Disclosures

• Speaker or spouse do not have actual or potential conflict of interest in relation to this presentation.
Learning Objectives

Technicians:
• Name the disease state and therapeutic class for select new agents approved during the first 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 first 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.

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References:
- fda.gov
- Pharmacist’s Letter

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Cardiology » Hypertension

• Increased risks of stroke, heart failure, heart attack, kidney failure, and death
• “The Silent Killer”
• 1 in 3 US adults
• 30% unaware, 40% not getting treatment, 67% not controlled adequately
• Goal: maintain appropriate BP
• Options: lifestyle modification, pharmacotherapy

azilsartan medoxomil

EDARBI™

• Eighth ARB!
• No studies to show improved clinical outcomes
• Avoid in PG, lactation, watch sCr in ≥ 75yo
• ADR: similar to placebo
• DIs: NSAIDs
• Store at room temperature
• DO NOT REPACKAGE!
• Dose: 80mg QD
• $90/month


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Pulmonology » COPD

- Triad of bronchitis, emphysema, asthma
- 32 M in US
- 90% COPD risk from smoking
- 4th leading cause of death in US
- Goals: improve functional status, symptoms
- Management: smoking cessation, bronchodilators, steroids, mucolytics, oxygen, vaccination, physiotherapy

Reference: (1) emedicine.medscape.com, Chronic Obstructive Pulmonary Disease, 8/4/11.
roflumilast

Daliresp™

• First PDE-4 inhibitor for decreasing frequency of severe COPD symptoms
• Active metabolite
• CI: moderate/severe liver impairment
• Cautions: not for bronchospasm; worsening mental health issues; suicidality; weight loss; drug interactions
• DI: rifampicin (P450 inducer) reduces roflumilast efficacy; erythromycin (P450 inhibitor) increases roflumilast ADRs via increased exposure

References:

Approved 02/28/2011

PO

Pregnancy Category C

NOT FOR USE IN CHILDREN

NOT for moderate to severe LIVER Failure

Store at Controlled Room Temperature

roflumilast

Daliresp™

• ADRs: D; wt loss; N; HA; back pain; insomnia; dizziness
• Store at room temperature
• Dose: 500 mcg po QD
• Pt Education: MedGuide w/ each refill
• Monitor: wt loss, mental health changes
• Cost $207/month
• Conclusions: Modest effect. Reserve for severe COPD. N/V common.

References:

Approved 02/28/2011

PO

Pregnancy Category C

NOT FOR USE IN CHILDREN

NOT for moderate to severe LIVER Failure

Store at Controlled Room Temperature
Self-Assessment

• Roflumilast is contraindicated in patients who
  • (A) are suicidal;
  • (B) have severe COPD;
  • (C) have moderate liver failure;
  • (D) All of the above.
  • (E) A and C only.

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Neurology » Partial Seizures

- Most common seizure type
- Simple vs. Complex Partial Seizures
- Start within limited/localized area of the brain
- 20 cases / 100,000 population (1-65yo)
- 80 cases / 100,000 (60-80 yo)
- Mortality 2-3x that of general population
- Options: anticonvulsants, surgery

References:
(2) emedicine.medscape.com, Epilepsy and Seizures, 6/16/2011.

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Self-Assessment

• Which of the following is **FALSE**?
  • (A) A medication guide must be provided with each ezogabine refill.
  • (B) Ezogabine can not be crushed.
  • (C) Patients on ezogabine should report suicidal thoughts immediately to a health care practitioner.
  • (D) Ezogabine is safe and effective in the treatment of childhood seizures.
Psychiatry » Depression

• Depression classifications
• Specific cause unknown
• CNS 5-HT, NE, DA
• MDD lifetime incidence: 20% F; 12% M
• Role in > 50% suicide attempts
• Death rate > 15%
• Treatment:
  – Medication (SSRIs, SNRIs, atypicals, TCAs, MAOIs)
  – Psychotherapy (CBT, psychodynamic, interpersonal)

References: (1) emedicine.medscape.com/article/286759-overview. (2) FDA News Release 1/21/11.
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vilazodone

VIIBRYD™

• Dosing: 10mg PO QD x 7D; 20mg PO QD x 7D; then 40mg PO QD

• Pt Education: food; med guide; machinery; avoid alcohol

• Monitor: suicidal thoughts; serotonin Sx

• Cost = other branded antidepressants²

• No comparative info; no evidence that is more rapid, causes fewer sexual SEs or doesn’t cause weight gain²


Self-Assessment

• Which of the following is TRUE about vilazodone?

