

New Drugs 2011: The First Half

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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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New Drugs 2011 – The First Half

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

LICE: spinosad TOP ^{NATROBA™}
HTN: azilsartan PO ^{EDARBI™}
COPD: roflumilast PO ^{DALIRESP™}
Fl: dextranomer/hyaluronidate INJ ^{SOLESTA™}
RTx: belatacept IV ^{NEULOX™}
PG Risk: hydroprogesterone IM ^{MAKENA™}
Seizures: ezogabine PO ^{FOTIGA™}
RLS: gabapentin enacarbil PO ^{HORIZANT™}
Depression: vilazodone PO ^{VIBRYD™}
SLE: belimumab IV ^{BENLYSTA™}
DM: linagliptin PO ^{TRADENTA™}
F13Def: factor XIII IV ^{CORFACT™}
Melanoma: ipilimumab IV ^{YERVOY™}
Thyroid CA: vandetanib PO ^{CAPRELSA™}
Prostate CA: abiraterone PO ^{ZYTIGA™}
PNET: everolimus PO ^{AFINITOR™}
CDAD: fidaxomicin ^{DIFDICE™}
HCV: boceprevir PO ^{VICTRELIS™}
HCV: telaprevir PO ^{INCIVEK™}
HIV: rilpivirine PO ^{EDURANT™}
CNS Scan: gadobutrol IV ^{GADAVIST™}
Dx Imaging: ioflupane 123 IV ^{DATSCAN™}

References: fda.gov/drugs.com; Pharmacist's Office
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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

References: (1) FDA News Release, 2/25/2011. (2) emedicine.medscape.com, Hypertension, 8/10/11.
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Approved 02/25/2011

azilsartan medoxomil

EDARBI™

PO

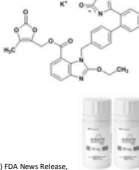
Pregnancy Category C/D

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

PROTECT FROM LIGHT

- Eighth ARB!
- No studies to show improved clinical outcomes 4,5
- 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/month⁴

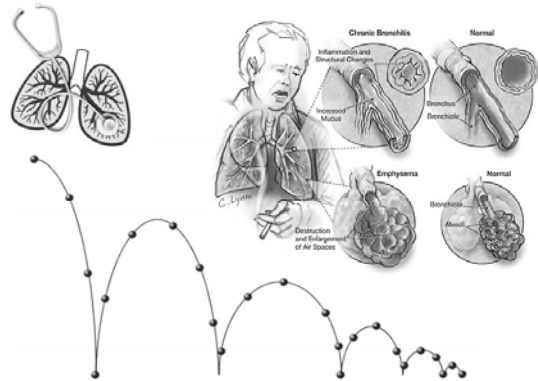


References: (1) Prescribing Information, EDARBI™ (azilsartan), Deerfield IL, Takeda Pharmaceuticals America, February 2011. (2) FDA News Release, 2/25/2011. (3) Pharmacist's Letter, April 2011. (4) The Medical Letter 2011; 53(1344):39. (5) Pharmacist's Letter, July 2011. (6) The Medical Letter 2011; 53(1369):59-60. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

Self-Assessment Question

- A caregiver has asked you to help set up their parent's medications in a weekly pill organizer to facilitate compliance. Will you include the patient's azilsartan in the organizer?
- (A) Yes.
- (B) No.


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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



References: (1) medicinenet.com, Chronic Obstructive Pulmonary Disease, 8/4/11. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

Approved 02/28/2011

MedGuide required

roflumilast

Daliresp™

PO


Pregnancy Category C

NOT FOR USE IN CHILDREN

NOT for moderate to severe LIVER Failure

Store at Controlled Room Temperature

- 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: (1) Prescribing Information, DALIRESP™ (roflumilast), St. Louis, MO: Forest Pharmaceuticals, February 2011. (2) FDA News Release, 3/1/2011. (3) Pharmacist's Letter, July 2011. (4) The Medical Letter 2011; 53(1369):59-60. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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MedGuide required

roflumilast

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PO


Pregnancy Category C

NOT FOR USE IN CHILDREN

NOT for moderate to severe LIVER Failure

Store at Controlled Room Temperature

- 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^{3,4}
- Conclusions: Modest effect. Reserve for severe COPD. N/V common.^{3,4}

