Question

- Based on the previous slide- How long does it take to gain FDA approval for a new drug?

vilazodone

- Brand name: Viibryd™
- Drug Class: a dual-acting potent and selective serotonin reuptake inhibitor and a 5-HT1A receptor partial agonist
- Use: The treatment of major depressive disorder (MDD)
- Dosage Form: 40mg tablet
- Manufacturer: Trovis Pharmaceuticals LLC
- Date of Approval: January 21, 2011

Major Depressive Disorder (MDD)

- a mental disorder characterized by an all-encompassing low mood accompanied by low self-esteem, and by loss of interest or pleasure in normally enjoyable activities
- adversely affects a person’s family, work or school life, sleeping and eating habits, and general health.
spinosad
- Brand name: Natroba™
- Drug class: pediculicide
- Use: topical treatment of head lice infestations
- Dosage form: Topical suspension
- Manufacturer: ParaPRO LLC
- Date of Approval: January 19, 2011

Female Head Louse
A picture of the parasite that causes head lice.

Head Louse Nit
A nit is the egg stage in the life cycle of the parasite that causes head lice. The nit is attached to the hair shaft by a strong cement.

testosterone
- Brand name: Fortesta™
- Drug Class: Steroid
- Use: Hypogonadism -- Male
- Dosage form: Gel
- Manufacturer: Endo Pharmaceuticals
- Date of Approval: December 29, 2010

Questions
- What are three characteristics of Major Depressive Disorder?
- What is a pediculicide used to treat?
- What is the dosage form for spinosad?
- What drug class is testosterone?
aliskiren, amlodipine and hydrochlorothiazide

- Brand name: Amturnide™
- Drug Class: direct renin inhibitor, calcium channel blocker and diuretic combination
- Use: Hypertension
- Dosage form: Tablet (purple) 150 mg / 5 mg / 12.5 mg; tablet (pink) 300 mg / 5 mg / 12.5 mg
- Manufacturer: Novartis Pharmaceuticals Corporation
- Date of approval: December 21, 2010

Renin inhibitors

- Dilate arteries and veins by blocking angiotensin II formation. This vasodilation reduces arterial pressure, preload and afterload on the heart.
- Down regulate sympathetic adrenergic activity by blocking the facilitating effects of angiotensin II on sympathetic nerve release and reuptake of norepinephrine.
- Promote renal excretion of sodium and water (natriuretic and diuretic effects) by blocking the effects of angiotensin II in the kidney and by blocking angiotensin II stimulation of aldosterone secretion. This reduces blood volume, venous pressure and arterial pressure.
- Inhibit cardiac and vascular remodeling associated with chronic hypertension, heart failure, and myocardial infarction.

drospirenone, ethinyl estradiol and levomefolate calcium

- Brand name: Safyral™
- Drug Class: estrogen/progestin oral contraceptive containing a folate
- Use: Prevent pregnancy
- Dosage form: Tablet
- Manufacturer: Bayer HealthCare Pharmaceuticals, Inc.
- Date of approval: December 16, 2010

- Raises folate levels for the purpose of reducing the risk of rare neural tube defects (NTDs) in a pregnancy conceived while taking SAFYRAL or shortly after discontinuing it. SAFYRAL provides the birth control YASMIN® (drospirenone 3 mg/ ethinyl estradiol 30 mcg) with 451 mcg levomefolate calcium, which is a B vitamin.

moxifloxacin

- Brand name: Moxeza™
- Drug Class: fluoroquinolone anti-infective
- Use: bacterial conjunctivitis
- Dosage form: ophthalmic solution
- Manufacturer: Alcon, Inc
- Date of approval: November 19, 2010
Pink eye (conjunctivitis) is redness & inflammation of the membranes covering the whites of the eyes and on the inner part of the eyelids.

Questions
- What three drug classes do the following belong to? aliskiren, amlodipine and hydrochlorothiazide.
- What does drospirenone, ethinyl estradiol and levomefolate calcium oral contraceptive contain that makes it different than the others on the market?

