New Drugs 2011:
The Second Half

Anna Nowobilski-Vasilios
PharmD MBA FASHP CNSC BCNSP
Principal, Anovation, Inc.
Adjunct Assistant Professor
Midwestern University – Chicago College of Pharmacy
Chicago State University – College of Pharmacy

Images: empr.com.

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Learning Objectives

Technicians:

- Name the disease state and therapeutic class for select new agents approved during the second half of 2011.
- Discuss the dosage form and route of administration for each new agent.
- Describe the most serious adverse effects for each class of agent.
- List special considerations related to storage, preparation, and dispensing for each new agent.

Pharmacists:

- Describe the therapeutic classification and indications for select new agents approved in the second half of 2011.
- Discuss the dosing, administration, and appropriate role of each new agent.
- List the major adverse effects, contraindications, and precautions for each new agent.
- Discuss special considerations related to storage, preparation, dispensing, and monitoring each new agent.

Disclosures: Speaker or spouse do not have actual or potential conflict of interest in relation to this presentation.

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General Wellbeing
Dermatology
Ophthalmology
Otolaryngology
Cardiology
Pulmonology
Gastroenterology
Urology
Nephrology
Obstetrics/Gynecology
Neurology
Psychiatry
Rheumatology
Immunology
Endocrinology
Hematology
Oncology
Infectious Disease
Radiology
Other

New Drugs 2011 – *Second Half*

- Macular Degeneration: aflibercept IO EYLEA™
- ACS: ticagrelor PO BRILINTA™
- COPD: indacaterol INH ARCAPTA™
- LGS: clobazam PO ONFI™
- HAE: icatibant SC FIRAZYR®
- Fe Overload: deferiprone PO FERRIPROX®
- DVT prophylaxis: rivaroxaban PO XARELTO®
- Stroke prophylaxis: rivaroxaban PO XARELTO®
- Myeolofibrosis: ruxolitinib PO JAKAFI™
- ALL: asparaginase Erwinia chrysanthemi IM ERWINAZE™
- Hodgkin Lymphoma: brentuximab IV ADCETRIS™
- ALCL: brentuximab IV ADCETRIS™
- Melanoma: vemurafenib PO ZELBORAF™
- NSCLC: crizotinib PO XALKORI®
- Scorpion Bite: Centruroides Immune Injection IM@ ANASCORP®

References: (1) fda.gov. (2) drugs.com. (3) Pharmacist's Letter.

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Ophthalmology » Exudative ARMD

- #1 cause of irreversible vision loss
- Nonexudative
- Exudative
- 1.75M (US)
- Increased depression
- Frequent falls
- Compromised ADL's
- Women increased risk
- Mild sxs; asymptomatic
- Treatment:
  - antiangiogenic agents
  - laser (verteporfin)

Reference: (1) emedicine.com, Exudative ARMD, 1/11/12. (2) FDA News Release, 11/18/11. (3) Images: upnorthhealth.com; seewithlasik.com.

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Approved 11/18/2011

IO

aflibercept

EYLEA™

- Inhibits binding and activation of VEGF receptors
- CI: eye infection/inflammation, hypersensitivity
- Caution: endopthalmitis, retinal detachment, ↑IOP, MI, stroke
- ADR: eye pain, conjuctival hemorrhage, vitreous floaters, cataract
- Dose: 2mg (0.05mL) intravitreal q4wks x 3 mos, then q8wks x 2 mos.
- Educate re driving, symptoms to report
- Monitor IOP, optic nerve head perfusion
- Comparable to ranibizumab

Pregnancy Category C

NOT FOR USE IN CHILDREN

Keep in Refrigerator DO NOT FREEZE

Do not drive or use machinery until vision has recovered

PROTECT FROM LIGHT

No Preservatives DISCARD unused portion

References: (1) Prescribing information, EYLEA™ (aflibercept). Tarrytown NY: Regeneron; Nov 2011. (2) Medical Letter 2012;1383:9. (3) Epocrates Rx Pro v4.1.1. (4) Micromedex v1.27.061100. (5) FDA News 11/18/11. (6) Image: multivu.com.

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Self-Assessment

- Which of the following VEGF inhibitors is *not* FDA-approved for wet age-related macular degeneration?
- [A] pegaptanib (Macugen),
- [B] ranibizumab (Lucentis),
- [C] bevacizumab (Avastin),
- [D] aflibercept (Eylea).

