New Drugs 2012

Anna Nowobilski-Vasilios
PharmD MBA FASHP CNSC BCNSP
Principal, Anovation *Care Management Innovation*
Adjunct Assistant Professor, Midwestern University CCP

Learning Objectives

Technicians:

- Name the disease state and therapeutic class for select new agents approved during the first half of 2012.
- 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 2012.
- 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.

20

New Drugs 2012-H1

Obesity: lorcaserin PO (BELVIQ)
Actinic keratosis: ingenol mebutate TOP (PICATO)
Glaucoma: tafluprost OP (ZIOPTAN)
RDS: lucinactant ITR (SURFAXIN)
Cystic Fibrosis: ivacaftor PO (KALYDECO)
Pancreatitis: pancrelipase PO (ULTRESA; VIOKACE)
Erectile Dysfunction: avanafil PO (STENDRA)
Urinary Incontinence: mirabegron PO (MYRBETRIQ)
Anemia of CKD: peginesatide IV/SC (OMONTYS)
Cushing's Syndrome: mifepristone PO (KORLYM)
Gaucher Disease: taliglucerase IV (ELELYSO)
MTX Toxicity: glucarpidase IV (VORAXAZE)
Renal CA: axitinib PO (INLYTA)
Basal Cell CA: vismodegib PO (ERIVEDGE)
Breast CA: pertuzumab IV (PERJETA)
Influenza Vaccine INH (FLUMIST Quadrivalent)
N.meningitidis/*H.flu* Vaccine IM (MENHIBRIX)
PET/Alzheimer's: florbetapir F18 IV (AMYVID)
Surgery: keratinocytes/fibroblasts TOP (GINTUIT)

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

General Wellbeing » Obesity

- > 2/3 adults in US are overweight or obese
- Substantial public health crisis
- $100B annual cost of managing obesity
- Risk of coronary heart disease
  - 1.72 @ BMI 25-28.9 kg/m^2
  - 3.44 @ BMI > 33 kg/m^2
- Similar ↑risk w/ stroke & HF
- Goal: weight loss to optimal BMI
- Treatment: diet, exercise, behavioral changes, anti-obesity medications …

References: (a) Obesity. Emedicine.medscape.com. August 2, 2012. (b) FDA approves Belviq to treat some overweight or obese adults. FDA News. June 27, 2012. (c) Drugs for Weight Loss. Pharmacist's Letter 2012; 28(8):280811.

Approved 6/27/2012

lorcaserin

BELVIQ®

C ? PO

Pregnancy Category X

NOT FOR USE IN CHILDREN

CAUTION in Kidney/ Liver Dysfunction

Store at Controlled Room Temperature

Do not use machinery or drive until effect is known

- 5-HT2C agonist WITH diet/exercise
  - BMI ≥ 30
  - BMI ≥ 27 w/ HTN, DM2, or dyslipidemia
- Thought to promote satiety … ↓ food intake
- 3 RDBPC trials 52-104 weeks, 8000 pts
  - 5% body wt loss: 47% vs 23% control w/o DM2; 38% vs 16% control w/DM2
  - 8.5% vs. 6.7% control DC 2º ADRs: HA, depression, dizziness
- Caution: serotonin syndrome, valvular heart disease, cognition, depression, suicidal thoughts, priapism
- Many DI's: SSRIs, SNRs, MAOIs, St. John's Wort, etc.
- 10 mg PO BID → DC if body wt not ↓5% in 12w
- Modestly effective

References: (a) BELVIQ® (lorcaserin) [package insert]. Woodcliff Lake NJ: Eisai, Inc., June 2012. (b) FDA approves Belviq to treat some overweight or obese adults. FDA News. June 27, 2012. (c) Weight Loss. Pharmacist's Letter 2012; 28:August. (d) Drugs for Weight Loss. Pharmacist's Letter 2012; 28(8):280811. (e) Micromedex v1535, Accessed 8/8/2012.

Self-Assessment 1

Which of the following is TRUE?

1. 1/3 of the US population is overweight or obese.
2. Successful weight loss programs rely on anti-obesity medications alone.
3. Lorcaserin (BELVIQ) is modestly effective.
4. Lorcaserin (BELVIQ) can safely be given in pregnancy.