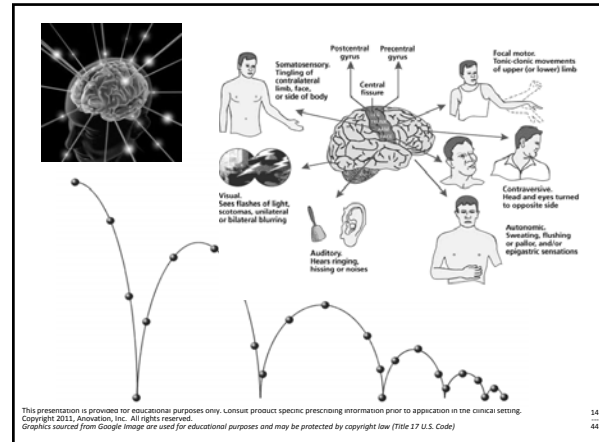


References: (1) Prescribing Information, DALIRESP™ (roflumilast), St. Louis, MO: Forest Pharmaceuticals, February 2011. (2) FDA News Release, 3/1/2011. (3) Pharmacist's Letter, July 2011. (4) The Medical Letter 2011; 53(1369):59-60. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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: [1] emedicine.medscape.com, Simple Partial Seizures, 6/16/2011. [2] emedicine.medscape.com, Epilepsy and Seizures, 6/16/2011. [3] emedicine.medscape.com, Complex Partial Seizures, 6/16/2011. [4] FDA News Release, 6/13/2011. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

MedGuide required **REMS**

ezogabine

POTIGA™

Approved 06/10/2011

PO

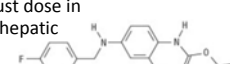
Pregnancy Category C

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

DO NOT CRUSH OR CHWY

- Adjunctive anticonvulsant for partial-onset seizures
- Caution: urinary retention; confusion/psychosis; QT prolongation; suicidal ideation
- ADR: dizziness, fatigue, confusion, vertigo, tremor, double-vision, attention problems, memory impairment
- DI: phenytoin, carbamazepine, digoxin, alcohol
- Store at Room Temperature
- Dose: start at 100 mg PO TID, increase at weekly intervals to 200-400 mg PO TID. Adjust dose in geriatrics, moderate/severe renal or hepatic impairment.
- MedGuide w/ each refill. Do not crush.

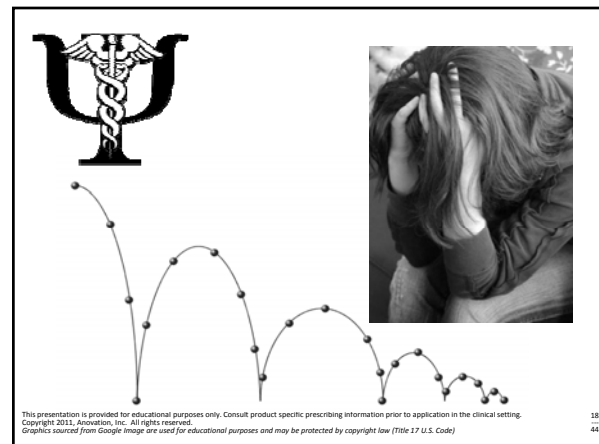


References: [1] Prescribing information, POTIGA™ (ezogabine), Research Triangle Park, NC, GlaxoSmithKline; June 2011. [2] FDA News Release, 6/13/2011. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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.


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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) medicine.medscape.com/urid/286799-overview. (2) FDA News Release 1/21/11. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

MedGuide required

REMS

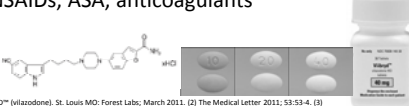
vilazodone

VIIIBRYD™

Approved 01/21/2011

PO

- SSRI/serotonin receptor partial agonist for MDD
- Warnings: MAOIs, suicide risk, serotonin syndrome, seizures, abnormal bleeding, mania/hypomania, hyponatremia
- ADR: D, N, V, dizziness, insomnia
- DI: MAOI's, serotonergics, CYP3A4 inhibitors & inducers, NSAIDs, ASA, anticoagulants



References: (1) Prescribing information, VIIIBRYD™ (vilazodone), St. Louis MO: Forest Labs; March 2011. (2) The Medical Letter 2011; 53:53-4. (3) Pharmacist's Letter; 27(7):270706. (4) tablet images, webmd.com. (5) package image, empor.com. (6) auxiliary labels, tps.online.com. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