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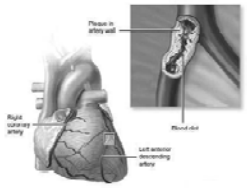
Cardiology » ACS

- Coronary artery disease
  - STEMI (30%)
  - NSTEMI (25%)
  - Unstable angina (38%)
- Atherosclerotic plaque rupture



- 50% cases clinically silent
- 6-month mortality rates
  - 13% NSTEMI
  - 8% unstable angina
- Goals
  - Preserve coronary artery patency
  - Blood flow thru lesions
  - Reduce myocardial O2 demand
- Treatment
  - Anti-ischemic therapy
  - Antithrombotic therapy
  - Anticoagulation therapy
- Education mnemonic ABCD

Reference: emedicine.com, Acute Coronary Syndrome, 1/17/2012. Image: medicalook.com.
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Approved 07/20/2011

MedGuide required

ticagrelor

BRILINTA™

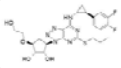
PO

Pregnancy Category C

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

- *Reversible* P2Y(12) ADP-receptor antagonist
- Prevents platelet aggregation in ACS
- CIs: intracranial hemorrhage, bleeding, severe hepatic impairment
- Increases risk of bleeding; DC 5d a/surgery
- DC increases risk of MI, stent thrombosis, death
- ADR: bleeding, dyspnea, HA, ↑sCr, cough, atrial fib
- Multiple DIs: CYP3A4/5 metabolism
- 180mg PO load, then 90mg PO BID w/ ASA < 100mg
- Pt Ed: report bleeding; MedGuide; may bruise; MD approval for DC; avoid additional ASA products
- $50/mo more than clopidogrel and prasugrel



References: (1) Prescribing information, BRILINTA™ (ticagrelor). Wilmington DE: AstraZeneca; July 2011. (2) FDA News, 7/20/11. (3) Micromedex v1.27.0b1100. (5) Pharmacist's Letter2011; 27(8):270801. (6) The Medical Letter 2011; 1372:69. (7) FDA News, 7/1/11. (8) Images: rxlist.com; drugdevelopment-technology.com.
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Self-Assessment

- Which of the following is TRUE about ticagrelor?
- [A] it should be used with 325 mg ASA daily
- [B] it should be stopped 5 days before surgery
- [C] it's less effective than clopidogrel for ACS
- [D] it's a prodrug

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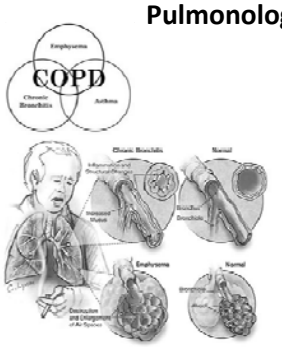
Pulmonology » COPD



- Triad: bronchitis, emphysema, asthma
- 32 M in US
- Smoking: 90% COPD risk
- 4th cause of death in US
- Goals
  - Improve functional status
  - Improve symptoms, QOL
- Management
  - Smoking cessation
  - Bronchodilators, steroids, anti-infectives, mucolytics
  - Oxygen
  - Vaccination
  - Physiotherapy

References: (1) emedicine.com, Chronic Obstructive Pulmonary Disease, 10/10/11. (2) Images: emedicine.com; copdpathophysiology.net.
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MedGuide required

indacaterol

ARCAPTA™

INH

Pregnancy Category C

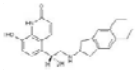
NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

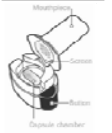
PROTECT FROM LIGHT

PROTECT FROM MOISTURE

DO NOT SWALLOW



- LABA for airflow obstruction in COPD
- CI: asthma
- Caution: asthma-related death, acute COPD, paradoxical bronchospasm, CV/convulsive disorders, hypokalemia, hyperglycemia
- ADR: cough, nasopharyngitis, HA, nausea
- Pharmacokinetics
- DIs: other adrenergics, xanthine derivative, steroids, non-potassium sparing diuretics, MAOIs, TCADs, QTc prolongers, beta-blockers
- 75 mcg oral INHALATION once daily via Neohaler. Onset w/in 5 minutes.
- Pt Ed: report worsening symptoms, ↓effectiveness; smoking cessation, vaccination