Ophthalmology » Glaucoma

- Optic nerve structural/functional disturbance
  - Possible with normal IOP
  - Ocular hypertension risk for glaucoma
  - Diverse condition
- Second leading cause of blindness in US
- Only 50% aware they have POAG
- Goal – lower IOP or remove cause
- Topical Options
  - beta-blockers, carbonic anhydrase inhibitors, alpha-2 agonists, cholinergic agonists
  - prostaglandin analogs … most widely used

References: (a) Primary Open-Angle Glaucoma. Emedicine.medscape.com. July 9, 2012. (b) FDA approves Zioptan to treat elevated eye pressure. FDA News. February 14, 2012. (c) Tafluprost (Zioptan) – A New Topical Prostaglandin for Glaucoma. The Medical Letter 2012; 54(1388):31.

Approved 2/10/2012

tafluprost

ZIOPTAN™

OP

Pregnancy Category C

NOT FOR USE IN CHILDREN

Keep in Refrigerator *DO NOT FREEZE*

Once pouch opened:

Store at Controlled Room Temperature

PROTECT FROM MOISTURE

No Preservatives *DISCARD unused portion*

- PF Prostaglandin analog to ↓ IOP in POAG or OH
- Trial of 643 w/ OAG or OH, ↓ IOP to WNL in 12 wks
  - Non-inferior to that with PF timolol eye gtts
  - Latanoprost slightly more effective than tafluprost in a preservative-containing trial of 533
- Warnings: hyperpigmentation, eyelash changes
- Store in original pouch, refrigerated
- Once pouch opened, use droppers within 28 days
- 1 gtt QPM into conjunctival sac of affected eye(s)
- Pt Ed: darkening of iris; darkening of eyelid; eyelash growth; aseptic technique; wait 5 min to instill another product
- $97/month; generic latanoprost $23/month
- Use for pts sensitive to preservatives

References: (a) FDA approves Zioptan to treat elevated eye pressure. FDA News. February 14, 2012. (b) ZIOPTAN™ (tafluprost) [package insert]. Whitehouse Station NJ: Merck & Co., Inc., February 2012. (c) Tafluprost (Zioptan) – A New Topical Prostaglandin for Glaucoma. The Medical Letter 2012; 54(1388):31. (d) Glaucoma. Pharmacist's Letter 2012; April(28). (e) Micromedex v1535, Accessed 8/8/2012.

Self-Assessment 2

Which of the following statements is FALSE?

1. Glaucoma is the 2nd leading cause of blindness in the US.
2. Tafluprost (ZIOPTAN) is preservative-free.
3. In the pharmacy, tafluprost (ZIOPTAN) is stored in the refrigerator.
4. Left-over solution from opened tafluprost (ZIOPTAN) droppers can be saved for the following dose.

Pulmonology » RDS

- Impaired surfactant synthesis in premature infants
- 20,000-30,000 newborns annually
  - ~ 50% born at 26-28 w gestation
  - < 30% born at 30-31 w gestation
- Acute Complications – alveolar rupture, infection, intracranial hemorrhage, patent ductus arteriosus, pulmonary hemorrhage, necrotizing enterocolitis, apnea of prematurity
- Chronic complications – bronchopulmonary dysplasia, retinopathy of prematurity, neurological impairment
- Goal - ↑ survival, ↓ severity of complications
- Treatment Options – antenatal steroids, resuscitation, gentle ventilation, supportive therapy … surfactant administration …

Reference: Respiratory Distress Syndrome. Emedicine.medscape.com. March 9, 2012.

Approved 3/6/2012

lucinactant

SURFAXIN®

iTR

NOT FOR USE IN ADULTS

Keep in Refrigerator *DO NOT FREEZE*

Once warmed:

SHAKE WELL

PROTECT FROM LIGHT

No Preservatives *DISCARD unused portion*

- Prevent of RDS in high risk premature infants
  - Compensates for surfactant deficiency
- Trial w/ 1294 infants
  - ↓ RDS @24h & ↓ RDS mortality @ day 14
- Watch oxygen/ventilator needs closely; suction if airway obstruction
- NOT for ADULT RDS 2° increased negative sequellae
- 5.8 mL/kg birth weight intratracheally
  - Up to 4 doses in 1st 48 hours of life, nmt that q6 hrs
- Aseptic technique
  - Clinician competent in intubation, ventilator management & premature infant care
  - Warm vial, shake vigorously until free-flowing
  - If not used immediately protect from light at RT up to 2h

Reference: SURFAXIN® (lucinactant) [package insert]. Warrington PA: Discovery Laboratories, Inc., March 2012.