Brand name: Kombiglyze XR™
Drug Class: dipeptidyl peptidase-4 (DPP-4) inhibitor
Use: Diabetes Mellitus Type II
Dosage form: 5mg/100mg ER Tablet
Manufacturer: Bristol-Myers Squibb Company and AstraZeneca
Date of approval: November 5, 2010

Brand name: Ofirmev™
Drug Class: analgesic
Use: fever, acute pain
Dosage form: injection 10mg/ml
Manufacturer: Cadence Pharmaceuticals, Inc
Date of approval: November 2, 2010
Cost $8-10/dose

Should be administered only as a 15-minute infusion.
Do not exceed the maximum recommended daily dose of acetaminophen.
Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death.
acetaminophen Information

- On January 13, 2011, FDA announced that it is asking manufacturers of prescription acetaminophen combination products to limit the maximum amount of acetaminophen in these products to 325 mg per tablet, capsule, or other dosage unit. FDA believes that limiting the amount of acetaminophen per tablet, capsule, or other dosage unit in prescription products will reduce the risk of severe liver injury from acetaminophen overdosing, an adverse event that can lead to liver failure, liver transplant, and death.

Questions

- What population should not be treated with saxagliptin and metformin?
- How should acetaminophen injection be administered?

ceftaroline fosamil

- Brand name: Teflaro™
- Drug Class: Cephalosporin antibiotic
- Use: Pneumonia, Skin and Structure Infection
- Dosage form: Injection 600mg
- Manufacturer: Forest Laboratories, Inc
- Date of approval: October 29, 2010

ceftaroline fosamil

- a broad-spectrum bactericidal cephalosporin with activity against both gram-positive and gram-negative microorganisms
- for the treatment of community-acquired bacterial pneumonia (CABP), including cases caused by *Streptococcus pneumoniae* bacteremia, and acute bacterial skin and skin structure infection (ABSSSI), including cases caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

lurasidone

- Brand name: Latuda™
- Drug Class: atypical antipsychotic
- Use: Schizophrenia
- Dosage form: 80mg tablet
- Manufacturer: Dainippon Sumitomo Pharma America, Inc.
- Date of approval: October 28, 2010

lurasidone

- Elderly people with dementia-related psychosis (a severe mental health problem) taking atypical antipsychotic drugs, are at an increased risk for death compared with those taking placebo (sugar tablet).
- Is not approved for the treatment of people with dementia-related psychosis. An increased risk for stroke and ministroke has been reported in elderly people with dementia-related psychosis.
norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate

- **Brand name:** Lo Loestrin Fe™
- **Drug Class:** estrogen/progestin
- **Use:** Contraception
- **Dosage form:** tablet
- **Manufacturer:** Warner Chilcott plc
- **Date of approval:** October 21, 2010

Instruct the patient to begin taking Lo Loestrin Fe on Day 1 of her menstrual cycle. One blue tablet should be taken daily for 24 consecutive days, followed by one white tablet daily for 2 consecutive days, followed by one brown tablet daily for 2 consecutive days.

Questions

- What disease is lurasidone not used for?
- For the oral contraceptive - norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate, how many days should be blue pill be taken? White pill? and brown pill?

asenapine

- **Brand name:** Saphris™
- **Drug Class:** atypical antipsychotic
- **Use:** treats the symptoms of psychotic conditions such as schizophrenia and bipolar disorder (manic depression) in adults.
- **Dosage form:** 5 & 10mg sublingual tablet
- **Manufacturer:** Organon
- **Date of approval:** September 3, 2010

Not for use in psychotic conditions related to dementia. May cause heart failure, sudden death, or pneumonia in older adults with dementia-related conditions. May be more sensitive to temperature extremes such as very hot or cold conditions. FDA pregnancy category C. It is not known if harmful to an unborn baby. Can pass into breast milk and may harm a nursing baby. Tell your doctor if you are pregnant or plan to become pregnant during treatment.

Questions

- In what pregnancy category is asenapine placed?
Pipeline news...Drug Topics Magazine Jan 2011
 # of new drugs under development continues to shrink
 Little chance that new blockbuster drugs will replace those losing patent protection
 FDA approvals moving at a sluggish pace- 29 approvals in 2009, 26 in 2008, 17 in 2010

FOCUS – Specialty Drugs
• Inflammatory conditions
• Multiple Sclerosis (MS)
• Cancer
• Anticoagulants
• Growth Deficiency

Growth of Generics
 25 of top 50 non-specialty brand name drugs going generic by 2012
 Emerging drug markets- China, Mexico, Brazil, Turkey- creating competition because of lower margins than those in US
 By mid-2012, 8 out of 10 drugs dispensed will be generic- donepezil, morphine ER, zolpidem CR, atorvastatin, montelukast, topical latanoprost, angiotensin receptor blockers (ARBs), 2nd generation antipsychotic agents

Questions
 What drugs will be released as generics in 2012?
 What medical conditions will be the focus for drug development?