References: (1) Prescribing information, ARCAPTA™ (indacaterol). East Hanover NJ: Novartis; July 2011. (2) Micromedex, v1.27.0b1100. (3) FDA News, 7/1/11. (4) Images: dailymed.nlm.nih.gov; rxlist.com.
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Self-Assessment

- Which of the following is TRUE about indacaterol?
- [A] It's used twice daily, just like the other LABAs (salmeterol, formoterol).
- [B] It's approved for COPD and asthma.
- [C] It's proven to reduce COPD exacerbations.
- [D] It requires dispensing with a Patient Medication Guide.

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Neurology » LGS

- Childhood epileptic encephalopathy
- 0.1/1000 male births; 0.02/1000 female births
- Multiple seizure types; mental retardation/regression; abnormal EEG
- Classifications: idiopathic, symptomatic, cryptogenic
- Variable prognosis
- Medical treatment:
  - first-line: valproic acid, benzodiazepines
  - OL effective: vigabatrin, zonisamide
  - DBPC effective: lamotrigine, topiramate, felbamate, rufinamide
- Surgery; Ketogenic Diet; Injury prevention
- Psychosocial family needs

Reference: emedicine.com, Lennox-Gastaut Syndrome, 1/26/12.

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Approved 10/24/2011

MedGuide required

clobazam

ONFI™

C IV | PO

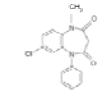
Pregnancy Category C

Do not use machinery or drive until effect is known

AVOID ALCOHOL

Store at Controlled Room Temperature

- Adjunct benzodiazepine for LGS seizures in ≥ 2yo
- Caution: CNS depression, avoid alcohol, DC gradually
- ADRs: sedation, drooling, constipation, cough, UTI, aggression, insomnia, fatigue
- DIs: CYP2D6, CYP2C19, alcohol, OCs
- Special Populations
- Start at 5mg/day, titrate to 20mg/day (≤30kg); to 40 mg/day (>30kg). Divided doses if > 5mg/day.
- Pt Ed: Medication Guide, sleepiness, avoid alcohol, non-hormonal contraceptives. Report depression, suicidal ideation, pregnancy. Multiple interactions!
- Monitor for s/s dependence, suicidal ideation, unusual behavior.



References: (1) Prescribing information, ONFI™ (clobazam). Deerfield IL: Lundbeck, Inc.; October 2011. (2) Micromedex, v1.27.0b1100. (3) FDA News, 10/24/11. (4) Images: rxlist.com; empr.com.

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Self-Assessment

- Which of the following is TRUE about clobazam?
- [A] It can be stopped abruptly.
- [B] It can cause sleepiness and suicidal ideation.
- [C] It can be taken without regard to meals or alcohol.
- [D] It does not effect oral contraceptives.

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Immunology » HAE

- Hereditary autosomal dominant
  - Low serum C1-INH
- Complement pathway activation
  - Angioedema; abdominal pain; airway obstruction
- Prevalence 1/50,000-150,000
  - 15,000-30,000 EDV's /year
- Type I (85%); Type II (15%); "Type III"
- Attack ppt by hormone levels, trauma, emotional stress
- Mortality 20-30% prior to current therapies
  - Correct diagnosis essential
- Prophylaxis: attenuated androgens, C1-INH
- Acute: C1-INH, C1 esterase INH, ecallantide, icatibant
- Supportive: intravascular fluid replacement, pain management, intubation, eradicate underlying causes

Reference: (1) emedicine.com, Hereditary Angioedema, 2/8/2012. (2) Images: cmm.ki.se.