MedGuide required

REMS

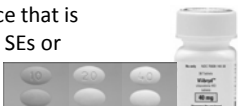
vilazodone

VIIIBRYD™

Approved 01/21/2011

PO

- 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

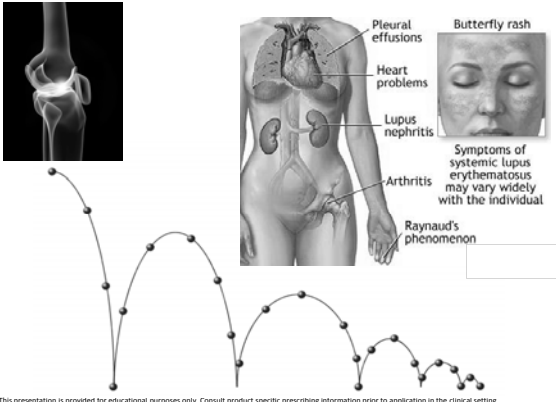


References: (1) Prescribing information, VIIIBRYD™ (vilazodone), St. Louis MO: Forest Labs; March 2011. (2) The Medical Letter 2011; 53:53-4. (3) Pharmacist's Letter; 27(7):270706. (4) tablet images, webmd.com. (5) package image, empor.com. (6) auxiliary labels, tps.online.com. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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.

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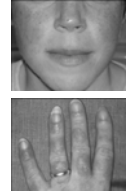


Symptoms of systemic lupus erythematosus may vary widely with the individual

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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 ...



References: (1) FDA News Release, 3/11/2011. (2) Pharmacist's Letter, May 2011. (3) medicine.medscape.com, 5/4, 7/26/11. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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

References: (1) Prescribing information, BENLYSTA® (belimumab), Rockville MD: Human Genome Sciences and Research Triangle Park NC: GlaxoSmithKline, March 2011; (2) auxiliary labels, tps-online.com; (3) FDA News Release, 3/9/2011; (4) Pharmacist's Letter, May 2011; (5) Medical Letter 2011 53(13)3663-65-6. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

Approved 03/09/2011

specialty medication **IV**

Pregnancy Category C

NOT FOR USE IN CHILDREN

Keep in Refrigerator DO NOT FREEZE

Mix Gently DO NOT SHAKE

PROTECT FROM LIGHT

No Preservatives DISCARD unused portion

LATEX FREE

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^{4,5}

References: (1) Prescribing information, BENLYSTA® (belimumab), Rockville MD: Human Genome Sciences and Research Triangle Park NC: GlaxoSmithKline, March 2011; (2) auxiliary labels, tps-online.com; (3) FDA News Release, 3/9/2011; (4) Pharmacist's Letter, May 2011; (5) Medical Letter 2011 53(13)3663-65-6. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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specialty medication **IV**

Pregnancy Category C

NOT FOR USE IN CHILDREN

Keep in Refrigerator DO NOT FREEZE

Mix Gently DO NOT SHAKE

PROTECT FROM LIGHT

No Preservatives DISCARD unused portion

LATEX FREE

Self-Assessment

- A 31-year old woman will be starting on belimumab for active SLE. What should she be told by her health care 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

References: (1) FDA News Release, 5/2/2011; (2) medicine.medicape.com, Type 2 Diabetes Mellitus, 8/2/11. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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^{3,4}
- No dose Δ with impaired RfX^{3,4}

References: (1) Prescribing information, TRADJENTA™ (linagliptin), Ridgefield CT: Boehringer Ingelheim Pharmaceuticals; July 2011; (2) FDA News Release, 5/2/2011; (3) Pharmacist's Letter 2011; 27(8):2706-4. (4) Medical Letter 2011; 53(13)67:49-50. (5) package image, empur.com; (6) tablet image, wend.com.

