New Drugs of 2006

• 97 New Drug Applications Approved
  – 49 New Dosage Form
  – 18 New Molecular Entity
  – 12 New Manufacturer/Formulation
  – 9 New Combination
  – 4 New Biologic Entity
  – 3 New Salt/Ester/Derivative
  – 2 Rx-to-OTC Switch
Andulafungin (Eraxis®)

- Echinocandin Antifungal
- Indication: candidemia, and other forms of *Candida* infections
- No hepatic metabolism, no effect on cytochrome P450 isoenzymes
- Precautions: hepatic dysfunction, failure, abnormalities

http://www.eraxisrx.com
Andulafungin (Eraxis®)

- Adverse effects: hypersensitivity, diarrhea, hypokalemia, elevated ALT
- Availability: 50 mg, 100 mg reconstitution
- Dose: Once-daily administration
  - Candidemia/Intraabdominal abcess/Peritonitis: 200 mg LD IV, then 100 mg IV qd for 14 days after last culture
  - Esophageal candidiasis: 100 mg LD IV, then 50 mg IV for 7 days after resolution of symptoms

http://www.eraxisrx.com
Avobenzone/ Ecamsule/ Octocrylene (Anthelios SX®)

- OTC topical sunscreen
- Ecamsule: unique sun filter
- UVA & UVB Protection
  - SPF 15 and highest UVA among those tested by manufacturer

http://www.anthelios.com
Biskalcitrate/Metronidazole/Tetracycline (Pylera®)

- Kit for *Helicobacter pylori*
- Used in combination with a PPI = high eradication rate
- Food decreases bioavailability of each drug, which may be beneficial when local gastric effects are needed
- Dosage: 1 cap tid pc x 10 days
- Precautions: hepatic or renal impairment
Biskalcitrate/Metronidazole/Tetracycline (Pylera®)

- Drug interactions/adverse effects:
  - Not during pregnancy
  - Metronidazole: alcohol, digoxin, oral contraceptives, cimetidine, serum creatinine, serum lithium, fluorouracil
  - Tetracycline: methoxyflurane, retinoids, acitretin (Soriatane®), photosensitivity, atovaquone (Mepron®), tongue discoloration
  - Biskalcitrate: tongue discoloration, stool discoloration, constipation, diabetic testing
Biskalcitrate/Metronidazole/Tetracycline (Pylera®)

• Patient counseling points:
  – No antacids, milk, dairy products: 1 to 2 hours
  – No calcium, iron, zinc: 2 hours after last dose or 4 hours before next dose
  – Do not take right before bed
  – Avoid sun/wear sunscreen/protective clothing
  – Oral contraceptives
  – Take with food and plenty of water: decrease nausea, vomiting, diarrhea, abdominal pain
Ciclesonide (Omnaris®)

• Glucocorticoid

• Indication: nasal symptoms of season and perennial allergic rhinitis in patients 12 years of age and older

• Ester pro-drug: requires activation in the nasal mucosa to an active metabolite (des-ciclesonide)
  – 100x greater affinity than parent compound and high local anti-inflammatory effects
Ciclesonide (Omnaris®)

- Metabolized in liver by cytochrome P450 3A4
- Cross-hypersensitivity
- Adverse effects: epistaxis, nasopharyngitis, ear pain, headache
- Availability: 50 mcg/spray
- Dosage: 2 sprays in each nostril once daily (200 mcg/d)
Darunavir (Prezista®)

- Priority review
- Protease inhibitor
- Indication: combination with ritonavir (Norvir®) and other antiretrovirals
- Drug interactions: CYP3A inhibitor
- Adverse effects: Sulfa allergy
- Availability: 300 mg tablets
- Dosage: 600 mg bid with ritonavir 100 mg bid with food

http://www.prezista.com
Dasatinib (Sprycel®)

- Priority review, Orphan drug
- Class: oral multi-tyrosine kinase inhibitor
  - Signal transducer in several cellular molecular pathways
- Indication: acute lymphoid leukemia, Philadelphia chromosome-positive (Ph+) and chronic myelogenous leukemia chronic phase that is resistant or tolerant to imatinib (Gleevec®)
Dasatinib (Sprycel®)

• Metabolized: cytochhorome P450 3A4
• Precautions: severe myelosuppression
  – Complete blood counts weekly x first 2 months, then monthly
• Availability: 70 mg tablets
• Dosage: 70 mg bid (am & pm)
  – With or without food
  – No antacids (2 hours), H2A or PPI

http://www.sprycel.com
Decitabine (Dacogen®)

