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Keeping Up: Review of New Drugs

Acknowledgement

- Thank you to Dr. Trish Freeman, RPh, PhD for the original creation and presentation of 'Keeping Up: Review of New Drugs.'

- With her permission, I am able to present the information to you today with all necessary updates.

Learning Objectives

At the conclusion of this program, the participant should be able to:

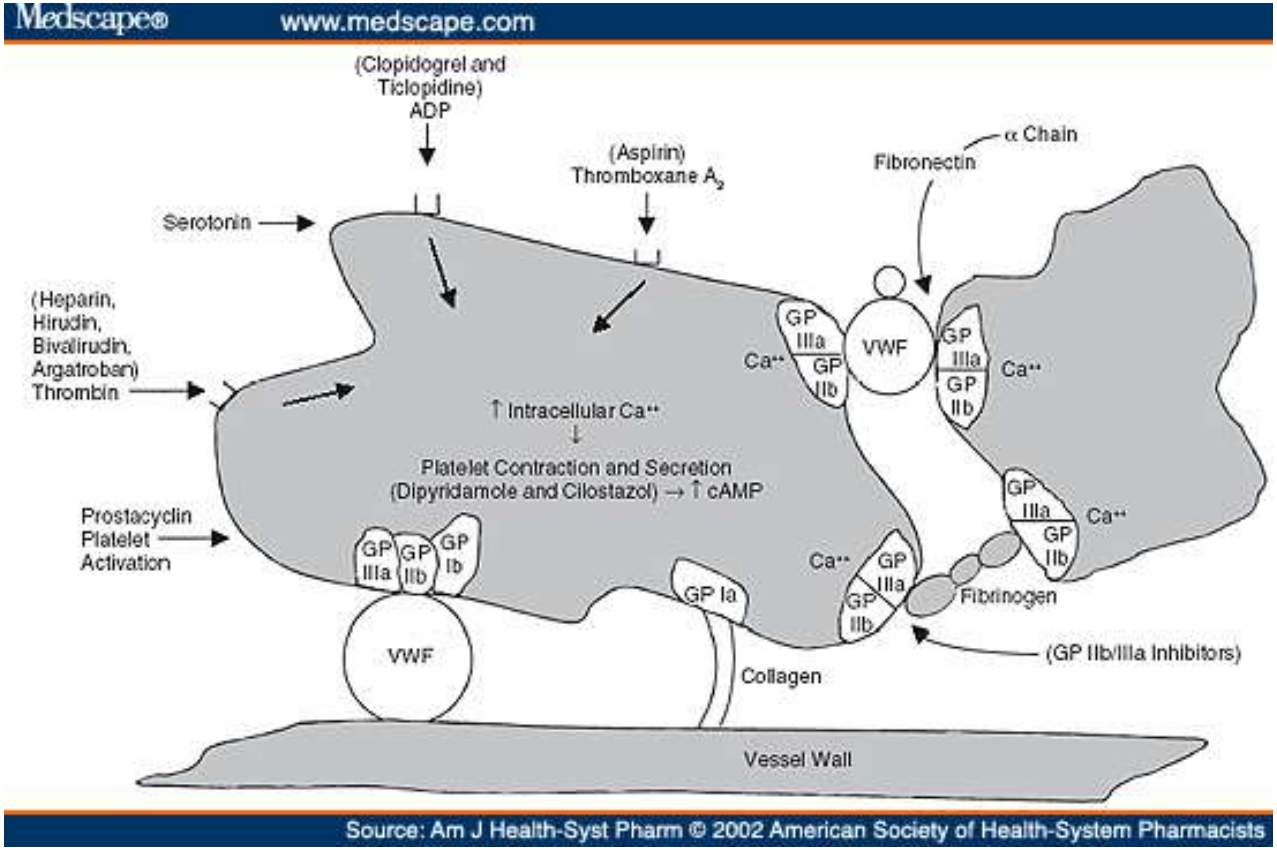
- Identify new molecular and biological entities, with the exception of diagnostic compounds, that entered the U.S. drug market from late 2009 through 2010
- Describe each agent's mechanism of action, dosage, adverse reactions, contraindications, and drug interaction profile
- Compare new medicines with other agents used for the same indications
- List special patient instruction and monitoring parameters for each of these agents

Prasugrel (Effient)
Eli Lilly

- Thienopyridine antiplatelet agent
- Prodrug similar to clopidogrel that requires metabolic conversion to active entity
  - Multiple CYP enzymes involved including 3A4, 2B6, 2C9 and 2C19
- Indications:
  - Reduce rate of thrombotic events in ACS who are to be managed with PCI including
    - UA or NSTEMI
    - STEMI managed with primary or delayed PCI
- Clinical efficacy superior to clopidogrel in trials, but higher incidence of fatal bleeding occurred with prasurgel