Approved 05/02/2011

Pregnancy Category B

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

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

References: (1) emedicine.medscape.com, Clostridium Difficile Colitis, 6/23/2011. (2) The Medical Letter 2011, 53(1358):14-15. (3) Pharmacist's Letter, July 2011. (4) Pharmacist's Letter, July 2011. (5) Pharmacist's Letter, July 2011. (6) FDA News Release, 5/23/2011. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google Image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

fidaxomicin

DIFICID™

Approved 05/27/2011

PO

Pregnancy Category B

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

- Bactericidal macrolide for CDAD
- Efficacy similar to vancomycin po
 - Fewer recurrences in non-NAP1
- Local GIT activity, poorly absorbed
- Not for systemic use
- ADR: N/V, abdominal pain, anemia, GI hemorrhage, neutropenia
- Store at room temperature
- 200 mg PO BID x 10 days, w/ or w/o food
- Pt Ed: stewardship principles
- \$2800/course vs \$1300/course for vanco

References: (1) Prescribing information, DIFICID™ (fidaxomicin), San Diego CA, Optimer Pharmaceuticals; May 2011. (2) The Medical Letter 2011, 53(1358):14-15. (3) Pharmacist's Letter, July 2011. (4) FDA News Release, 5/23/2011. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google Image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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.

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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

Natural History of HCV Infection

Exposure (Innocent)

20% (1/5) Resolved

80% (4/5) Chronic

Stable

10% (1/10) Cirrhosis

5% (1/20) HCC, Transplant, Death

5% (1/20) Slowly Progressive

N = 100

10% (1/10) Cirrhosis

5% (1/20) HCC, Transplant, Death

5% (1/20) Slowly Progressive

10% (1/10) Cirrhosis

5% (1/20) HCC, Transplant, Death

5% (1/20) Slowly Progressive

The evolution of efficacy with interferon-based therapy over the last 10 years

Interferon α-2b 24 weeks: 25%

Interferon α-2b 48 weeks: 35%

PEG-Interferon α-2b 24 weeks + Ribavirin: 45%

PEG-Interferon α-2b 24 weeks + Ribavirin + Protease Inhibitor: 55%

PEG-Interferon α-2b 24 weeks + Ribavirin + Protease Inhibitor + NS5A Inhibitor: 65%

References: (1) emedicine.medscape.com, Hepatitis C, 7/26/11. (2) FDA News Release, 5/13/2011 and 5/23/2011. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google Image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

Approved 05/13/2011

boceprevir

VICTRELIS™

PO

- 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 wks⁴
- Potential new standard for HCV genotype 1

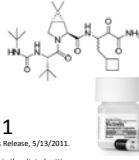
Pregnancy Category X*

NOT FOR USE IN CHILDREN

REFRIGERATE

TAKE WITH FOOD

PROTECT FROM HEAT



References: (1) Prescribing information, VICTRELIS™ (boceprevir), Wyeth/Janssen Station NJ; Merck & Co; May 2011. (2) FDA News Release, 5/13/2011. (3) Pharmacists Letter, August 2011. (4) The Medical Letter 2011; 53(1369):57-59. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

Approved 05/23/2011

telaprevir

INCIVEK™

PO

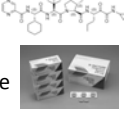
- Protease inhibitor for HCV, genotype 1
- **Must** be used in combo w/ PEG-IFN/ribavirin
- CI: ribavirin PG category X; *many* DI's
- Caution: serious skin reactions; anemia
- ADRs: rash, N, D, fatigue, HA, anal irritation
- Store at room temperature; use w/in 28d
- 750 mg PO TID (q7-9hrs) w/ fatty food
- Use 2 non-hormonal contraceptives
- Monitor: CBC, Hgb, HCV-RNA, PG, adherence
- Cost: \$55.5K for 12 wks⁴
- Potential new standard for HCV genotype 1

Pregnancy Category X*

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

TAKE WITH FOOD



References: (1) Prescribing information, INCIVEK™ (telaprevir), Cambridge MA; Vertex Pharmaceuticals; MAY 2011. (2) FDA News Release, 5/23/2011. (3) Pharmacists Letter, August 2011. (4) The Medical Letter 2011; 53(1369):57-59. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

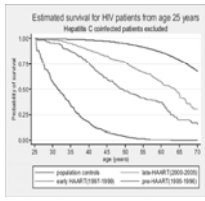
Self-Assessment

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

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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.)