• (A) It works faster than SSRIs;

• (B) It has a lower risk of weight gain;

• (C) It should be taken with food;

• (D) It is less expensive than other antidepressants.
Rheumatology » SLE

- Serious autoimmune disease affecting joints, skin, lungs, heart, kidneys, brain
- US: 250K – 1.5M; African American (F) have 3x higher incidence than Caucasian (F)
- 10-year survival rate > 90%
- 1/3 US fatalities < 45 yo
- Goals: symptoms, flares, SE
- Options: NSAIDs, antimalarials, immunosuppressants, immunomodulator …
belimumab

**BENLYSTA®**

- Human mAb against human B lymphocyte stimulator protein for adults with active autoantibody-positive SLE
- Cautions: anaphylaxis; increased mortality; serious infection; depression; suicidal; live vaccines
- ADR: N, D, fever, depression, pharyngitis, infusion reactions
- Lower response in African Americans
- Reconstitute w/ SWI to 80mg/mL
- Dilute in NSS. INCOMPATIBLE w/ DEXTROSE. Use w/in 8 hours of reconstitution


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belimumab

**BENLYSTA®**

- Dose: 10mg/kg over 1 hr IV q 2wks x 3, then q4 wks. Pre-medicate.
- Pt Ed: Med Guide required prior to each dose. Wear protective clothing and sunscreen. Use adequate birth control.
- Monitoring: Assess overall health prior to each infusion.
- Cost Issues: $35,000/year
- Hospitals order via wholesaler; MDs through specialty distributors
- Conclusions: modestly effective, cost limiting, limitations in African-Americans


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Self-Assessment

- A 31-year old woman will be starting on belimumab for active SLE. What should she be told by her healthcare provider?
- (A) Don’t get the live nasal flu vaccine within 30 days of starting belimumab;
- (B) Be sure to wear protective clothing and sunscreen;
- (C) Talk to your doctor about any increase in depression;
- (D) All of the above.

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Endocrinology » Diabetes

• Resistance to insulin and inadequate insulin, leading to high blood sugar
• 26 M (CDC, 2011); 79 M pre-diabetes
• 27% don’t know they have DM
• Heart disease, blindness, nerve, and kidney damage
• Goals: maintain appropriate blood sugar
• Options: ongoing education, diet, exercise, pharmacotherapy

linagliptin

TRADJENTA™

• Third DPP-4 adjunct to diet/exercise in DM2
• CI: hypersensitivity
• Warnings: lower sulfonylurea dose
• ADR: URI, ↑TGs, ↑wt, muscle/back pain
• DI: rifampin
• Dose: 5 mg PO QD – w/ or w/o food
• Monitor: blood glucose; A1C
• Priced similar to other DPP-4’s
• No dose Δ with impaired RFx

References: (1) FDA New Release, 5/2/2011. (2) emedicine.medscape.com, Type 2 Diabetes Mellitus, 8/2/11.
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Self-Assessment Question

• An advantage of linagliptin over sitagliptin or saxagliptin is that it ...
  • (A) is less expensive;
  • (B) lowers A1C better;
  • (C) can be used in type 1 diabetes;
  • (D) doesn’t need dose adjustment in impaired kidney function.

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Infectious Disease » CDAD

- AB-associated diarrhea and colitis by *C. diff.*
- Colonization vs disease
- 20% hospitalized pts » 30% develop diarrhea
- Mortality in frail elderly up to 25%
- toxic megacolon » colonic perforation » death
- Options: DC AB; ABs (metronidazole, vancomycin, fidaxomicin); support symptoms
- Infection control: Contact precautions; Soap and water during outbreak (not EtOH); Environmental cleaning


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Self-Assessment

• Which of the following statements is FALSE?
  • (A) Washing hands with soap and warm water is the best way to prevent the spread of *C. difficile*.
  • (B) Alcohol-based hand scrubs don’t kill *C. difficile* spores.
  • (C) Fidaxomicin works at least as well as oral vancomycin.
  • (D) Fidaxomicin is less expensive than using intravenous vancomycin orally.