Self-Assessment 3

Lucinactant (SURFAXIN) is …

1. administered intratracheally using aseptic technique.
2. warmed and shaken until it is free-flowing.
3. stored in the refrigerator if not used immediately.
4. 1 and 2 above are correct.

Pulmonology » Cystic Fibrosis

- Autosomal recessive disorder
- Defective CFTR gene
  - ↓ mucus hydration → sticky mucus
  - Increased viscosity of secretions in respiratory tract, pancreas, GI tract, sweat glands
  - Chronic lung disease & exocrine pancreatic insufficiency
- Most common lethal inherited disease in Caucasians … 30,000 pts w/ CF in US
- Median survival 40 years, M>F
- Therapeutic Goals – maintain lung function; supplement enzymes, vitamins, minerals; manage complications
- Treatment by multidisciplinary CF centers

References: Cystic Fibrosis. Emedicine.medscape.com. May 15, 2012.

Approved 1/31/2012

ivacaftor

KALYDECO™

specialty medication | PO | Pregnancy Category B | NOT FOR USE IN < 6 YO | Store at Controlled Room Temperature | Take with Fatty Food

- CFTR protein enhancer, ↑s chloride transport
- 1st drug to address CAUSE
- CF w/ G551D mutation (1,200 pts)
- 48w RDBC in 161 > 12yo: 10.4% ↑FEV1
  - ↑ lung fxn, ↓ respiratory symptoms, ↑ wt gain
  - 33% vs 59% pulmonary exacerbation
- 48w RDBC in 52 6-11yo: 12.5% ↑ FEV1☂
- ↑ LFTs; multiple CYP3A interactions
- 150 mg PO q12h w/ high-fat meal
- Avoid grapefruit & Seville oranges
- Monitor FEV1; LFTs q3m x1yr; then qYR
- Limited Distribution; $294,000/year


References: (a) KALYDECO™ (ivacaftor) [package insert]. Cambridge MA: Vertex Pharmaceuticals, Inc., January 2012. (b) Cystic Fibrosis. Pharmacist's Letter 2012Q; March 2012 (28). (c) Ivacaftor (Kalydeco) for Cystic Fibrosis. The Medical Letter 2012; 54(1388):29. (d) Micromedex v1535, Accessed 8/7/2012.

Self-Assessment 4

Which of the following is FALSE about ivacaftor?

1. It is the first drug to address the cause of Cystic Fibrosis.
2. It will benefit 30,000 CF patients in the US.
3. It enhances chloride transport.
4. It improves lung function and decreases exacerbations.

Gastroenterology » EPI

- Pancreatic enzyme deficiency
  - amylase, protease, lipase
  - Inability to digest food, esp. fatty food
- Pancreatic causes: chronic pancreatitis, cystic fibrosis, pancreatic duct obstruction, SDS
- 200,000 in US w/ pancreatic insufficiency
- Steatorrhea, weight loss, watery diarrhea
- Goal – facilitate food absorbtion
- Treatment – lifestyle modification, vitamin supplementation, and … pancreatic enzyme replacement

References: (a) Exocrine Pancreatic Insufficiency. Emedicine.medscape.com. July 6, 2012. (b) FDA approves two new pancreatic enzyme products to aid food digestion. FDA News. March 1, 2012.

Approved 3/1/2012

pancrelipase

ULTRESA™ and VIOKACE™

PO

Pregnancy Category C | Store at Controlled Room Temperature | PROTECT FROM MOISTURE | Take with FOOD | *DO NOT* CRUSH OR CHEW

Pregnancy Category C | NOT FOR USE IN CHILDREN | Store at Controlled Room Temperature | PROTECT FROM MOISTURE | Take with FOOD | *DO NOT* CRUSH OR CHEW