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Approved 8/25/2011

icatibant

FIRAZYR®

specialty medication | SC

Pregnancy Category C

NOT FOR USE IN CHILDREN

DO NOT FREEZE

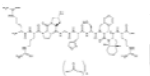
Do not use machinery or drive until effect is known

PROTECT FROM LIGHT

No Preservatives DISCARD unused portion

LATEX FREE

- Bradykinin B2 receptor antagonist for HAE attacks
- ADRs: injection site reactions, pyrexia, dizziness
- DI: ACEIs
- 30 mg SC (abdomen). May repeat in 6 hrs. No more than 3 doses/24 hrs.
- Pt Ed: Seek medical attention after administration for laryngeal attack
- Only self-administered tx for HAE attacks
- Store between 2-25ºC (36-77ºC)
- No comparative studies
- ~$2500/dose



References: (1) Prescribing information, FIRAZYR® (icatibant). Lexington WA: Shire Orphan Therapies; August 2011. (2) The Medical Letter 2011;1378:96. (3) Medical Letter 2010;1345:66. (4) Micromedex, v1.27.0b1100. (5) FDA News, 10/25/11. (6) Images: rxlist.com; empr.com.

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Self-Assessment

- Which of the following HAE treatments could a patient be trained to self-administer?
- [A] C1 inhibitor (CINRIZE)
- [B] C1 inhibitor (BERINERT)
- [C] ecallantide (KALBITOR)
- [D] icatibant (FIRAZYR)

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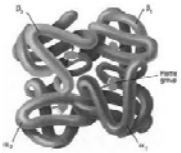
Hematology » Iron Overload

- Anemia in thalassemias requires transfusion therapy
- Excess iron accumulates in tissues
  - Cardiac involvement
  - Pulmonary hypertension
  - Liver involvement
  - Endocrine dysfunction
  - Neutrophil phagocytosis defect
- Mortality 3x general US
- Goal: prevent harmful iron accumulation
- Increased survival from current therapies
  - deferoxamine (SC/IV), deferasirox (PO), deferiprone (PO)
- Cardiac/Lung transplant
- Compliance major issue with IV/SC treatments



References: (1) emedicine.com, Transfusion-Induced Iron Overload, 10/17/2011. (2) Image: nhibi.nih.gov.
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Approved 10/14/2011

deferiprone

FERRIPROX®

PO

Pregnancy Category D

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

- Second-line iron chelator for transfusional iron overload due to thalassemia syndromes
- CI: hypersensitivity, ANC < 1500, QT prolongation
- Caution: agranulocytosis, fetal harm
- ADRs: chromaturia, N, V, abdominal pain, ↑ALT, neutropenia
- DI: neutropenic drugs, space 4 hrs w/ polyvalent cations
- 25-33 mg/kg PO TID, rounded to nearest 250 mg
- Pt Ed: Report s/s infection, palpitations, dizziness, lightheadedness, syncope, seizures.
- Monitor ANC, serum ferritin, serum ALT, plasma Zn
- No comparative studies.

References: (1) Prescribing information, FERRIPROX® (deferiprone). Rockville MD: ApoPharma USA; October 2011. (2) The Medical Letter 2012; 1384:15. (3) Micromedex, v1.27.0b1100. (4) FDA News, 10/14/11. (5) Images: rxlist.com; empr.com.
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Self-Assessment

- Which of the following is TRUE for deferiprone?
- [A] It should be interrupted when the patient develops an infection.
- [B] It is indicated for the treatment of iron overload due to sickle cell anemia.
- [C] It has been proven to improve survival in thallasemia syndromes.
- [D] It is infused subcutaneously.

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Hematology » Anticoagulation

- Knee/Hip Replacement & DVT prevention
- Immobilization
- DVT p/ knee or hip replacement 40-70%
- PE p/ knee 7%, fatal 2%
- Prevention
  - Mechanical
  - Pharmacological
    - ASA
    - warfarin
    - heparin
    - LMWH
    - rivaroxaban (7/11)
- Atrial Fibrillation & Stroke Prophylaxis
- AF stroke risk 4.5%/year
- Anticoagulated AF stroke risk 1.4%/year
- Anticoagulation in AF
  - warfarin
  - dabigatran (10/10)
  - rivaroxaban (11/11)
  - apixaban (Phase III)