Prasugrel (Effient)
Eli Lilly

- Mechanism of Action:
  - Inhibits platelet activation and aggregation mediated by the P2Y12 ADP receptor



Prasugrel (Effient)
Eli Lilly

- Contraindications:
  - Active bleeding
  - Prior TIA or stroke

- Warnings/precautions:
  - Significant, sometimes fatal hemorrhage
  - Patients 75 years of age and older
  - CABG
  - Discontinue 7 days prior to elective surgery
  - Body weight <60 kg
  - Propensity to bleed
  - Concomitant use of anticoagulants or NSAIDs

Prasugrel (Effient)
Eli Lilly

- Usual Dose:
  - 60 mg load followed by 10 mg daily with 75 to 325 mg daily of ASA
  - May decrease dose to 5 mg daily in patients under 60 kg
  - May be administered without regards to food

Prasugrel (Effient)
Eli Lilly

- Adverse effects:
  - Bleeding/hemorrhage
  - TTP
  - Nausea
  - Headache
  - Dyspnea
  - Fatigue
- Drug Interactions:
  - Warfarin
  - NSAIDs
  - CYP inhibitors/inducers ***not clinically significant***

Sumatriptan (Sumavel DosePro) Zogenix, Inc.

- New dosage form of sumatriptan
- 5-HT receptor antagonist indicated for:
  - acute treatment of migraine attacks, with or without aura
  - acute treatment of cluster headaches
  - Not intended for prophylactic treatment of migraines

Sumatriptan (Sumavel DosePro) Zogenix, Inc.

- Contraindications:
  - IV administration
  - IHD, CV dx
  - History of stroke or TIA
  - PVD
  - Hypertension
  - Ergot/triptan use
- Warnings:
  - Serious cardiac events, including MI
  - Cerebrovascular events, some fatal
  - GI ischemic events
  - Raynaud's syndrome
  - Serotonin syndrome
  - Hypertension
  - seizures

Sumatriptan (Sumavel DosePro) Zogenix, Inc.

- Usual dose:
  - 6 mg subQ to the abdomen or thigh
    - Do not administer in the arm or other body areas
  - 12 mg total in 24 hour period
- Adverse effects:
  - Injection site reactions
  - Warm/hot sensations
  - Heaviness / pressure in head and chest
  - Flushing
  - Dizziness/vertigo
  - Sedation
  - Sinus cavity/jaw discomfort

Sumatriptan (Sumavel DosePro) Zogenix, Inc.

- Drug interactions:
  - MAOIs – doubles plasma levels of sumatriptan
  - Ergot alkaloids
  - Other triptans
  - SSRI/SNRI due to risk for serotonin syndrome

Dronedarone (Multaq)

Sanofi Aventis

- New antiarrhythmic drug indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent a fib/flutter
  - ATHENA trial showed 24% decrease in CV –related hospitalizations and death over 2 years
- Use in patients with a recent episode of a fib/flutter and associated risk factors and who are in sinus rhythm or who will be cardioverted
  - Age > 70; HTN
  - DM
  - Prior CVA
  - LVEF <40%

Dronedarone (Multaq)

Sanofi Aventis

- Similar in structure to amiodarone (Cordarone) but thought to be safer alternative?
  - Heart failure exacerbation
  - Bradycardia
  - QT prolongation
  - N/V/D
  - Rash
  - Increased serum creatinine
  - NO significant pulmonary adverse events or thyroid adverse events were reported

Dronedarone (Multaq)

Sanofi Aventis

- Contraindications and Warnings:
  - NYHA Class IV heart failure
  - NYHA Class II – III heart failure with a recent decompensation requiring hospitalization or referral to heart failure clinic
    - ANDROMEDA study showed 2 fold in increase in mortality in these groups
  - QT interval >500 ms
  - HR <50 BPM
  - Severe hepatic impairment
  - Pregnancy
  - hypokalemia/ hypomagnesmia