References: (1) emedicine.medscape.com, HIV Disease, 8/12/2011. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

Approved 05/20/2011

rilpivirine

EDURANT™

PO

- 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

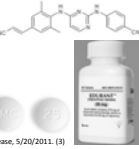
Pregnancy Category B

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

PROTECT FROM LIGHT

TAKE WITH FOOD

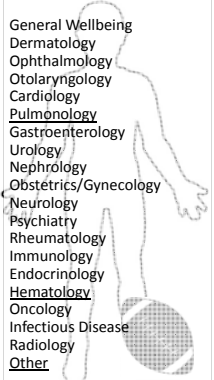


References: (1) Prescribing information, EDURANT™ (rilpivirine), Raritan NJ; Tibotec Therapeutics; May 2011. (2) FDA News Release, 5/20/2011. (3) epocrates.com, accessed 8/14/2011. This presentation is provided for educational purposes only. Consult product specific prescribing information prior to application in the clinical setting. Copyright 2011, Anovation, Inc. All rights reserved. Graphics sourced from Google image are used for educational purposes and may be protected by copyright law (Title 17 U.S. Code)

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.

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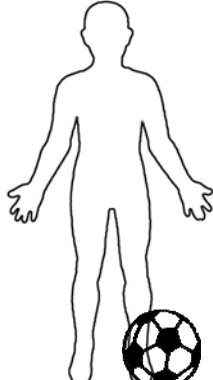


New Drugs 2011 – The 2nd Half

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

References: fda.gov/4ugs.com; Pharmacist's Letter.
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 DVT: rivaroxaban PO XARELTO®
 ACS: ticagrelor PO BRILINTA™
 SCORPION-IG centruroides Immune INJ ANASCORP®



New Drugs 2011 – The First Half

Questions?

annanv@anovation.us

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**NEW DRUGS AND BIOLOGICALS H1-2011
RESOURCE LIST**

Specialty	Generic Name	Brand Name	Company	Rte	Class & Indication	Approval
Dermatology	spinosad	NATROBA™	ParaPRO Pernix	TOP	Topical suspension for treatment of head lice for children > 4yo and adults	1/18/2011
Radiology	ioflupane I 123	DaTscan™	GE Healthcare	IV	Diagnostic imaging agent to evaluate patients with suspected Parkinsonian syndromes	1/14/2011
Psychiatry	vilazodone	VIIBRYD™	Trovis	PO	SSRI/serotonin receptor partial agonist for major depressive disorder in adults	1/21/2011
OB/GYN	hydroxyprogesterone caproate	MAKENA™	Baxter / Ther-Rx	IM	New dosage form. Injectable progestin to reduce the risk of singleton birth.	2/3/2011
Hematology	factor XIII	CORIFACT®	CSL Behring	IV	Pooled human plasma factor XIII concentrate for congenital factor XIII deficiency	2/17/2011
Cardiology	azilsartan medoxomil	EDARBI™	Takeda	PO	Angiotensin II receptor blocker (ARB) for high blood pressure	2/25/2011
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
Rheumatology	belimumab	BENLYSTA®	Human Genome GSK	IV	B-lymphocyte stimulator-specific inhibitor for systemic lupus erythematosus (SLE).	3/10/2011
Radiology	gadobutrol	GADAVIST™	Bayer	IV	Gadolinium-based contrast agent for CNS scans	3/14/2011
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 thyroid cancer ineligible for surgery	4/6/2011
Neurology	gabapentin enacarbil	HORIZANT™	GSK	PO	New dosage form. New indication. Once-daily gabapentin prodrug for moderate-to-severe restless legs syndrome (RLS).	4/6/2011
Oncology	abiraterone acetate	ZYTIGA™	Centocor Ortho Biotech	PO	CYP17 inhibitor for late-stage metastatic castration-resistant prostate cancer refractory to prior docetaxel. Used in combination with prednisone.	4/28/2011
Endocrinology	linagliptin	TRADJENTA™	Boehringer Ingelheim	PO	Dipeptidyl peptidase-4 (DDP-4) inhibitor for type 2 diabetes mellitus.	5/2/2011
Oncology	everolimus	AFINITOR®	Norvartis	PO	Progressive metastatic pancreatic neuroendocrine tumors (PNET) or refractory to surgery	5/6/2011
Infectious Disease	boceprevir	VICTRELIS™	Merck	PO	Protease inhibitor for chronic hepatitis C multi-drug treatment	5/13/2011

**NEW DRUGS AND BIOLOGICALS H1-2011
RESOURCE LIST**

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

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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