- Orphan
- Novel injectable antimetabolite chemotherapeutic agent
- Indication: myelodysplastic syndrome (MDS) and secondary MDS of all French-American-British subtypes, and intermediate-1, intermediate-2 and high risk International Prognostic Scoring System groups

http://www.dacogen.com
Decitabine (Dacogen®)

- MOA: Replaces cytosine in DNA, but cannot be methylated
- Drug interaction: studies not done
- Adverse effects: myelosuppression, bleeding, infection
- Dosage: 15 mg/m² IV over 3 hours every 8 hours for 3 days, repeated every 6 weeks for a minimum of 4 cycles

http://www.dacogen.com
Kunecatechins (Veregen®)

- Derived from green tea leaves
  - Gallic acid, caffeine, theobromine
- Indication: topical treatment of external genital and perianal warts
- Availability: 15 gm ointment
- Dosage: 0.5 cm strand of ointment applied tid (max duration of 16 weeks)
- Local skin reactions are frequent, continue therapy unless severity unacceptable
Lubiprostone (Amitiza®)

• Indication: chronic idiopathic constipation
  – Increases intestinal fluid secretion, which increases motility

• Precautions: not during pregnancy

• Adverse effects: nausea (dose-dependent), diarrhea

• Availability: 24 mcg capsule

• Dosage: 1 capsule bid po with food
Paliperidone (Invega®)

- Atypical antipsychotic with OROS extended-release technology that provides continuous release over 24 hours
- Indication: schizophrenia
- Major active metabolite of risperidone
- Precaution: QTc prolongation
- Availability: 3, 6 and 9 mg ER tablets
- Dosage: 6 mg/d (am) with or without food (max 12 mg/d, lowest effective 3 mg/d)
Posaconazole (Noxafil®)

- Priority review
- Broad-spectrum oral triazole antifungal
- More potent and effective than itraconazole (Sporanox®) against invasive molds and pathogenic yeasts
- Indication: prophylaxis against invasive Aspergillus and Candida in severely immunocompromised patients
- Drug interactions: Inhibits CYP3A4 enzymes

http://www.noxafil.com
Posaconazole (Noxafil®)

- **Drug interactions:** Inhibits CYP3A4 enzymes
- **Precaution:** QT prolongation, hepatic dysfunction
- **Availability:** Oral suspension 200 mg/5 mL
- **Dosage:** 200 mg (5 mL) po tid
  - Febrile neutropenia/refractory infection: 400 mg bid or 800 mg qd
  - Food increases absorption

http://www.noxafil.com
Ranolazine (Ranexa®)

- New class: metabolic modulator
- Indication: chronic stable angina
- MOA: Unknown, but thought ultimately generate more ATP (adenosine triphosphate)
  - increases the energy available to the cells in the heart and improves the use of cardiac substrates
- Adverse effects: dizziness, nausea, constipation, minor QTc changes
Ranolazine (Ranexa®)

- Precaution: existing QT prolongation, hepatic impairment
- Drug interactions: drugs that prolong QT interval
- Availability: 500 mg ER tablets
- Dosage: 500 mg bid (max 1000 mg bid)
  - Approved for use in combination with beta-blockers, amlodipine or nitrates

http://www.ranexa.com
Rasagiline Mesylate (Azilect®)

- Indication: Parkinson’s disease
- MOA: Irreversible MOAI
- Precautions: tyramine, existing cardiovascular problems, headaches/migraine
- Drug interactions: at least 14 days between d/c and initiation of another MAOI, meperidine, dextromethorphan, SSRIs, tricyclics, SNRIs, tramadol

http://www.azilect.com
Rasagiline Mesylate (Azilect®)

- Adverse effects: weight loss, orthostatic and postural hypotension, dry mouth, abnormal involuntary movement, hallucinations
- Availability: 0.5 mg and 1 mg tablets
- Dosage:
  - Monotherapy: 1 mg
  - Adjunct therapy: 0.5 mg qd up to 1 mg qd
Sitagliptin phosphate (Januvia®)

• Indication: adjunctive treatment of Type 2 DM with diet and exercise
• MOA: Dipeptidyl peptidase (DPP)-IV inhibitor (slows the inactivation of incretin hormones)
  – Increases insulin release and decreases glucagon levels in circulation
• Drug interactions: digoxin (monitor dig)
Sitagliptin phosphate (Januvia®)

• Adverse effects: nasopharyngitis, upper respiratory infection, headache
• Availability: 25, 50 and 100 mg tablets
• Dosage: 100 mg po once daily
  – CrCl 30 mL/min - <50 mL/min = 50 mg qd
  – CrCl <30 mL/min = 25 mg qd

http://www.januvia.com
Sunitinib (Sutent®)