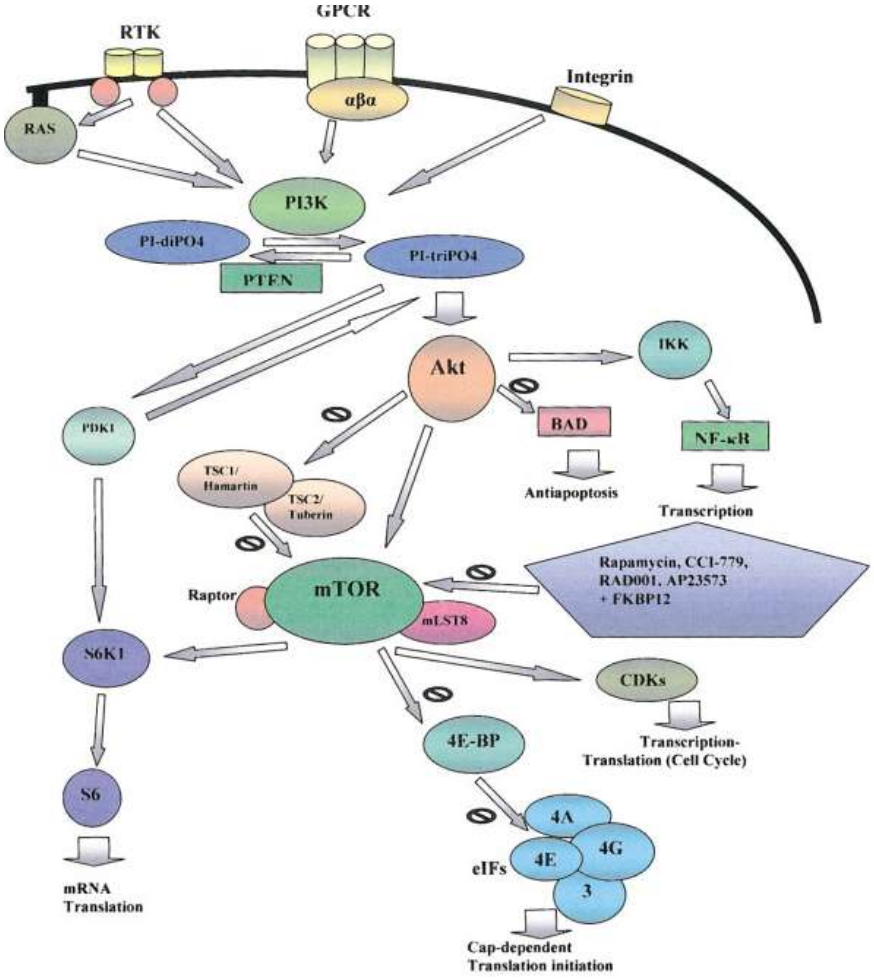
Dronedarone (Multaq)
Sanofi Aventis

- Recommended dose:
  - 400mg BID with meals
- Drug Interactions
  - QT – prolonging drugs
  - Strong CYP3A inhibitors
  - CYP3A substrates
  - CYP2D6 substrates
  - Other antiarrhythmics
  - CCBs
  - Digoxin
  - Beta Blockers
  - Statins

Everolimus (Zortress)
Novartis

- Everolimus is an immunosuppressant analog of sirolimus
- FDA approved to for rejection prophylaxis of renal transplants
- Everolimus is a m-TOR inhibitor by binding to FK binding protein-12 (FKBP-12) inactivating any serine-theronine kinase activity.

Everolimus (Zortress)
Novartis



Picture adapted from: Panwalker A, Verstovsek S, Giles FJ, et al. Mammalian target of rapamycin inhibition as therapy for hematologic malignancies. Cancer 2004;100:657-66.

Everolimus (Zortress)
Novartis

- Drug Interactions
  - CYP3A4 substrate
- Recommended Dose
  - 0.75 mg PO twice daily and adjusted in 4 – 5 day intervals based on serum concentrations, tolerability, and response.

Everolimus (Zortress)
Novartis

- May be taken with or without food; requires consistency

- Adverse effects
  - Increased risk of renal and venous thrombosis; Immunosuppressant activity results in increase risk of infections; development of malignancy
  - Hypercholesteremia, hyperglycemia, electrolyte abnormalities, N/V/D, cough, dyspnea

Morphine sulfate/naltrexone (Embeda) King Pharmaceuticals

- Combination opioid agonist/antagonist for indicated for management of moderate to severe pain
  - For use when a continuous opioid analgesic is needed for an extended period of time
  - NOT indicated for PRN use
- Unique, abuse-resistant design
  - The opioid antagonist (naltrexone) embedded in the pellet core
  - When taken as directed, no naltrexone released, when crushed, chewed, or dissolved, naltrexone is released and euphoria is significantly reduced

Morphine sulfate/naltrexone (Embeda) King Pharmaceuticals

- Recommended dose:
  - Varies based on severity of pain and degree of opioid tolerance
  - Available in 20, 30, 50, 60, 80 and 100 mg capsules
  - May be administered once or twice daily
  - Capsule may be opened and sprinkled on apple sauce
- Adverse Effects:
  - Similar to other opioid analgesics
- Drug Interactions:
  - Similar to other opioid analgesics

