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2016 Drug Blockbusters and Patent Expiration Review

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Disclosure

Nicolle Rychlick, Pharm.D., has nothing to disclose.
Objectives

• Identify key drug patents anticipated to expire in 2016

• Summarize the impact of new branded drug launches

• Analyze potential clinical strategies to manage new branded drug products
Generic Availability

- HealthTrust vendor conversations
- 20-40 days for generic launch and distribution availability
- Generally no less than 30% savings
- Weekly newsletter announcements
- Contract change report
2016 Patent Expirations

- **Infectious Disease**
  - Cubicin
  - Tygacil
  - Ambisome
  - Tamiflu
- **Cardiology**
  - Crestor
  - Benicar
  - Multaq
  - Aggrastat
- **Respiratory**
  - Advair Diskus
  - Combivent Respimat
- **Other**
  - Lupron depot
  - Entereg
  - Gleevec
  - Sensipar
  - Nexium
Infectious Disease
Cubicin

- Indicated for complicated skin and skin structure infections and *Staphylococcus aureus* bacteremia
- Patent expires June 2016
- Hospira likely to come to market first
- Teva a possible competitor
Tygacil

• Indicated for complicated skin and skin structure infections, complicated intra-abdominal infections and community-acquired bacterial pneumonia

• Patent expires April 2016
Ambisome

• Indicated for empirical therapy for presumed fungal infection in febrile, neutropenic patients, *Cryptococcal* meningitis in HIV patients and *Aspergillus*, *Candida* or *Cryptococcus* species and treatment of visceral leishmaniasis

• Patent expires October 2016
Tamiflu

• Indicated for treatment of acute, uncomplicated influenza patients who have been symptomatic for no more than two days

• Patent expires December 2016

• Litigation could delay expiration and launch till 2021
Cardiology
Crestor

- Indicated for treatment of hyperlipidemia
- Patent expires May 2016
- Multiple generic entrants expected
Benicar

- Indicated treatment for hypertension
- Patent expires October 2016
Multaq

- Indicated to reduce the risk of hospitalization for atrial fibrillation
- Patent expires July 2016
- Litigation has delayed launch till at least 2017
Aggrastat

• Indicated to reduce the rate of thrombotic cardiovascular events in patients with non-ST elevation acute coronary syndrome

• Patent expires October 2016
Respiratory
Advair Diskus

• Indicated for the treatment of asthma and maintenance treatment for chronic obstructive pulmonary disease

• Patent expires August 2016
Combivent Respimat

• Indicated for patients with chronic obstructive pulmonary disease on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator

• Patent expires October 2016

• Over 20 patents that could delay release
Other drugs
Lupron depot

• Indicated for palliative treatment of advanced prostate cancer, endometriosis, uterine leiomyomata (fibroids), and in children with central precocious puberty (CPP)

• Patent expires December 2016
Enterexg

- Indicated to accelerate the time to upper and lower gastrointestinal recovery following surgery
- Patent expires March 2016
Gleevec

• Indicated for treatment of chronic myeloid leukemia, acute lymphoblastic leukemia and other blood cancers
• Patent expired February 2016
• Sun Pharma launched February 1
• Six-month exclusivity for generic
Sensipar

• Indicated for secondary hyperparathyroidism in patients with chronic kidney disease and treatment of hypercalcemia

• Patent expires December 2016
Nexium

• Indicated for treatment of gastroesophageal reflux disease, risk reduction of NSAID-associated gastric ulcer, H. pylori eradication

• Patent expires May 2016
2016 Blockbusters
Pulmonary arterial hypertension

• Sample of available therapies
  – Vasodilators/prostacyclin pathway agonists
    • Flolan (epoprostenol)
    • Orenitram (treprostinil)
    • Ventavis (iloprost)
  – Endothelin receptor antagonists
    • Tracleer (bosentan)
    • Letairis (ambrisentan)
  – PDE5 inhibitors
    • Revatio (sildenafil)
    • Adcirca (tadalafil)
  – High-dose calcium channel blockers
    • Cardizem (diltiazem)
    • Adalat (nifedipine)
    • Norvasc (amlodipine)
Uptravi (Selexipag)

• Indicated for the treatment of pulmonary arterial hypertension (PAH) to delay disease progression and reduce the risk of hospitalization for PAH