Infectious Disease » HCV

• RNA virus
• Chronic → Cirrhosis → HCC
• 3.2M/US; 30,000 new/yr
• 8,000 – 10,000 deaths/yr
• Goal: HCV SVR, prevent progression to cirrhosis/HCC
• Tx: PEG-IFN, ribavirin, protease inhibitor; liver transplant

boceprevir

**VICTRELIS™**

- Protease inhibitor for HCV, genotype 1
- Must be used in combo w/ PEG-IFN/ribavirin
- CI: ribavirin PG category X; many DI’s
- Caution: Increased anemia & neutropenia
- ADRs: fatigue, N, HA, taste changes
- Refrig until dispensed. OK @ RT x 3 mos.
- 800 mg PO TID (q7-9hrs) w/ food
- Use 2 non-hormonal contraceptives
- Monitor: CBC, HCV-RNA, PG, adherence
- Cost: $29K for 24 wks

**Potential new standard for HCV genotype 1**


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telaprevir

**INCIVEK™**

- Protease inhibitor for HCV, genotype 1
- Must be used in combo w/ PEG-IFN/ribavirin
- CI: ribavirin PG category X; many DI’s
- Caution: serious skin reactions; anemia
- ADRs: rash, N, D, fatigue, HA, anal irritation
- Store at room temperature; use w/in 28d
- 750 mg PO TID (q7-9hrs) w/ fatty food
- Use 2 non-hormonal contraceptives
- Monitor: CBC, Hgb, HCV-RNA, PG, adherence
- Cost: $55.5K for 12 wks

**Potential new standard for HCV genotype 1**


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Self-Assessment

- Boceprevir or telaprevir must be used ...
- (A) alone;
- (B) with pegylated interferon;
- (C) with ribavirin;
- (D) with both pegylated interferon and ribavirin.

Infectious Disease » HIV

- Blood-borne, sexually transmissible virus
- Seroconversion » asymptomatic infection » AIDS
- 2006: 1.1M w/ HIV in US
- Untreated mortality > 90%
- Goal: prevent immune system deterioration
- Options: HAART (NRTIs, PIs, NNRTIs, fusion inhibitor, etc.)
rilpivirine
EDURANT™

- NNRTI for HIV-1 multi-drug HAART
- Blocks HIV viral replication
- CI: hypersensitivity, many CI’d DIs.
- Caution: depression; severe renal impairment; HBV or HCV co-infection; redistribution/accumulation body fat
- ADRs: depression; insomnia; HA; rash
- Store at RT in original bottle
- Dose: 24 mg PO QD w/ meals
- Cost $7,700/year

Self-Assessment

- Which of the following is TRUE about rilpivirine?
  - (A) Rilpivirine must be taken on an empty stomach.
  - (B) St. John's Wort may not be taken with rilpivirine.
  - (C) Rilpivirine can be placed in a pill organizer to improve compliance.
  - (D) All of these are true.
<table>
<thead>
<tr>
<th>Specialty</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Company</th>
<th>Rte</th>
<th>Class &amp; Indication</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatology</td>
<td>spinosad</td>
<td>NATROBA™</td>
<td>ParaPRO Pernix</td>
<td>TOP</td>
<td>Topical suspension for treatment of head lice for children &gt; 4yo and adults</td>
<td>1/18/2011</td>
</tr>
<tr>
<td>Radiology</td>
<td>ioflupane I 123</td>
<td>DaTscan™</td>
<td>GE Healthcare</td>
<td>IV</td>
<td>Diagnostic imaging agent to evaluate patients with suspected Parkinsonian syndromes</td>
<td>1/14/2011</td>
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<tr>
<td>Psychiatry</td>
<td>vilazodone</td>
<td>VIIBRYD™</td>
<td>Trovis</td>
<td>PO</td>
<td>SSRI-serotonin receptor partial agonist for major depressive disorder in adults</td>
<td>1/21/2011</td>
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<tr>
<td>OB/GYN</td>
<td>hydroxyprogesterone caproate</td>
<td>MAKENA™</td>
<td>Baxter / Ther-Rx</td>
<td>IM</td>
<td>New dosage form. Injectable progestin to reduce the risk of singleton birth.</td>
<td>2/3/2011</td>
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<tr>
<td>Hematology</td>
<td>factor XIII</td>
<td>CORIFACT®</td>
<td>CSL Behring</td>
<td>IV</td>
<td>Pooled human plasma factor XIII concentrate for congenital factor XIII deficiency</td>
<td>2/17/2011</td>
</tr>
<tr>
<td>Cardiology</td>
<td>azilsartan medoxomil</td>
<td>EDARBI™</td>
<td>Takeda</td>
<td>PO</td>
<td>Angiotensin II receptor blocker (ARB) for high blood pressure</td>
<td>2/25/2011</td>
</tr>
<tr>
<td>Pulmonology</td>
<td>roflumilast</td>
<td>DALIRESP™</td>
<td>Forest</td>
<td>PO</td>
<td>Oral phosphodiesterase type 4 (PDE-4) enzyme inhibitor to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations.</td>
<td>2/28/2011</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>belimumab</td>
<td>BENLYSTA®</td>
<td>Human Genome GSK</td>
<td>IV</td>
<td>B-lymphocyte stimulator-specific inhibitor for systemic lupus erythematosus (SLE).</td>
<td>3/10/2011</td>
</tr>
<tr>
<td>Radiology</td>
<td>gadobutrol</td>
<td>GADAVIST™</td>
<td>Bayer</td>
<td>IV</td>
<td>Gadolinium-based contrast agent for CNS scans</td>
<td>3/14/2011</td>
</tr>
<tr>
<td>Oncology</td>
<td>ipilimumab</td>
<td>YERVVOY™</td>
<td>BMS</td>
<td>IV</td>
<td>Monoclonal antibody against cytotoxic T-lymphocyte antigen (CTLA-4) for late stage metastatic melanoma</td>
<td>3/25/2011</td>
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<tr>
<td>Oncology</td>
<td>vandetanib</td>
<td>CAPRELSA®</td>
<td>AstraZeneca</td>
<td>PO</td>
<td>Kinase inhibitor for metastatic medullary thyroid cancer ineligible for surgery</td>
<td>4/6/2011</td>
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<tr>
<td>Oncology</td>
<td>abiraterone acetate</td>
<td>ZYTIGA™</td>
<td>Centocor Ortho Biotech</td>
<td>PO</td>
<td>CYP17 inhibitor for late-stage metastatic castration-resistant prostate cancer refractory to prior docetaxel. Used in combination with prednisone.</td>
<td>4/28/2011</td>
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<tr>
<td>Endocrinology</td>
<td>linagliptin</td>
<td>TRADJENTA™</td>
<td>Boehringer Ingelheim</td>
<td>PO</td>
<td>Dipeptidyl peptidase-4 (DDP-4) inhibitor for type 2 diabetes mellitus.</td>
<td>5/2/2011</td>
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<tr>
<td>Oncology</td>
<td>everolimus</td>
<td>AFINITOR®</td>
<td>Norvartis</td>
<td>PO</td>
<td>Progressive metastatic pancreatic neuroendocrine tumors (PNET) or refractory to surgery</td>
<td>5/6/2011</td>
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<td>Infectious Disease</td>
<td>boceprevir</td>
<td>VICTRELIS™</td>
<td>Merck</td>
<td>PO</td>
<td>Protease inhibitor for chronic hepatitis C multi-drug treatment</td>
<td>5/13/2011</td>
</tr>
</tbody>
</table>