Morphine sulfate/naltrexone (Embeda) King Pharmaceuticals

- Warnings
  - Misuse or abuse by tampering with the capsule can cause rapid release and absorption of both morphine and naltrexone
    - Morphine dose might be fatal, particularly if person is opioid-naïve
    - In opioid-tolerant persons, the absorption of naltrexone might increase risk of precipitating withdrawal
  - Indicated for use in opioid-tolerant individuals only
  - Patients should not consume alcoholic beverages or use Rx or OTC medications containing alcohol

Fentanyl buccal soluble film (Onsolis)
Meda Pharmaceuticals

- New dosage form of fentanyl
- Indicated for management of breakthrough pain in patients with cancer, 18 years of age and older **who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain**
  - Not indicated in opioid-intolerant patients
- Recommended dose:
  - 200 mcg initially up to a maximum of 4 x 200 mcg films or a single 1200 mcg film, to achieve adequate analgesia without undue adverse effects
  - Maximum of one dose per episode and no more than 4 doses in 24 hours
  - Doses must be separated by at least 2 hours
- Available as a buccal film in 200, 400, 600, 800 and 1200 mcg strengths

Fentanyl buccal soluble film (Onsolis)
Meda Pharmaceuticals

- Due to abuse potential will be available through a restricted distribution program
- FOCUS
  - Prescribers and pharmacies must enroll
  - Requirement of FDAs REMS program
  - Strict education needed as dose can be fatal to children and non-opioid tolerant adults

•Use tongue to wet the inside of cheek or rinse mouth with water to wet the area

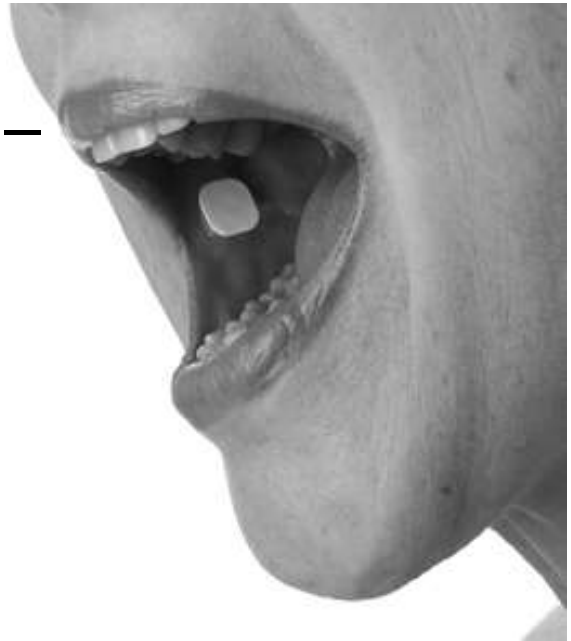
• Hold the film in place on a clean, dry finger with the pink side facing up

• Place the film inside mouth with the pink side against the inside of moistened cheek and press and hold film against cheek for 5 seconds