References: (1) emedicine.com, Deep Venous Thrombosis Prophylaxis in Orthopedic Surgery, 7/12/11. (2) medscape.com, Thromboembolism after total knee arthroplasty. (3) medscape.com, Rivaroxaban, Dabigatran, or Warfarin? Medscape Pharmacists, 11/18/11. (4) FDA News, 7/5/11, 11/4/11.
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Approved 7/1/2011

rivaroxaban

XARELTO®

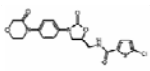
PO

Pregnancy Category C

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

- Factor Xa inhibitor
  - DVT prophylaxis in knee/hip replacement surgery
  - Stroke/systemic embolism in nonvalvular atrial fibrillation
- CI: bleeding, hypersensitivity
- Caution: DC ↑stroke risk, epidural/spinal hematoma, pregnancy related hemorrhage.
- ADRs: bleeding
- DIs: anticoagulants, CYP3A4/5, NSAID/ASA
- Knee/hip: 10mg PO QD w/ or w/o food
- Nonvalvular atrial fib: 20mg PO QD w/ dinner, decreased dose w/ CrCl < 50 mL/min.
- Pt Ed: Stopping. Report invasive procedures, concomitant meds/herbals, unusual bleeding/bruising, pregnancy.
- Monitor renal fx, bleeding, neurological impairment.
- Appears to be more effective than enoxaparin after hip/knee
- No antidote, not dialyzable



References: (1) Prescribing information, XARELTO® (rivaroxaban). Titusville NJ: Janssen Pharmaceuticals; December 2011. (2) The Medical Letter 2011; 1371:65. (3) The Medical Letter 2011; 1379:97. (3) Micromedex, v1.27.0b1100. (4) FDA News, 7/5/11, 11/4/11. (5) Images: rxlist.com; multivu.prnewswire.com.
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Self-Assessment

- The new anticoagulant rivaroxaban is FDA-approved for which of the following indications?
- [A] Deep venous thrombosis (DVT) prophylaxis in knee and hip replacement surgery.
- [B] Cardiac event prophylaxis in acute coronary syndrome (ACS).
- [C] Stroke prevention in nonvalvular atrial fibrillation.
- [D] All of the above.
- [E] A and C only.

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Hematology » Myelofibrosis

- Bone marrow disorder
- Fibrous tissue replaces marrow
- Liver/spleen hematopoiesis & enlargement
- Anemia, bleeding disorders, ↑ infection risk
- JAK2 stem cell mutation
- Symptomatic treatment: transfusion, radiation, chemotherapy, stem cell transplant, erythropoietin, androgens, splenectomy
- Survival 5 years to decades.

References: (1) ncbi.nlm.nig.gov/pubmedhealth, Myelofibrosis, 6/2/10. (2) FDA News 11/16/11. (3) mayoclinic.com, Myelofibrosis, 12/13/11.
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Approved 11/16/2011

MedGuide required

ruxolitinib

JAKAFI™

specialty medication

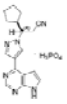
PO

Pregnancy Category C

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

- Kinase inhibitor for myelofibrosis
- Caution: thrombocytopenia, anemia, neutropenia, infection
- ADRs: fatigue, diarrhea, SOB, HA, dizziness, nausea
- DIs: lower start dose w/ CYP3A4 inhibitors
- Start 20 mg PO BID. Modify w/ platelet count, response, strong CYP 3A4 inhibitors, renal impairment, hepatic impairment.
- Pt Ed: Report s/s infection, unusual bleeding/bruising. Advise of all meds, OTCs, herbals, supplements.
- Monitor CBC/platelets.
- Reimbursement Issues



References: (1) Prescribing information, JAKAFI™ (ruxolitinib). Wilmington DE: Incyte Corporation; November 2011. (2) FDA News, 11/16/11. (3) Images: rxlist.com, empr.com.
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Self-Assessment

- Which of the following is TRUE about ruxolitinib?
- [A] hematological adverse effects to ruxolitinib are managed by dose reduction, treatment interruption, or transfusion.
- [B] ruxolitinib dosing is decreased when concurrently administered with CYP3A4 inhibitors such as clarithromycin and grapefruit juice.
- [C] Ruxolitinib dosing is modified with thrombocytopenia, renal impairment, and hepatic impairment.
- [D] All of these statements are true.