- 4th & 5th pancreatic enzyme products
- Pork-derived lipase, protease, amylases
- Unapproved pancreatic enzyme sunset April 2010
- NOT interchangeable
- ULTRESA: EC delayed-release capsule for CF
  - Trial 1 DBPC crossover, 24 pts, 8-37yo w/ CF. CFA 89% vs 56%; CNA 84% vs 59%
  - Trial 2, 9 pts, 7-11yo w/ CF. CFA 83% vs 35%
  - 2 Safety Trials: HA pharyngolaryngeal pain, nosebleed
- VIOKACE: uncoated tablet used w/ PPI for chronic pancreatitis
  - RDBPC, 50 pts, 24-70yo w/ EPI. CFA 86% vs 58%
  - 1 Safety Trial: biliary tract stones, anal pruritus
- Caution: pork allergy, fibrosing colonopathy w/ hi-dose, caution in gout, renal impairment, hyperuricemia, theoretical risk of viral transmission.
- Not absorbed in GIT


References: (a) Exocrine Pancreatic Insufficiency. Emedicine.medscape.com. July 6, 2012. (b) ULTRESA™ (pancrelipase) [package insert]. Birmingham AL: Aptalis Pharma US, Inc., March 2012. (c) VIOKACE™ (pancrelipase) [package insert]. Birmingham AL: Aptalis Pharma US, Inc., March 2012. (d) (FDA) FDA approves two new pancreatic enzyme products to aid food digestion. FDA News. March 1, 2012. (e) (ML) In Brief: Pancreatic Enzyme Products. The Medical Letter 2012; 1357:12. (f) Gastroenterology. Pharmacist's Letter 2012; 26:October. (g) Micromedex v1535, Accessed 8/8/2012.

Self-Assessment 5

Which of the following is FALSE about the pancreatic enzymes approved in 2012?

1. ULTRESA is a delayed-release capsule.
2. VIOKACE is indicated in children with pancreatic insufficiency due to CF.
3. ULTRESA and VIOKACE should be protected from moisture.
4. ULTRESA and VIOKACE are NOT interchangeable.

Urology » Overactive Bladder

- Urgency & urinary incontinence
- Voiding > 8x/24hrs
- Underlying detrusor overactivity
  - Neurological, muscular, idiopathic
- 33 M Americans w/ OAB
- Impaired QOL: ↑depression, ↓sleep, ↑nocturnal falls … coping strategies
- Treatment Options: pharmacotherapy, behavioral therapy, surgery (rare)

References: (a) Overactive Bladder. Emedicine.medscape.com. June 29, 2012. (b) FDA approves Myrbetriq for overactive bladder. FDA News. June 28, 2012.

Approved 6/28/2012

mirabegron

MYRBETRIQ™

PO

Pregnancy Category C

NOT FOR USE IN CHILDREN

Store at Controlled Room Temperature

DO NOT CRUSH OR CHEW

- Beta-3 agonist for OAB
- Relaxes detrusor muscle to ↑ bladder capacity
- 3 DBPCMC Trials, 4115 pts w/ OAB
  - ↓times urinated, ↓urination accidents, ↑ urine volume/void
- 3 DBPC Trials, 2736 pts
  - most common ADRs for TX DC: nausea, HA, HTN, diarrhea, constipation, dizziness, ↑HR
- Caution: ↑BP, antimuscarinic drugs, CYP2D6 interactions, digoxin
- Reduce dose in renal & hepatic impairment.
- Don't give in ESRD or severe hepatic impairment.
- 25 mg po QD; may ↑ to 50 mg QD p/ 8 weeks.
- Modestly effective & may increase BP

References: (a) Overactive Bladder. Emedicine.medscape.com. June 29, 2012. (b) MYRBETRIQ™ (mirabegron) [package insert]. Northbrook IL: Astellas Pharma US, Inc., June 2012. (c) FDA approves Myrbetriq for overactive bladder. FDA News. June 28, 2012. (d) Overactive Bladder. Pharmacist's Letter 2012; 28:May. (e) Micromedex v1535, Accessed 8/8/2012.

Self-Assessment 6

Overactive Bladder (OAB) decreases QOL by:

1. Increasing depression.
2. Increasing coping strategies.
3. Increasing nocturnal falls.
4. All of the above.

Nephrology » Anemia of CKD

- Kidneys responsible for 90% of EPO production
- EPO production deficiency in CKD
- Stage III CKD, 5.2% concurrent anemia
- Stage IV CKD, 44.1% concurrent anemia
- M/M depends on underlying causes & stage
- Options: ESA to Hgb 11-12 g/dL

Reference: Anemia of Chronic Disease and Renal Failure. Emedicine.medscape.com. May 1, 2012.