• Leave the film in place until dissolves – usually within 15 to 30 minutes

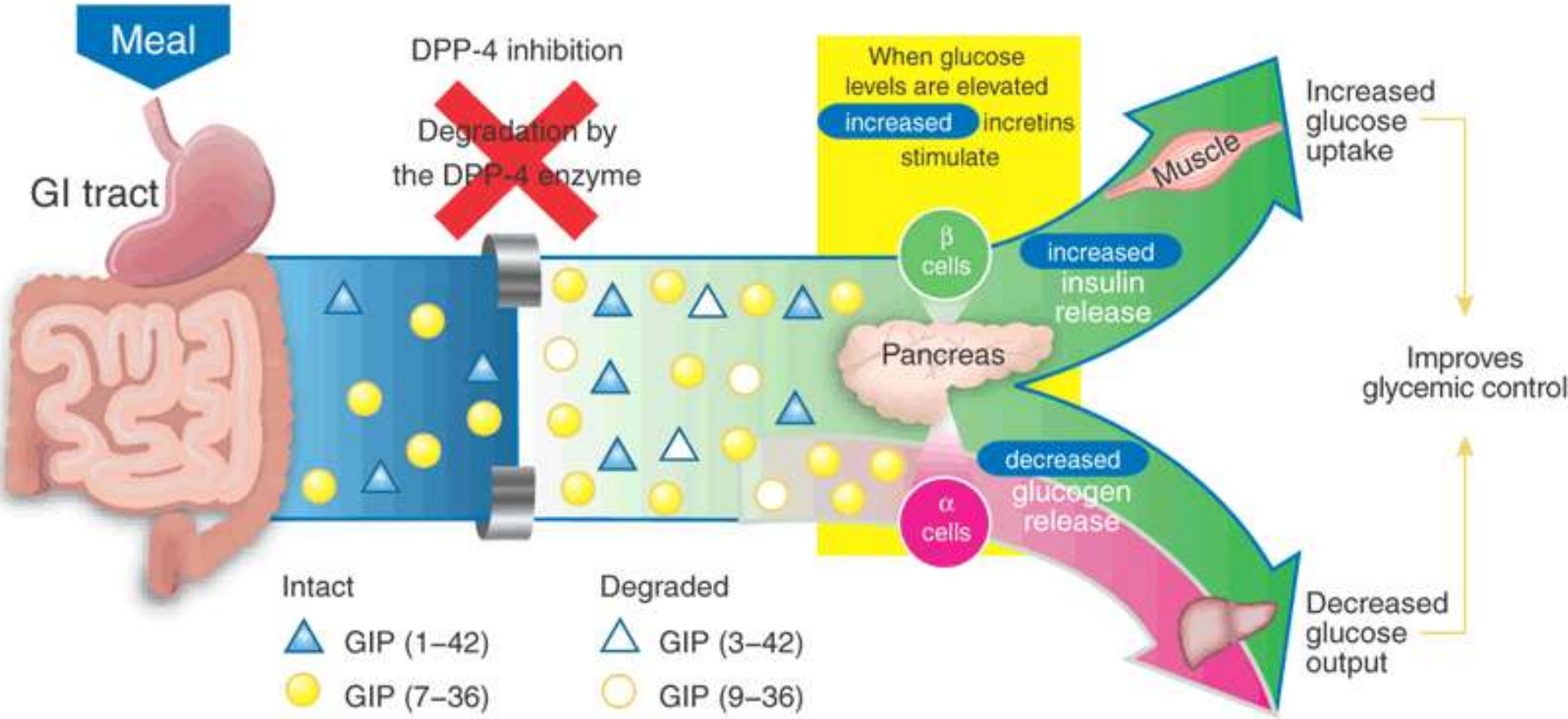
• Avoid touching or moving the film while it dissolves

• No food until after the film dissolves, but can drink after 5 minutes



Saxagliptin (Onglyza) AstraZenca

- DPP-4 inhibitor to improve glucose control in patients with type 2 diabetes
  - Used as adjunct to diet and exercise
  - Has not been studied in combination with insulin
- MOA:
  - DPP-4 inhibitors slow the inactivation of incretin hormones such as glucagon-like peptide 1 (GLP-1) which are released by the intestines during the day and work to regulate insulin secretion from the pancreas
  - GLP-1 is rapidly inactivated by the enzyme DPP-4
- Joins sitagliptin (Januvia)


Meal
GI tract
DPP-4 inhibition
Degradation by
the DPP-4 enzyme
When glucose
levels are elevated
increased incretins
stimulate
β
cells
increased
insulin
release
Pancreas
Muscle
Increased
glucose
uptake
Improves
glycemic control
α
cells
decreased
glucogen
release
Decreased
glucose
output
Intact
GIP (1–42)
GIP (7–36)
Degraded
GIP (3–42)
GIP (9–36)

Saxagliptin (Onglyza) AstraZenca

- Recommended dose:
  - 2.5 to 5 mg once daily taken without regards to meals
  - Use lower dose in patients with renal insufficiency (CrCl <50 mL/min)
  - Use lower dose in patients on strong CYP3A4/5 inhibitors
- Adverse effects:
  - Respiratory tract and urinary tract infections
  - Headache
  - Peripheral edema; esp. in combination with TZDs
  - Hypoglycemia; esp. in combination with sulfonylureas
  - Hypersensitivity reactions

Incretin-based Therapies

Incretin mimetics[6,21-23]

- Route of Administration:

Injectable

- GLP-1 receptor agonist:
- Synthetic GLP-1 analogues that mimic some effects of incretin hormones
- Peptides

Incretin enhancers[6,21,24]

- Route of Administration:

Oral

- DPP-4 inhibitors
- Increase circulating levels of endogenous intact GLP-1 and GIP
- Low molecular weight agents