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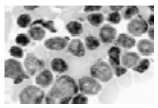
Hematology » ALL

- Malignant bone marrow disease
- Lymphoid precursor cells
  - Anemia, thrombocytopenia, neutropenia
  - Proliferation in marrow, liver, spleen, lymph nodes
- Most common cancer in US children
  - Less common in adults than AML
  - 1000 new cases/year in each population group
- Most adults evaluated for clinical trial
  - Only 20-40% cured w/ current regimens
- Treatment phases:
  1. Induction » 4-5 drug regimen; 65-85% remission
  2. Consolidation » 4-5 drug regimen
  3. Maintenance » appears necessary
  4. CNS prophylaxis » intrathecal chemotherapy



Reference and Image: emedicine.com, Acute Lymphoblastic Leukemia, 2/2/2012.
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Approved 11/18/2011

asparaginase *Erwinia chrysanthemi*

ERWINAZE™

IM

Pregnancy Category C

Keep in Refrigerator DO NOT FREEZE

Mix Gently DO NOT SHAKE

No Preservatives DISCARD unused portion

PROTECT FROM LIGHT

- *Erwinia chrysanthemi*-derived asparaginase for ALL regimens in patients allergic to *E.coli*-derived asparaginase.
- CI: hypersensitivity; pancreatitis, thrombosis, coagulation issues
- Caution: hyperglycemia
- ADRs: abnormal transaminases, N, V
- *E.coli* substitution: 25,000 IU/m2 per dose
- Pegaspargase substitution: 24,000 IU/m2 IM 3x/week x 6 doses for each dose
- Pt Ed: Report s/s allergic reaction, abdominal pain, ↑thirst/urination, arm/leg swelling, SOB, chest pain
- Monitor serum glucose

References: (1) Prescribing information, ERWINAZE™ (asparaginase *Erwinia chrysanthemi*). Langhorne PA: EUSA Pharma; November 2011. (2) FDA News, 11/18/11. (3) Epocrates Rx Pro v4.1.1. (4) Micromedex v1.27.061100. (5) FDA News, 11/18/11. (6) Image: empr.com.
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Self-Assessment

- Asparaginase *Erwinia chrysanthemi* is contraindicated in patients …
- [A] allergic to *E.coli*-derived asparaginase.
- [B] hypersensitive to asparaginase.
- [C] with serious pancreatitis, thrombosis, or hemorrhage during prior asparaginase therapy.
- [D] B and C only.

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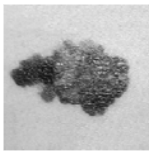
Oncology » Melanoma



- Malignant melanocyte transformation
- Recognition crucial, prior to metastasis
- 5% of all skin cancers
  - 3x deaths as nonmelanoma skin CA
- Incidence rising by 6% annually
- Lifetime risk 1/1500 (1935); 1/75 (2000)
- Risk Factors: family history, characteristics, immunosuppressive states, sun exposure over time
- Presentation mnemonic: ABCDE
- Surgery curative » early stage
- Medical treatment » later stages
  - antineoplastics, biological response modifiers

References: emedicine.com, (1) Melanoma, 11/4/11; (2) Malignant Melanoma, 2/10/12. (3) Image: visualsonline.cancer.gov.
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Approved 8/17/2011

specialty medication | PO

vemurafenib

ZELBORAF™

- Kinase inhibitor for unresectable/metastatic melanoma with BRAF V600E mutation.
- Caution: cuSCC, dermatologic reactions, QT prolongation, LFT abnormalities, photosensitivity, fetal harm.
- ADRs: arthralgia, rash, pruritus, fatigue, N, alopecia
- DIs: CYP1A2, 2D6, 2C9, 3A4, warfarin.
- Store in original container. Disposal cautions.
- 960 mg (4x240mg) PO BID. Dose modification for ADRs.
- Pt Ed: Avoid sun exposure. Report skin changes. DIs.
- Monitor lytes, LFTs, bilirubin, derm eval, ECG, uveitis.
- $9,400/month

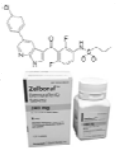
Pregnancy Category D

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

Mix Gently DO NOT SHAKE

AVOID SUN EXPOSURE



References: (1) Prescribing information, ZELBORAF™ (vemurafenib). South San Francisco CA: Genentech USA; August 2011. (2) The Medical Letter 2011; 1374:77. (3) Epocrates Rx Pro v4.1.1. (4) Micromedex v1.27.061100. (5) FDA News, 8/17/11. (6) Images: rxlist.com; baseluna.net.
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Self-Assessment

- Which of the following is FALSE about vemurafenib?
- [A] It must be stored in its original container.
- [B] Sun exposure must be avoided.
- [C] It is safe to use in pregnancy.
- [D] It is indicated only for BRAF V600E mutation positive melanoma.