REMS

Approved 3/27/2012

peginesatide

OMONTYS®

IV/SC

Pregnancy Category C

NOT FOR USE IN CHILDREN

Keep in Refrigerator *DO NOT FREEZE*

DO NOT FREEZE

PROTECT FROM LIGHT

- ESA for anemia of CKD in DIALYSIS only
- Synthetic pegylated peptide, stimulates erythropoiesis
- 2 Trials, 1626 HD pts, ≥52w, noninferior to epoetin re Hgb
- Safety: 22.8% vs 24,4% death, stroke, MI, HF, unstable angina, arrhythmia
- CI: uncontrolled HTN
- RTU. Syringe & SDV PF. Discard MDV 28 days after 1st use.
- Start at 0.04 mg/kg q MO IV or SC, adjust to Hgb
- If no response in 12 wks, will most likely not respond
- Monitor BP, Hgb, iron stores
- Comparable S/E to epoetin in pts w/ ESRD on dialysis
- Administered less frequently, less expensive
- Long-term safety data lacking

References: (a) OMONTYS (peginesatide) [package insert]. Deerfield IL: Takeda Pharmaceuticals, March 2012. (b) Peginesatide (Omontys) for Anemia in Chronic Kidney Disease. The Medical Letter 2012; 54(1392):45. (c) Micromedex v1535, Accessed 7/29/2012.

Self-Assessment 7

Peginesatide (OMONTYS) is indicated for:

1. Anemia of CKD in dialysis patients.
2. Anemia of CKD in non-dialysis patients.
3. Anemia of chronic disease, including cancer.
4. All of the above.

Oncology » MTX Toxicity

- MTX 1^{o} kidney excretion
- High dose
  - nephrotoxicity
  - Bone marrow suppression
  - Oral/GI ulceration
  - Liver toxicity
- Goal: Reduce toxicity
- Options: leucovorin, IV hydration, urine alkalinization … & …

Reference: The Medical Letter 2012; 1385:19.

Approved 1/17/2012

glucarpidase

VORAXAZE®

IV

Pregnancy Category C

Keep in Refrigerator *DO NOT FREEZE*

No Preservatives *DISCARD unused portion*

- Recombinant enzyme for toxic [MTX]
  - Converts to glutamate & DAMPA
- 2 unpublished (PI) single-arm, open-label studies
  - Endpt: RSCIR [MTX] ≤ 1 mcmol @ 15 min x 8 days; > 95% ↓[MTX]
  - Safety data available for 290 pts; only 22 evaluated for efficacy
- ADRs – rare serious allergic reactions; generally well tolerated
- Continue leukovorin (not w/in 2h) & hydration/alkalinization
- Preparation: reconstitute w/ 1 mL SWI; use w/in 4h if Refrig
- Dose: 50 units/kg IV bolus over 5 minutes
- Monitor: [MTX] normalization

References: (a) VORAXAZE® (glucarpidase) [package insert]. West Conshohocken PA: BTG International, Inc.; January 2012. (b) The Medical Letter 2012; 1385:19. (c) Micromedex v1534, Accessed 7/27/2012.

Self-Assessment 8

Glucarpidase (VORAXAZE)

1. Is a monoclonal antibody that lowers toxic methotrexate concentrations.
2. Is usually well tolerated, but can cause serious anaphylactic reactions.
3. Can be stored for 24 hours after reconstitution, if refrigerated.
4. All of the above.

Oncology » Breast Cancer

- HER2 overexpression in 20% of breast cancers
- More aggressive, worse prognosis before HER2-targeted therapies (trastuzumab)
- After 20 yrs of increasing incidence, now decreasing
  - Reduced use of HRT
- 207,090 new F cases/yr in US (2010), 1970 new M
- 39,840 F deaths in US (2010), 390 M deaths
- Treatment Options; surgery for early-stage, adjuvant therapy for micrometastasis.
- HER2-targeted therapies: trastuzumab, lapatinib … now … pertuzumab

Reference: Breast Cancer. Emedicine.medscape.com. August 1, 2012.