Liraglutide (Victoza)
Novo Nordisk

- New human GLP-1 analogue that acts as a GLP-1 receptor agonist administered via subQ injection
  - 97% amino acid homology to native GLP-1
- Mechanism of Action:
  - increases intracellular cyclic AMP (cAMP) leading to insulin release in the presence of elevated glucose concentrations
  - decreases glucagon secretion in a glucose-dependent manner and delays gastric emptying.
- Indication:
  - as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Liraglutide (Victoza)
Novo Nordisk

- Recommended dose:
  - 0.6 mg per day for one week administered once daily at any time of day, independently of meals
  - Increase to 1.2 mg daily after 1 week, if acceptable glycemic control is not reached, may increase to max dose of 1.8 mg
  - Inject subcutaneously in the abdomen, thigh or upper arm
  - Follow dose-titration to avoid GI adverse effects
- How Supplied:
  - Solution for subcutaneous injection, pre-filled, multi-dose pen that delivers doses of 0.6 mg, 1.2 mg, or 1.8 mg (6 mg/mL, 3 mL)
  - Refrigerate until first use, room temp storage acceptable after first use for 30 days

Liraglutide (Victoza)
Novo Nordisk

- The FDA approval of Victoza was based on five double-blind, randomized, controlled clinical trials, one of 52 weeks duration and four of 26 weeks duration, in 3,978 subjects
- As monotherapy, significantly reduced A1c greater than 8 mg daily glimepiride
- Also showed significantly reduced A1c as add-on therapy to glimepiride, metformin and thiazolidinediones
- May need to lower doses of sulfonylureas when initiate add-on therapy with liraglutide
- Has not been studied in combination with insulin, or in patients with type I diabetes

Liraglutide (Victoza)
Novo Nordisk

- Warnings/Precautions:
  - Thyroid C-cell tumors at clinically relevant exposures in rodents
  - Not known whether Victoza causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) in humans
  - Pancreatitis
  - Severe hypolglycemia when used in combination with sulfonylurea
- Contraindications:
  - personal or family history of MTC or in patients with Multiple Endocrine Neoplasia Syndrome type 2 (Men2)

Liraglutide (Victoza)
Novo Nordisk

- Adverse Effects:
  - Nausea
  - Vomiting
  - Diarrhea
  - Constipation
  - Headache
  - Anti-liraglutide antibody formation

Ulipristal (Ella)
Watson

- MOA: Selective progesterone receptor modulator with progesterone agonist/antagonist activity
- Dose: 30 mg up to 120 hours (5 days) after intercourse).
- Adverse events: HA, Abdominal Pain, N/V. If a patient throws up within the first 3 hours of dose, the patient should receive another dose.
- Available by prescription only.

Pitavastatin (Livalo)
Kowa Pharmaceuticals, Inc

- New HMG-CoA reductase inhibitor
- Indications:
  - Primary hyperlipidemia and mixed dyslipidemia as adjunct to diet to reduce
    - TC
    - LDL-C
    - Apo B
    - TG

    and to increase HDL

Pitavastatin (Livalo)
Kowa Pharmaceuticals, Inc

- Warnings:
  - Myopathy and rhabdomyolysis
    - Dose –dependent
      - doses > 4mg daily associated with severe myopathy in premarketing studies
    - Additional risk factors include age >65, renal impairment, hypothyroidism and concurrent fibrate use
  - Renal insufficiency
    - Not studied in patients with CLcr <30 mL/min
  - Liver dysfunction
    - Persistent elevations can occur - monitor

Pitavastatin (Livalo)
Kowa Pharmaceuticals, Inc

- Usual dose:
  - 4 mg daily with or without food at any time of the day
  - Initial dose 2mg for patients with normal renal function
  - Initial dose 1 mg in patients with CrCl <60 mL/min
- Contraindications:
  - Cyclosporine
  - Pregnancy (Category X)

Pitavastatin (Livalo)
Kowa Pharmaceuticals, Inc

ADVERSE EFFECTS:

- Myalgia
- Back pain
- Diarrhea
- Constipation

DRUG INTERACTIONS:

- Lopinavir/ritonavir – avoid use
- Erythromycin - max dose 1 mg daily
- Rifampin – max dose 2 mg daily
- Fibrates

Asenapine (Saphris)
Schering-Plough

- New atypical antipsychotic for sublingual administration
- Indications:
  - Acute treatment of schizophrenia in adults
  - Acute treatment of manic or mixed episodes associated with bipolar 1 disorder in adults

Asenapine (Saphris)
Schering-Plough

- Usual Dose:
  - 5 mg sublingually BID for schizophrenia
  - 10 mg sublingually BID for bipolar disorder
    - Decrease to 5 mg BID if AEs occur
- Patient instructions:
  - place tablet under tongue, will dissolve in seconds
  - Refrain from eating or drinking for 10 min