**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 H1-2011
### RESOURCE LIST

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Company</th>
<th>Rte</th>
<th>Class &amp; Indication</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious Disease</td>
<td>rilpivirine</td>
<td>EDURANT™</td>
<td>Tibotec</td>
<td>PO</td>
<td>Non-nucleoside reverse transcriptase inhibitor (NNRTI) for HIV-1 multi-drug therapy</td>
<td>5/20/2011</td>
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<td>Infectious Disease</td>
<td>telaprevir</td>
<td>INCIVEK™</td>
<td>Vertex</td>
<td>PO</td>
<td>Protease inhibitor for chronic hepatitis C multi-drug treatment</td>
<td>5/23/2011</td>
</tr>
<tr>
<td>Gastorenterology</td>
<td>dextranomer</td>
<td>SOLESTA®</td>
<td>Oceana</td>
<td>INJ</td>
<td>Submucosal anal injection for the treatment of fecal incontinence.</td>
<td>5/27/2011</td>
</tr>
<tr>
<td>Infectious Disease</td>
<td>fidaxomicin</td>
<td>DIFICID™</td>
<td>Optimer</td>
<td>PO</td>
<td>Macrolide antibiotic for treatment of life-threatening <em>Clostridium difficile</em>-associated diarrhea (CDAD)</td>
<td>5/27/2011</td>
</tr>
<tr>
<td>Neurology</td>
<td>ezogabine</td>
<td>POTIGA™</td>
<td>GSK</td>
<td>PO</td>
<td>Anticonvulsant for partial-onset seizures</td>
<td>6/10/2011</td>
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<tr>
<td>Nephrology</td>
<td>belatacept</td>
<td>NULOJIX®</td>
<td>BMS</td>
<td>IV</td>
<td>Immunosuppressant for the prevention of kidney transplant rejection.</td>
<td>6/15/2011</td>
</tr>
</tbody>
</table>

Sources: Pharmacist’s Letter; FDA.gov; drugs.com; manufacturer websites
Note: Brand Name hyperlink leads to prescribing information; approval hyperlink leads to FDA News Release

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