1)
  - Reduction in thrombotic cardiovascular events in patients with a history of MI or PAD
- Dosing
  - 2.08 mg ~ 2.5 vorapaxar sulfate
  - Once Daily

Vorapaxar (Zontivity™)
Merck
- Adverse Events
  - Bleeding, including life-threatening and fatal bleeding
- Drug Interactions
  - Strong CYP3A inhibitors and inducers
- Contraindications/Precautions
  - History of Stroke, TIA, or ICH
  - Active Bleeding
### Ledipasvir/sofosbuvir (Harvoni™) Gilead

- **Ledipasvir**
  - NS5A Inhibitor
- **Sofosbuvir**
  - HCV nucleotide analog NS5B inhibitor

- Indicated for the treatment of Chronic Hepatitis C (CHC) genotype 1
  - Treatment Naïve and Treatment Experienced

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### Dosing

- Fixed dose combination (90 mg ledipasvir/400 mg Sofosbuvir)
- Once Daily with/without food

### Length of Therapy

- **Treatment Naïve**
  - 12 weeks
- **Treatment Experienced**
  - Without Cirrhosis: 12 weeks
  - With Cirrhosis: 24 weeks

- No specific dosing for ESRD

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### Precautions

- Should not be dosed with sofosbuvir

### Drug Interactions

- P-glycoprotein inducers
- Antacids
- Rosuvastatin

### Adverse Reactions

- Fatigue
- Headache
## Combination Antiviral (Viekira Pak™)
**AbbVie**

- **Indicated for the treatment of Chronic Hepatitis C (CHC) genotype 1**
  - Without decompensated liver disease

- **Ombitasvir**
  - NS5A inhibitor
- **Paritaprevir**
  - NS3/4A Protease inhibitor
- **Ritonavir**
  - CYP3A inhibitor
- **Dasabuvir**
  - NS5B polymerase inhibitor

### Genotype 1a, without cirrhosis
- Viekira Pak + ribavirin

### Genotype 1a, with cirrhosis
- Viekira Pak

### Genotype 1b, without cirrhosis
- Viekira Pak + ribavirin

### Genotype 1b, with cirrhosis
- Viekira Pak + ribavirin

- Two ombitasvir 12.5 mg, paritaprevir 75 mg, ritonavir 50 mg tablets once daily (AM) and one dasabuvir 250 mg tablet twice daily (AM and PM) with food

### Contraindications
- Ribavirin therapy
- Hepatic Impairment
- CYP3A and CYP 2C8 inhibitors and inducers

### ALT Elevations
- D/C ethinyl estradiol BCs

### Drug Interactions/Ribavirin Contraindications
- Significantly safer without ribavirin
<table>
<thead>
<tr>
<th><strong>Umeclidinium (Incruse Ellipta™)</strong></th>
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<tbody>
<tr>
<td><strong>GSK</strong></td>
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<tr>
<td>Anticholinergic inhaler for the treatment of COPD</td>
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<tr>
<td>Dosed once daily</td>
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<tr>
<td>Same delivery mechanism as other Ellipta inhalers</td>
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<tr>
<td>Not studied in comparison to other anticholinergics</td>
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<thead>
<tr>
<th><strong>Olodaterol (Striverdi Respimat™)</strong></th>
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<tr>
<td><strong>Boehringer Ingelheim</strong></td>
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<tr>
<td>Long Acting Beta-2 agonist indicated for the treatment of COPD</td>
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<td>BB Warning for Asthma related death</td>
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<tr>
<td>Not indicated for the treatment of Astham</td>
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<tr>
<td>Two inhalations once daily at the same time of day</td>
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<tr>
<td>Consistent with other LABA Medications</td>
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<tr>
<td>Warnings and Precautions</td>
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<tr>
<td>Adverse Reactions</td>
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<tr>
<td>Drug Interactions</td>
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<tr>
<th><strong>Netupitant/palonosetron (Alynzeo™)</strong></th>
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<tr>
<td><strong>Eisai</strong></td>
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<tr>
<td>Indicated for the prevention of acute and delayed N/V associated with cancer chemotherapy</td>
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<tr>
<td>Palonosetron</td>
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<tr>
<td>5-HT3 antagonist</td>
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<tr>
<td>Netupitant</td>
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<tr>
<td>NK1 receptor antagonist</td>
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<td>Dosage</td>
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<tr>
<td>One Capsule (300 mg netupitant/0.5 mg palonosetron) 1 hour prior to chemotherapy</td>
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</tbody>
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### Netupitant/palonosetron (Akynzeo™)
**Eisai**
- **Precautions**
  - Hypersensitivity reactions with or without known hypersensitivity to 5-HT<sub>3</sub> receptor antagonists
- **Drug Interactions**
  - CYP3A4 substrate
  - CYP3A4 inducers
  - Avoid in patients with severe hepatic and renal impairment

### Efinaconazole (Jublia™)
**Valeant**
- **Topical azole antifungal**
  - Indicated for the topical treatment of onychomycosis
- **Application**
  - Apply once daily for 48 weeks
  - Must use the integrated applicator
  - Ensure the site of infection in covered
- **Adverse Reactions**
  - Ingrown toenails
  - Application site dermatitis/vesicles/pain