Dalfampridine (Ampyra) Acorda Therapeutics

- Potassium channel blocker that enhances conduction in damaged nerves
  - Exact mechanism has not been fully elucidated
- Specifically indicated as a treatment to improve walking in patients with multiple sclerosis

Dalfampridine (Ampyra) Acorda Therapeutics

- Recommended dose:
  - 10 mg twice daily, taken with or without food
  - This is the maximum dose and should not be exceeded
  - doses should be taken approximately 12 hours apart
  - Patients should not take double or extra doses if a dose is missed
  - Do not chew, crush, divide or dissolve tablets

Dalfampridine (Ampyra)
Acorda Therapeutics

- Contraindications:
  - History of seizures
  - Moderate to severe renal impairment (Clcr <50 mL/min
  - Stop therapy and do not resume if patient experiences a seizure while receiving Ampyra
- Warnings/Precautions:
  - Mild renal impairment (Crcl 51 – 80 mL/min)
    - Monitor baseline creatinine and estimate clearance prior to initiating therapy
  - Increased risk for UTIs

Dalfampridine (Ampyra)
Acorda Therapeutics

- Adverse effects:
  - Urinary tract infection
  - Insomnia
  - Dizziness
  - Headache
  - Nausea
  - Asthenia
  - Back pain
  - Balance disorder
  - Multiple sclerosis relapse
  - Paresthesia
  - Constipation
  - Dyspepsia
  - Seizures

Aztreonam (Cayston) Gilead

- New inhalation form of aztreonam indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa* or in patients colonized with *Burkholdereria cepacia*
  - Both adults and children 7 years of age and older
- Available as single-use vial for reconstitution with a 1 mL ampule of sterile diluent
- Designed for administration via inhalation using an Altera Nebulizer System
  - Bronchodilator should be administered first

Aztreonam (Cayston) Gilead

- Adverse effects:
  - Cough
  - Nasal congestion
  - Wheezing
  - Pharyngolaryngeal pain
  - Chest discomfort
  - Pyrexia
  - Abdominal Pain
  - Vomiting

- Recommended dose :
  - one single-use vial (75 mg of aztreonam) administered 3 times a day for a 28-day course (followed by 28 days off Cayston therapy)
  - dosage is not based on weight or adjusted for age
  - doses should be administered at least 4 hours apart

Capsaicin (Qutenza) NeurogesX

- Transdermal patch containing 8% capsaicin in a localized dermal delivery system
  - Capsaicin is a synthetic equivalent of the naturally occurring compound found in chili peppers
- Mechanism of action:
  - Capsaicin is an agonist for the transient receptor potential vanilloid I receptor (TRPVI), an ion channel-receptor complex expressed on nociceptive nerve fibers in the skin
  - Topical administration of capsaicin causes an initial enhanced stimulation of the TRPVI nociceptors that may be associated with painful sensations
  - Pain relief thought to be mediated by a reduction in TRPV 1 expressing nociceptive nerve endings

Capsaicin (Qutenza) NeurogesX

- Specifically indicated for the management of neuropathic pain associated with postherpetic neuralgia
- Recommended initial dose is a single, 60-minute application of up to four patches
- Treatment may be repeated every three months or as warranted by the return of pain (not more frequently than every three months)
- Adverse effects:
  - Application site erythema
  - Application site pain
  - Application site pruritus
  - Application site papules

New Dosage Forms of Diclofenac

- Diclofenac potassium (Cambia) – oral solution for acute treatment of migraine headaches; mix 50 mg packet in 30 – 60 ml water prior to administration
- Diclofenac potassium (Zipsor) – liquid filled capsules for relief of mild to moderate pain; 25 mg QID
- Diclofenac sodium (Pennsaid) - topical solution for osteoarthritis of the knee
  - recommended initial dose of the drug is 40 drops per knee, 4 times a day
  - spread evenly around front, back and sides of the knee, 10 drops at a time
  - repeat this procedure until 40 drops have been applied and the knee is completely covered with solution

Other New Dosage Forms

- Exalgo (hydromorphone hydrochloride) extended release
  - Schedule II mu-opioid agonist
  - Utilizes the OROS PUSH-PULL osmotic delivery system to release hydromorphone at a controlled rate over an extended period
  - Specifically indicated for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time
    - 8mg to 64 mg daily ; available in 8, 12 and 16 mg tablets
    - Tablets administered every 24 hours with or without food
    - discontinue all other extended-release opioids when initiating Exalgo therapy