Approved 6/8/2012

pertuzumab

PERJETA™

IV

Pregnancy Category D

NOT FOR USE IN CHILDREN

Keep in Refrigerator *DO NOT FREEZE*

Mix Gently DO NOT SHAKE

PROTECT FROM LIGHT

No Preservatives *DISCARD unused portion*

- Recombinant humanized mAb against HER2 receptor
- Combo w/ trastuzumab and docetaxel for HER2+ metastatic breast CA w/o prior metastatic tx; different binding site than trastuzumab
- RMCDBPC Trial (CLEOPATRA), 808 pts" +6.1 mo PFS
- Safety endpoints: febrile neutropenia, ↓s LVEF
- 840 mg over 60 min IV, then 420mg over 30-60 min q3w
- Modify dose for delayed/missed doses, LVEF < 40%, trastuzumab hold/DC
- Observe pt 60 min p/ #1, 30 min p/ subsequent infusions
- Dilute in 250 mL NS, refrigerate x 24h – do NOT use D5W
- Pt Ed: pregnancy prevention, pregnancy registry
- HER2 status, pregnancy test, LVEF q3m, infusion reactions
- $4075/vial

References: (a) PERJETA™ (pertuzumab) [package insert]. South San Francisco CA: Genentech, Inc., May 2012. (b) Pertuzumab (Perjeta) for HER2-Positive Metastatic Breast Cancer. The Medical Letter 2012; 54(1395D):59. (c) Micromedex v1535, Accessed 8/7/2012.

Self-Assessment 9

Pertuzumab (PERJETA) …

1. Is a recombinant monoclonal antibody against the HER2 receptor.
2. Fits on a different HER2 binding site than trastuzumab (HERCEPTIN).
3. Should not be diluted into D5W.
4. All of the above.

Infectious Disease » Vaccine

- *N. meningitidis* (C&Y) and *H. influenza* type b
- Early symptoms indistinguishable from other childhood illnesses
- N. meningitis prevalence 1-2 / 100,000
- Hib incidence ↓d by 99% since vaccine (1988)
- Fulminant meningococcemia fatal w/o ABs; 50% mortality w/ ABs
- Hib meningitis mortality 5%; 50% neurologic sequelae; 6% permanent hearing loss

References: (a) Meningococcal Infections. Emedicine.medscape.com. October 17, 2011. (b) Haemophilus Influenzae Infections. Emedicine.medscape.com. January 10, 2012. (c) FDA approves new combination vaccine that protects children against two bacterial diseases. FDA News. June 14, 2012.

Approved 6/14/2012

N. meningitidis-H. influenzae Vaccine

MENHIBRIX®

IM

VIS

Pregnancy Category C

NOT FOR USE IN < 6wo or >19mo

NOT FOR USE IN ADULTS

Keep in Refrigerator or Room Temp

DO NOT FREEZE

- Combo vaccine for 6w to 18 mos
- *Active immunization to prevent Neisseria meningitidis* serogroups C and Y and *Haemophilus influenzae* type b
- 6 Trials; 7,521 infants, antibody response predictive of protection
- Safety trials; 7,500 infants; ADRs: pain, redness and swelling at the injection site, irritability and fever
- Guillain-Barré (weigh continuation), fainting, apnea (preemies)
- Probable interaction w/ live measles virus vaccine
- 0.5mL IM at 2, 4, 6, and 12-15 mos old. First as early as 6 weeks, 4th as late as 18 mos.
- Administer immediately after reconstitution w/ diluent
- Do not mix with other vaccines is same syringe or vial

References: (a) MENHIBRIX (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine) [package insert]. Research Triangle Park NC: GlaxoSmithKline, June 2012. (b) FDA approves new combination vaccine that protects children against two bacterial diseases. FDA News. June 14, 2012. (c) Micromedex v1535, Accessed 8/8/2012.

Self-Assessment 10

The new *N. meningitidis-H. influenzae* Vaccine (MENHIBRIX) is indicated for use in …

1. infants < 6 weeks old.
2. children from 6 weeks to 19 months.
3. Adults.
4. All of the above.