Focus of Drug Development
 Cardiovascular- blood thinners
 Rivaroxaban- factor xA inhibitor for the prevention of venous thromboembolism (VTE)
 Apixaban- -direct factor Xa inhibitor for treatment of atrial fibrillation (AF) and prevention of VTE
Cardiovascular
- Tricagrelor- Oral P2Y12 adenosine diphosphate (ADP) receptor agonist for the treatment of arterial thrombosis
- Elinogrel- reversible P2Y12 ADP receptor antagonist for the prevention of MI and stroke in patients with chronic coronary heart disease

Central Nervous System
- TC-514- nicotinic acid channel blocker for adjunct treatment of major depressive disorder (MDD)
- Cariprazine- an atypical antipsychotic for treating schizophrenia and bipolar disorder

Diabetes
- Inhaled insulin- Ultra rapid-acting insulin for type 1 & 2 diabetes
- LY2189265 & Lixisenatide- glucagon-like peptide-1 (GLP-1) analog to treat type 2 diabetes- sub Q
- Albiglutide- a novel dipeptidyl-peptidase-4-resistant GLP-1 for type 2 diabetes
- Dapagliflozin- sodium glucose co-transporter-2 (SGLT2) inhibitor (new class of drug)

Respiratory
- Aclidinium- long-acting, dry powder inhaler (DPI) with a muscarinic antagonist (anticholinergic) bronchodilator to treat COPD
- Fluticasone furoate/vilanterol trifenatate-long acting beta 2 agonist + glucocorticoid agonist for tx of COPD and asthma

Alzheimer’s Disease
- Donepezil transdermal patch- once-weekly for tx of mild, moderate, or severe Alzheimer’s disease
- Bapineuzumab IV- for mild to moderate Alzheimer’s
- Latrepirdine- mild-to moderate Alzheimer’s
Questions
 What new dosage form of insulin is being developed?
 What new dosage form for donepezil is being developed?

Pain Management
 Ibuprofen/high-dose famotidine- for reduction of the risk of development of upper GI ulcers in patients with arthritis & pain
 Immediate-release oxycodone/niacin- for mild to moderate pain – designed to deter misuse and abuse
 Fentanyl buccal tablet- for breakthrough pain associated with specific chronic conditions in opioid-tolerant patients

Questions
 Name three new oxycodone combination drugs being developed
 For what population is Ibuprofen/high-dose famotidine being developed?

Pain management
 Diclofenac patch- once-a-day NSAID for topical treatment of pain associated with musculoskeletal injuries
 Oxycodone CR- once-daily CR abuse-deterrent product for pain
 Oxycodone CR/naltrexone- abuse deterrent analgesic with opioid antagonist

Pain Management
 Ketamine intranasal- for acute moderate to severe pain and breakthrough pain
 Ketoprofen 10% transdermal- topical tx
 Morphine + oxycodone- immediate release for tx of post-op pain and acute pain
Multiple Sclerosis
- Dimethyl fumarate - oral immunomodulator with neuroprotective and anti-inflammatory effects for tx relapsing-remitting MS (RRMS)
- Cladribine (already approved for leukemia/lymphomas) - purine nucleoside analog

Lupus/Rheumatoid arthritis/psoriasis
- Belimumab - human monoclonal antibody - new class BLyS-specific inhibitors that recognize and inhibit the biological activity of B-lymphocyte stimulator
- Tasocitinib, Apremilast - oral biologic studied for psoriasis and rheumatoid arthritis

Hepatitis C/ Cystic fibrosis (CF)
- Hepatitis C - Oral protease inhibitors and long-acting interferons will be blockbuster treatments
- CF-mannitol inhalation powder - for improvement in lung function

New OTCs
- Advil Congestion relief - Ibuprofen + phenylephrine
- Diabetic Tussin Cold & Flu, night time - acetaminophen, dextromethorphan, hydrobromide, diphenhydramine
- Theraflu Max-D Severe cold & flu - acetaminophen, dextromethorphan, guaifenesin, pseudoephedrine
- Nip-it throat spray - Blend of Vit. B, C, aloe, echinacea, goldenseal

Questions
- What will be blockbuster treatments for Hepatitis C?

Last Question
- If you had the chance to work in the area of drug development, what disease state would you focus on and why?
Your disease may kill you before these are available, but at least you'll die SAFE.