### Naloxegol (Movantik™)
**AstraZeneca**
- **Opioid antagonist** indicated for the treatment of opioid-induced constipation (OIC) in adults patient with chronic non-cancer pain
- **Dosage**
  - 12.5 mg tablets
  - 25 mg tablets
  - Take on an empty stomach 1 hour prior to first meal of the day or 2 hours after the first meal
- **Drug Interactions**
  - CYP3A4 inhibitors and inducers
### Immunotherapy for Allergies

- Grass Pollen Allergen Extract
  - Grastek
  - Oralair
- Ragweed Pollen Allergen Extract
  - Ragwitek

### 2014-2015 Influenza Vaccine Update

- Trivalent
  - A/California/7/2009 (H1N1)pdm09-like virus
  - A/Texas/50/2012 (H3N2)-like virus
  - B/Massachusetts/2/2012-like virus.

- Quadrivalent
  - Trivalent +
  - B/Brisbane/60/2008-like virus

- LAIV for pediatric patients 2-8 years of age

### Peramivir (Rapivab™)

*BioCryst*

- Influenza virus neuraminidase inhibitor
  - Treatment of acute uncomplicated influenza in patients > 18 years of age (Influenza A, limited data on B strains)

- 600 mg IV over 15 minutes

- Dosing in Renal Impairement
  - 30-49 mL/min: 200 mg
  - 10-29 mL/min: 100 mg

- Administered as a single dose within 2 days of the onset of influenza symptoms
# New Dosage Forms

- **Insulin** (Afrezza™)
  - Inhaled Insulin
- **Aveed®** (Testosterone)
- **Natesto®** (Testosterone)
  - Intranasal
- **Vogelxo™** (Testosterone)
  - Topical Gel Formulation
- **Omega-3 Fatty Acids** (Epanova®, Omtryg®)
  - New formulation for hypertriglyceridemia

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# New Dosage Forms

- **TRIUMEQ™** (abacavir sulfate, dolutegravir, lamivudine)
  - First fixed combination medication not made by Gilead
- **Saxenda®** (liraglutide)
  - GLP-1 indicated for weight loss
- **Spiriva Respimat™** (tiotropium)

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# New Combinations

- **Evotaz™**
  - Atazanavir/cobicistat
- **PrezcoBix™**
  - Darunavir/cobicistat
- **Namzaric™**
  - Memantine/donepezil
- **Prestalia®**
  - Perindopril/amlodipine
- **Glyxambi™**
  - Empagliflozin/linagliptin
- **Rytary®**
  - Carbidopa/levodopa
### Drugs that went Generic in 2014

- Lovaza®
- Omega-3
- Loestrin® 24 Fe
  - Ethinyl estradiol/Norethindrone acetate
- Avelox®
- Moxifloxacin
- Evista®
- Raloxifene
- Lunesta®
- Eszopiclone
- Nexium®
- Esomeprazole

### Generic Drugs in 2015

- Namenda®
  - Memantine
- Welchol®
  - Colesevelam tablet and oral suspension
- Abilify®
  - Aripiprazole
- Oxytrol®
  - Oxybutynin patch
- AndroGel 1%®
  - Testosterone
- Avodart®
  - Dutasteride
- Emend®
  - Aprepitant

### OTC UPDATE
NEW THERAPIES

Flonase®
- Flonase Allergy Relief
  - Fluticasone 50 mcg Spray
- Will also be indicated for nasal and eye allergy symptoms
- 24-hour dosing
- Early 2015

Nexium 24 HR®
- Esomeprazole DR 22.3 mg
  - Once daily for the treatment of frequent heartburn
- Adults ages 18 and older
  - 1 capsule daily for 2 weeks
  - Repeat 2 week therapy every 4 months
- May take 1-4 days for full effect
- Joins:
  - Prilosec OTC
  - Zegerid OTC
  - Prevacid OTC
Mucinex™ Allergy®
- Fexofenadine 180 mg
- Once daily for the treatment of Allergic Rhinitis
  - Allegra®

SUPPLEMENTS

Booty Goo
- Zinc oxide (25%)
- Peruvian balsam
- Vitamin E, aloe
- Acidum Boricum
  - (antibacterial germicide)
- White petrolatum
- Mineral oil
- Castor oil
Tropical Mango Omega Boost

- Nordic Naturals
- 525 mg total Omega 3
  - 270 mg EPA
  - 165 mg DHA
- Added to foods/drinks
  - Increased supplementation

JetRyte

- Jet Lag Treatment
  - Sodium
  - Potassium
  - Vitamins B6, B12, C

Good to Go

- Psyllium husk powder
- Chia seed powder
- Prune extract
- Apricot extract
- Aloe vera latex powder
- Senna leaf powder
Glucerna Advance
- Abbott
- Added CV ingredients
  - Plant-based phytosterols
  - Omega 3s
  - Antioxidants for the immune system (vitamins C and E, and selenium)
  - Chromium

Pill Terminator
- Bottled compound
  - Single use
  - Up to 300:
    - Pills
    - Capsules
    - Liquids/Powders

E-CIGARETTES
E-cigarettes

- 2011 – $250 million
- 2012 – $500 million
- Estimated for 2014 – $1.7 billion
- 250 e-cigarette brands available
- Variety of Data available as it related to smoking cessation
- Safety data not clear


Questions?