7

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

New Drugs 2012-H2

Obesity: phentermine/topiramate PO (QSYMIA)
Hypertriglyceridemia: icosapent PO (VASCEPA)
COPD: aclidinium bromide INH (TUDORZA)
Colonoscopy Prep: sodium picosulfate/ magnesium oxide/citric acid PO (PREPOPIK)
Multiple myeloma: carfilzomib IV (KYPROLIS)
(Ph-) ALL: vinCRIStine liposome IV (MARQIBO)
Colon Cancer: ziv-aflibercept IV (ZALTRAP)
(as of 08/09/12)

QUESTIONS?

annanv@anovation.us

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

NEW DRUGS AND BIOLOGICALS 2012
RESOURCE LIST

Specialty	Generic Name	Brand Name	Company	Rte	Class & Indication	Approval
Oncology	glucarpidase	VORAXAZE	BTG International	IV	Carbiztoeotudase for the treatment of toxic plasma methotrexate concentrations in patient with delayed methotrexate clearance due to impired renal function.	1/17/2012
Oncology	axitinib	INLYTA	Pfizer	PO	Kinase inhibor for advanced renal cell cancer after failure of one prior systemic therapy.	1/27/2012
Oncology	vismodegib	ERIVEDGE	Genentech	PO	Hedgehog pathway inhibitor for adult metastatic basal cell carinoma.	1/30/2012
Pulmonology	ivacaftor	KALYDECO	Vertex	PO	Cystic fibrosis trnasmembrance conductance regulator (CFTR) for the treatment of cystic fibrosis (CF) in patients 6 years old and older who have a G551D mutation in the CFTR gene.	1/31/2012
Dermatology	ingenolmebutate	PICATO	Leo Pharma	TOP	Topical gel for actinic keratosis	1/23/2012
Opthalmology	tafluprost	ZIOPTAN	MSD	OP	Prostaglandin analog for reducing elevated intraocular pressure in open-angle glaucoma or ocular hypertension.	2/10/2012
Endocrinology	mifepristone	KORLYM	Corcept Therapeutics	PO	cortisol receptor blocker for hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery	2/17/2012
Infectious Diseases	quadrivalent influenza vaccine	FLUMIST Quadrivalent	MedImmune	INH	Vaccine to prevent seasonal influenza in people ages 2-49yo. Contains four influenza strains (2 A and 2 B)	2/29/2012
Gastroenterology	pancrelipase	ULTRESA	Aptalis Pharma	PO	Delayed-release capsule for children and adults with cystic fibrosis who cannot digest food normally because their pancreas does not make enough pancreatic enzymes	3/1/2012
Gastroenterology	pancrelipase	VIOKACE	Aptalis Pharma	PO	In combination with a proton pump inhibitor for adults with chronic pancreatitis who cannot digest food normally.	3/1/2012
Pulmonology	lucinactant	SURFAXIN	Discovery Labs	ITR	intratracheal suspension for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk of RDS	3/6/2012
Surgery	keratinocytes and fibroblasts in bovine collagen	GINTUIT	Organogenesis	TOP	allogeneic cellularized scaffold product indicated for topical (non-submerged) application to a surgically created vascular wound bed in the treatment of mucogingival conditions in adults	3/9/2012
Nephrology	peginesatide	OMONTYS	Affymax	IV-SQ	erythropoiesis-stimulating agent (ESA) for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis	3/27/2012
Radiology	Florbetapir F18	AMYVID	Avid Radiopharmaceuticals	IV	radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline	4/6/2012

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 2012
RESOURCE LIST

Specialty	Generic Name	Brand Name	Company	Rte	Class & Indication	Approval
Urology	avanafil	STENDRA	Vivus	PO	phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction	4/27/2012
Metabolic Disease	taliglucerase alfa	ELELYSO	Pfizer / Protalix Bio Therapeutics	IV	hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type 1 Gaucher disease.	5/1/2012
Oncology	pertuzumab	PERJETA	Genentech	IV	HER2/neu receptor antagonist indicated in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease	6/8/2012
Infectious Diseases	meningitis & haemophilus influenzae vaccine	MENHIBRIX	Glaxo Smith Kline	IM	Active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups C and Y and Haemophilus influenzae type b. MENHIBRIX is approved for use in children 6 weeks of age through 18 months of age	6/14/2012
General Wellbeing	lorcaserin hydrochloride	BELVIQ	Eisai	PO	Serotonin 2C receptor agonist as an adjunct to a reduced-calorie diet and exercise, for chronic weight management in adults with an initial BMI > 30kg/m2 or BMI > 27kg/m2 with one weight-related co-morbid condition.	6/27/2012
Urology	mirabegron	MYRBETRIQ	Astellas	PO	Beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.	6/28/2012

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

20

Provided as a professional courtesy by:

1006 South Michigan Avenue, Suite 702 | Chicago Illinois 60605 | 312-608-1495 tel | 312-268-5112 fax | www.anovation.us

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.