- Priority review
- Indication: Advanced renal cell cancer (RCC) or for the treatment of GI stromal tumors (GISTs) after disease progression while on or intolerance to imatinib (Gleevec®)
- MOA: oral tyrosine kinase inhibitor
- Precautions: pregnancy, cardiac or cerebrovascular events w/in 12 months
Sunitinib (Sutent®)

• Drug interactions: Potent CYP3A4 inhibitors and inducers, grapefruit juice

• Adverse effects: left ventricular dysfunction resulting in CHF, bleeding, neutropenia

• Availability: 12.5, 25 and 50 mg capsules

• Dosage: 50 mg po qd for 4 weeks, off for 2 weeks with or without food
  – Dose adjustments in 12.5 mg increments

http://www.sutent.com
Telbivudine (Tyzeka®)

- Indication: chronic HBV in patients with evidence of viral replication and either elevated ALT or AST or histologically active disease
- MOA: Inhibits HBV DNY polymerase
- Precautions: renal disease/impairment
- Adverse effects: muscle-related
- Not in < 16 years of age

http://www.tyzeka.com
Telbivudine (Tyzeka®)

- Availability: 600 mg tablets
- Dosage: 600 mg po once daily
  - CrCl 30-49 mL/min = 600 mg po once every 48 hours
  - CrCl < 30 mL/min not on dialysis = 600 mg po once every 72 hours
  - Intermittent hemodialysis: 600 mg po once every 96 hours (after hemodialysis)

http://www.tyzeka.com
Varenicline (Chantix®)

• Priority review
• Indication: aid to smoking-cessation
• MOA: nicotine receptor agonist
  – Decreases nicotine cravings and withdrawal symptoms
  – Blocks the effects of nicotine at receptors
  – Binds to serotonin receptors, too
• Precautions: renal dysfunction

http://www.chantix.com
Varenicline (Chantix®)

• Drug interactions: combination with NRT leads to increased adverse reactions
• Adverse effects: nausea/vomiting, sleep disturbance, constipation, flatulence
• Availability:

• Dosage:
  – Days 1 – 3: 0.5 mg qd
  – Days 3 – 7: 0.5 mg bid
  – Days 8 – end of treatment: 1 mg bid (12 weeks)

http://www.chantix.com
Vorinostat (Zolinza®)

- Priority review, Orphan drug
- First in a new class of synthetic hybrid polar compounds: histone deacetylase (HDAC) inhibitors
- Indication: Cutaneous T-cell lymphoma (CTCL) in patients with progressive, persistent, or recurrent disease on or following 2 other systemic therapies
- MOA: HDAC inhibitor
  - Stimulation of immune system and blockage of angiogenesis

http://www.zolinza.com
Vorinostat (Zolinza®)

- Precautions: thrombocytopenia, anemia, thromboembolic disease, diabetes, QT prolongation
- Drug interactions: anticoagulants, anti-inflammatory drugs, platelet inhibitors
- Adverse effects: GI, hyperglycemia
- Availability: 100 mg capsules
- Dosage: 400 mg po once daily with food
  - If intolerant: 300 mg po once daily

http://www.zolinza.com
New Biologics

• Alglucosidase (Myozyme®)
  – Priority review, orphan
  – Enzyme-replacement therapy for endogenous acid alpha-glucosidase
  – Pompe disease (glycogen storage disease)

• Idursulfase (Elaprase®)
  – Priority review, orphan
  – Purified form of human iduronate-2-sulfatase
  – Hunter syndrome (mucopolysaccharidosis)

http://www.myozyme.com
New Biologics

• Panitumumab (Vectibix®)
  – Priority review
  – Human immunoglobulin (Ig) G2 antibody that binds to the extracellular domain of the human epidermal growth factor receptor
  – EGFR-expressing colorectal cancer

• Ranibizumab (Lucentis®)
  – Priority review
  – Recombinant humanized monoclonal antibody fragment
  – Neovascular, age-related macular degeneration
Hot Drugs for Nursing
Source: American Nurse Today

• Gardasil® (quadrivalent human papillomavirus (types 6, 11, 16 and 18) recombinant vaccine)
• Eraxis® (anidulafungin)
• Chantix® (varenicline)
• Exubera® (insulin, human; dry powder for inhalation)
• Caduet® (amlodipine besylate, atorvastatin calcium)
Hot Drugs for Nursing
Source: American Nurse Today

• Atripla® (efavirenz, emtricitabine, tenofovir disoproxil fumarate)
• Januvia® (sitagliptin)
• Kepivance® (palifermin)
• Boniva® injection (ibandronate sodium)
• Symlin® (pramlintide acetate)
• Tygacil® (tigecycline)
• Emend® (aprepitant)