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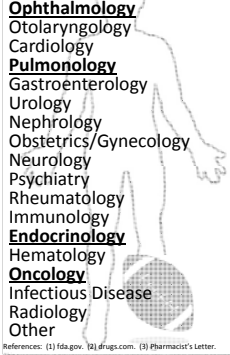
General Wellbeing
Dermatology
Ophthalmology
Otolaryngology
Cardiology
Pulmonology
Gastroenterology
Urology
Nephrology
Obstetrics/Gynecology
Neurology
Psychiatry
Rheumatology
Immunology
Endocrinology
Hematology
Oncology
Infectious Disease
Radiology
Other



New Drugs 2012 – *First Half*

ACTINIC KERATOSIS: ingenol TOP PICATO™

GLAUCOMA: tafluprost OPHTH ZIOPTAN™

CF: ivacaftor PO KALYDECO™

CUSHING's: mifepristone PO KORLYM™

MTX TOXICITY: glucarpidase IV VORAXAZE™

RENAL CA: axitinib PO INLYTA™

BASAL CELL CA: vismodegib PO ERIVENGE™

References: (1) fda.gov. (2) drugs.com. (3) Pharmacist's Letter.
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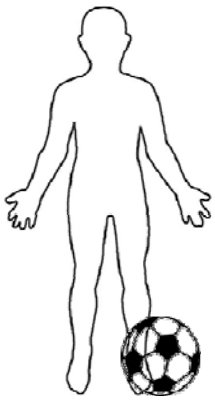

New Drugs 2011 – *The 2nd Half*

Questions?

annanv@anovation.us

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NEW DRUGS AND BIOLOGICALS 2011
RESOURCE LIST

Specialty	Generic Name	Brand Name	Company	Rte	Class & Indication	Approval
Cardiology	azilsartan medoxomil	EDARBI™	Takeda	PO	Angiotensin II receptor blocker (ARB) for high blood pressure	2/25/2011
Cardiology	ticagrelor	BRILINTA™	AstraZeneca	PO	Antiplatelet for acute coronary syndrome (ACS)	7/20/2011
Dermatology	spinosad	NATROBA™	ParaPRO Pernix	TOP	Topical suspension for treatment of head lice	1/18/2011
Endocrinology	linagliptin	TRADJENTA™	Boehringer Ingelheim	PO	Dipeptidyl petidase-4 (DDP-4) inhibitor for type 2 diabetes mellitus.	5/2/2011
Gastorenterology	dextranomer microspeheres and hyalouronidate	SOLESTA®	Oceana	INJ	Submucosal anal injection for the treatment of fecal incontinence.	5/27/2011
Hematology	asparaginase Erwinia chrysanthemi	ERWINAZE™	EUSA Pharma	IM	Chemotherapeutic for acute lymphoblastic leukemia (ALL) in patients allergic to E. coli-derived asparaginase	11/18/2011
Hematology	brentuximab vedotin	ADCETRIS™	Seattle Genetics	IV	Anti-CD30 monoclonal antibody for Hodgkin lymphoma and anaplastic large cell lymphoma (ALCL).	8/19/2011
Hematology	deferiprone	FERRIPROX®	ApoPharma	PO	Iron chelator for the treatment of transfusional iron overload due to thalassemia syndromes.	10/14/2011
Hematology	factor XIII	CORIFACT®	CSL Behring	IV	Pooled human plasma factor XIII concetrate for congenital factor XIII deficiency	2/17/2011
Hematology	rivaroxaban	XARELTO®	Janssen	PO	Factor Xa inhibitor for DVT prophylaxis after knee or hip replacement surgery and to reduce the risk of stroke in atrial fibrillation.	7/1/2011; 11/4/11
Hematology	ruxolitinib	JAKAFI™	Incyte	PO	Kinase inhibitor for the treatment of patients with myelofibrosis.	11/16/2011
Immunology	icatibant	FIRAZYR®	Shire Human Genertic Therpies	SC	Bradykinin B2 receptor antagonist for acute hereditary angioedema (HAE) attacks in adults	8/25/2011
Infectious Disease	boceprevir	VICTRELIS™	Merck	PO	Protease inhibitor for chronic hepatitis C.	5/13/2011
Infectious Disease	fidaxomicin	DIFICID™	Optimer	PO	Macrolide antibiotic for treatment of life-threatening *Clostridium defficile*-associated diarrhea (CDAD)	5/27/2011
Infectious Disease	rilpivirine	EDURANT™	Tibotec	PO	Non-nucleoside reverse transcriptate inhibitor (NNRTI) for HIV-1 infection.	5/20/2011
Infectious Disease	telaprevir	INCIVEK™	Vertex	PO	Protease inhibitor for chronic hepatitis C.	5/23/2011