Other New Dosage Forms

- Doxepin (Silenor):
  - New formulation of doxepin for use in treatment of insomnia due to difficulties with sleep maintenance
    - originally approved in 1969 as the first tricyclic antidepressant
    - Doses of 25 – 150 mg used for these indications
  - Mechanism of action for sleep secondary to histamine type 1 receptor antagonism
  - 6 mg daily 30 min before bedtime; decrease to 3mg in elderly
  - Not to be taken within 3 hours of a meal

Other New Dosage Forms

- Ketorolac tromethamine (Sprix):
  - intranasal dosage form of ketorolac for short-term (up to 5 days) use for treatment of moderate to moderately-severe pain that requires opiate-level analgesia
  - 1 spray (15.75 mg) in each nostril every 6 – 8 hours, max dose is 126 mg in 24 hours (4 doses)
  - Patients 65 years or older, patients with renal insufficiency or patients weighing less than 50 kg should use one spray in ONE nostril every 6 – 8 hours for max of 63 mg in 24 hours

Other New Dosage Forms

- Ondansetron (Zuplenz)
  - Oral Soluble Film
    - Approved for postoperative, highly and moderately emetogenic cancer chemotherapy-induced, and radiotherapy-induced nausea and vomiting
  - Dosing is consistent; Adults max 24 mg/day PO
  - Place film on tongue and it will dissolve in 4 to 20 seconds. Once dissolved, the patient may swallow with or without liquid.

New Ophthalmic Products

- Two new fluoroquinolones for treatment of bacterial conjunctivitis
  - Gatifloxacin (Zymaxid)
    - 1 drop every two hours in the affected eye(s) while awake, up to 8 times on Day 1
    - 1 drop two to four times daily in the affected eye(s) while awake on Days 2 through 7
  - Besifloxacin (Besivance)
    - 1 drop in affected eye(s) TID four to twelve hours apart x 7 days
- One new antihistamine product for itching associated with allergic conjunctivitis
  - Bepotastine (Bepreve)
    - 1 drop to eyes BID

New Vaccine Products

- Meningococcal Vaccine (Menveo)
  - A vaccine to prevent meningococcal disease caused by *Neisseria meningitidis* serogroups A,C,Y, and W-135 in person 11 to 55 years of age.
- Pneumococcal 13-valent conjugate vaccine (Prevnar 13)
  - A vaccine to prevent *Streptococcus pneumoniae*-related infections in children 6 weeks through 5 years.

Other New Dosage Forms

- Metoclopramide hydrochloride (Metozolv ODT)
  - Oral disintegrating form of metoclopramide for short-term treatment of GERD (4-12 weeks) in those who fail to respond to conventional therapy and diabetic gastroparesis
  - 10 – 15 mg ACHS
  - Take on empty stomach 30 min before eating
- Therapy should not exceed 12 weeks 2nd to risk of tardive dyskinesia

Other New Dosage Forms

- Colchicine (Colcrys) – for gout flares and familial Mediterranean fever
- Miconzaole (Oravig) – 50 mg buccal tablet to be dissolved in upper gum region once daily x 14 days for oral pharyngeal candidiasis
- Rifaximin (Xifaxan 550) – 550 mg BID to reduce risk of hepatic encephalopathy in patients with liver failure (alone or in combination with lactulose

Other New Dosage Forms

- Pregabalin (Lyrica)
  - New oral solution formulation
- Pramipexole (Mirapex ER)
  - New extended-release formulation for Parkinson's Disease
- Memantine (Namenda XR)
  - New extended-release formulation for Alzheimer’s Disease
- Trazodone (Oleptro)
  - New extended-release formulation for depression

New Combinations

- Vimovo = naproxen + esomeprazole
  - treatment of arthritis in patients at risk for NSAID-associated ulcers
- Dutasteride/tamsulosin (Jalyn)
  - Combination of a 5-alpha reductase inhibitor and an alpha-1A blocker for the treatment of benign prostatic hyperplasia (BPH)
  - One capsule (0.5mg dutasteride/0.4mg tamsulosin) PO daily.
  - Should be taken 30 minutes after same meal each day.

REMS: Risk Evaluation and Mitigation Strategies

- REMS is a strategy by the FDA to manage a known or potential serious risk associated with a drug or biological product
- will be required for a given drug if FDA finds that a REMS is necessary to ensure that the benefits outweigh the risks of the product
- can include a Medication Guide, Patient Package Insert, a communication plan, elements to assure safe use, and an implementation system

REMS: Risk Evaluation and Mitigation Strategies

- List of approved REMS can be accessed at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm
- Many drugs require medication guides as part of REMS that should be provided to any patient prior to taking the medication
  - Current approved medication guides can be accessed at http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

Questions?