• MOA: Oral prostacyclin receptor (IP receptor) agonist; structurally distinct from prostacyclin that selectively binds to the IP receptor
Uptravi (Selexipag)

• No renal or hepatic dosing required
• Significant drug interactions with CYP2C8 inhibitors (e.g. gemfibrozil) causing an increase in drug exposure
• Most common adverse reactions reported were headache, diarrhea, jaw pain and nausea (>20%)
Uptravi (Selexipag)

- Manufacturer: Actelion
- Starting dose of 200 mcg per day, increasing dose by 200 mcg twice weekly to maximum dose of 1600 mcg twice daily
- Non-contracted
- WAC Cost: $9340.20/60 count bottle (200mcg tablet)
- Available in eight strengths, all different colored tablets
Anticoagulation

- **Praxbind** (idarucizumab)
  - Manufacturer: Boehringer Ingelheim
  - Indicated for emergency surgery/urgent procedures or life-threatening or uncontrolled bleeding reversal of dabigatran
  - Recommend dose is 5 grams
  - WAC cost: $3,500 per 5 gram dose
  - Will continue to complete safety studies to maintain approval
HealthTrust Member Portal

Anticoagulation Initiative

Vaccines

The anticoagulation clinical initiative focuses on Novel Oral Anticoagulants (NOACs) and reversal agents. The HealthTrust Pharmacy Services Group is committed to support members by proactively evaluating sourcing opportunities and developing clinical strategies and resources for implementation. Under the “Related Documents” section are a number of documents, each designed to provide valuable and useful information about this initiative.

Should you have any questions regarding the anticoagulation clinical initiative, please contact the Clinical Pharmacy Services Group, at hpg.clinicalpharmacy@healthtrustpg.com.

Related Documents

- Kcentra P&T Print and Present
- Kcentra P&T Print ant Present
- HTU 2014 – Management of Bleeding and Anticoagulation Reversal – Part 1
- HTU 2014 – Management of Bleeding and Anticoagulation Reversal – Part 2
- Praxbind Drug Monograph November 2015
- Praxbind Drug Monograph November 2015
Anticoagulation

• Andexanet alfa Phase II
  – Manufacturer: Portola Pharmaceuticals
  – For the reversal of direct and indirect Factor Xa inhibitors
  – BLA application accepted by FDA 2/17/2016, with a target FDA action by 8/17/2016
  – Phase III trial ANNEXA published November 2015
    • All primary and secondary endpoints were met
    • Study participants received a bolus followed by a 2-hour infusion

• Third agent developed by Perosphere in Phase II
Oncology

• Opdivo (nivolumab)
  – Manufacturer: Bristol-Myers Squibb
  – Indications for metastatic melanoma, metastatic non-small cell lung cancer, advanced renal cell carcinoma
  – Dosing as a single agent is 3mg/kg every two weeks
  – Non-contracted
  – WAC Cost: $973.59 40mg/4mL single dose vial

• Phase III trials showed extended survival
Critical Care

- Bridion (sugammadex)
  - Manufacturer: Merck
  - Indication for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide
  - Recommended dose of 2-4 mg/kg; 16 mg/kg for high dose rocuronium
  - WAC cost: $950 100mg/mL 2mL vial
Endocrinology

• Basaglar (insulin glargine)
  – Manufacturer: Lilly
  – Indication to improve glycemic control for patients with type 1 or 2 diabetes mellitus
  – Launch December 15, 2016
  – Launching with pen only
Drugs to watch

• Anti-infectives
  – Dalvance, Teflaro, Avycaz, Zerbaxa

• Cardiology
  – Entresto, Kengreal, serelaxin

• Biosimilars
  – infliximab, peg-filgrastim, epoetin-alfa
Management of blockbusters

• Review products as soon as possible
  – Clinical and patient need
  – Is it an improvement?
• P&T committee review of drug pipelines
• Identify physician champions
• Determine formulary status
  – Formulary, restricted?
  – Non-formulary
• Contact your GPO for resources or questions
  – Hpg.clinicalpharmacy@healthtrustpg.com
Resources

- ASHP daily newsletters
- FDA weekly updates
- AMCP Dossier
- Clinicaltrials.gov
- Vendor press releases
- FDA Orange Book
- Law360.com
- FiercePharma newsletters
- MPR Drugs (empr.com)
Questions