NEW DRUGS AND BIOLOGICALS 2011
RESOURCE LIST

Specialty	Generic Name	Brand Name	Company	Rte	Class & Indication	Approval
Nephrology	belatacept	NULOJIX®	BMS	IV	Immunosuppressant for the prevention of kidney transplant rejection.	6/15/2011
Neurology	clobazam	ONFI™	Catalent Pharma	PO	Benzodiazepine for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS).	10/24/2011
Neurology	ezogabine	POTIGA™	GSK	PO	Anticonvulsant for partial-onset seizures	6/10/2011
Neurology	gabapentin enacarbil	HORIZANT™	GSK	PO	Gabapentin prodrug for restless legs syndrome.	4/6/2011
Oncology	abiraterone acetate	ZYTIGA™	Centocor Ortho Biotech	PO	CYP17 inhibitor for refractory prostate cancer.	4/28/2011
Oncology	crizotinib	XALKORI®	Pfizer	PO	Kinase inhibitor for advanced non-small cell lung cancer (NSCLC).	8/26/2011
Oncology	everolimus	AFINITOR®	Norvartis	PO	Progressive metastatic pancreatic neuroendocrine tumors (PNET) or refractory to surgery	5/6/2011
Oncology	ipilimumab	YERVOY™	BMS	IV	Monoclonal antibody against cytotoxic T-lymphocyte antigen (CTLA-4) for late stage metastatic melanoma	3/25/2011
Oncology	vandetanib	CAPRELSA®	AstraZeneca	PO	Kinase inhibitor for metastatic medullary thryroid cancer ineligible for surgery	4/6/2011
Oncology	vemurafenib	ZELBORAF™	Genentech	PO	Kinase inhibitor for metastatic melanoma with BRAF(V600E) mutation and diagnostic test.	8/17/2011
Ophthalmology	aflibercept	EYLEA™	Regeneron	IO	Soluble decoy receptor for VEGF-A and P1GF used in wet age-related macular degeneration (AMD).	11/18/2011
Psychiatry	vilazodone	VIIBRYD™	Trovis	PO	SSRI/serotonin receptor partial agonist for major depressive disorder	1/21/2011
Pulmonology	indacaterol maleate	ARCAPTA™	Novartis	INH	Long-acting beta2-adrenergic agonist long term maintenance bronchodilator treatment of COPD	7/1/2011
Pulmonology	roflumilast	DALIRESP™	Forest	PO	oral phosphodiesterase type 4 (PDE-4) enzyme inhibitor to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations.	2/28/2011
Radiology	gadobutrol	GADAVIST™	Bayer	IV	Gadolinium-based contrast agent for CNS scans	3/14/2011
Radiology	ioflupane I 123	DaTscan™	GE Healthcare	IV	Diagnostic imaging agent to evaluate patients with suspected Parkinsonian syndromes	1/14/2011
Rheumatology	belimumab	BENLYSTA®	Human Genome & GSK	IV	B-lymphocyte stimulator-specific inhibitor for systemic lupus erythematosus (SLE).	3/10/2011

NOTE: This chart is provided for reference purposes only. Product specific prescribing information (see Brand Name links) should be consulted prior to application in the clinical setting.

NEW DRUGS AND BIOLOGICALS 2011
RESOURCE LIST

Specialty	Generic Name	Brand Name	Company	Rte	Class & Indication	Approval
Toxicology	Centruroides (Scorpion) Immune F(ab')2 (Equine) Injection	ANASCORP®	Rare Disease Therapeutics	IV	Equine immune globulin antivenom for human scorpion stings.	8/3/2011

Sources: Pharmacist's Letter; FDA.gov; drugs.com; manufacturer websites

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