TrendsRx® Drug Pipeline & News

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Pipeline Highlights from January 25, 2008 – February 28, 2008 and Recent Selected Health Care News Highlights

A monthly publication highlighting recent events in the pharmaceutical industry

Pipeline

Selected First Generic Product Approvals/Launches[1,2*]

alendronate sodium (Fosamax®)	Dosage Form; Strength(s)	Tablet(s); 5 mg, 10 mg, 35 mg, 40 mg and 70 mg
	Approval Date†	February 6, 2008
	Launch Date‡	February 6, 2008
	Comments	The reference brand is used for the treatment and prevention of osteoporosis in postmenopausal women, treatment to increase bone mass in men with osteoporosis, treatment of glucocorticoid-induced osteoporosis in men and women and treatment of Paget's disease of bone in men and women. This product is AB-rated.
calcium acetate (Phoslo®Gel Caps)	Dosage Form; Strength(s)	Capsule; 169 mg
	Approval Date†	February 26, 2008
	Launch Date‡	To be determined
	Comments	The reference brand is used for the control of hyperphosphatemia in end stage renal failure and does not promote aluminum absorption. This product is AB-rated.
cefuroxime (Ceftin®)	Dosage Form; Strength(s)	Oral, powder for suspension; 125 mg/5 mL, 250 mg/5 mL
	Approval Date†	February 5, 2008
	Launch Date‡	February 6, 2008
	Comments	The reference brand is used in the treatment of pediatric patients aged three months to 12 years with mild-to-moderate infections caused by susceptible strains of designated microorganisms and conditions. This product is AB-rated.
irinotecan (Camptosar®)	Dosage Form; Strength(s)	Injectable; 20 mg/mL
	Approval Date†	February 20, 2008
	Launch Date‡	February 27, 2008
	Comments	The reference brand is used as a component of first-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum, and for patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial fluorouracil-based therapy. This product is AB-rated.
pramipexole (Mirapex®)	Dosage Form; Strength(s)	Tablet(s); 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 1.5 mg
	Approval Date†	February 19, 2008
	Anticipated Launch Date‡	To be determined
	Comments	The reference brand is used for treatment of Parkinson's disease and Restless Legs Syndrome; however, the generic product will only have an indication for signs and symptoms of idiopathic Parkinson's disease. This product is AB-rated.

Recent Supplemental New Drug Application (sNDA) Approvals[1,2*]

Asmanex® Twisthaler® 110 mcg (mometasone furoate inhalation powder) **Schering-Plough Corporation**	Dosage Form	Inhalation powder
	Indication(s)	Maintenance treatment of asthma as prophylactic therapy in patients 4 to 11 years of age
	Approval Date	February 4, 2008
	Comments	This is a new indication for an already-approved product. Launch is anticipated in second half of 2008.

Recent New Drug Application (NDA) Approvals[1,2*]

Emend® (fosaprepitant dimeglumine) **Merck & Co., Inc.**	Dosage Form; Strength(s)	Injection, intravenous; 115 mg base/vial
	Indication(s)	In combination with other antiemetic agents for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin and the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy
	Approval Date	January 25, 2008
	Anticipated Launch Date‡	To be determined
Simcor® (simvastatin/ extended release niacin) **Abbott Laboratories, Inc.**	Dosage Form; Strength(s)	Tablet(s); 20 mg/500 mg, 20 mg/750 mg and 20 mg/1000 mg
	Indication(s)	To reduce total cholesterol, low-density lipoprotein, Apo B, non-high-density lipoprotein (HDL)-cholesterol, or triglycerides, or to increase HDL in patients with primary hypercholesterolemia and mixed dyslipidemia when treatment with simvastatin or niacin extended-release monotherapy is considered inadequate; and to reduce triglycerides in patients with hypertriglyceridemia when treatment with simvastatin or niacin extended-release monotherapy are considered inadequate
	Approval Date	February 15, 2008
	Anticipated Launch Date‡	First Quarter, 2008

Recent Biologic License Application (BLA) Approvals[1,2*]

Arcalyst™ (rilonacept) **Regeneron Pharmaceuticals, Inc.**	Dosage Form; Strength(s)	Injection, subcutaneous; 220 mg/vial
	Indication(s)	Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) including, Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older
	Approval Date	February 27, 2008
	Launch Date‡	March, 2008
	Comments	Arcalyst will be available through the Caremark Specialty Pharmacy Services Network
Xyntha™ (antihemophilic factor [recombinant] plasma/albumin free) **Wyeth Pharmaceuticals, Inc.**	Dosage Form; Strength(s)	Injection, intravenous; 250 IU, 500 IU, 1000 IU and 2000 IU per vial
	Indication(s)	Control and prevention of bleeding episodes in patients with hemophilia A; surgical prophylaxis in patients with hemophilia A
	Approval Date	February 21, 2008
	Launch Date‡	Third Quarter, 2008
	Comments	Product is formerly known as Refacto® AF

Recent Supplemental Biologic License Application (sBLA) Approvals[1,2*]

Avastin® (bevacizumab) **Genentech, Inc.**	Dosage Form	Injection, intravenous infusion
	Indication(s)	In combination with paclitaxel for the treatment of patients who have not received chemotherapy for metastatic HER2 negative breast cancer
	Approval Date	February 22, 2008
	Comments	This is a new indication for an already-approved product. This product is available through Specialty Pharmacy.
Humira® (adalimumab) **Abbott Laboratories**	Dosage Form	Injection, subcutaneous
	Indication(s)	Reduction of signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients four years of age and older
	Approval Date	February 22, 2008
	Comments	This is a new indication for an already-approved product. This product is available through Specialty Pharmacy.

* Adapted from RxPipeline Services Week In Review. For more information contact: pipeline@caremark.com<mailto:pipeline@caremark.com>

† The Approval Date is established by the FDA, but does not necessarily mean a generic product is available as of that date, or that such product is available.

‡ This Launch Date/Anticipated Launch Date may not reflect the date of availability for this medication. Due to circumstances beyond the control of Caremark, information related to prospective medication launch dates is subject to change without notice. This information should not be solely relied upon for decision-making purposes.

News

Medication Safety

Information regarding select medication safety issues can be found on the Caremark Web site at www.caremark.com > For Health Professionals > Drug Safety Alerts.

Reports of Suicidality in Antiepileptic Medications[3]

On January 31, 2008, the US Food and Drug Administration (FDA) issued an alert stating the Agency analyzed reports of suicidality from placebo-controlled clinical studies of 11 drugs used to treat epilepsy as well as psychiatric disorders and other conditions.

- Patients receiving antiepileptic drugs had approximately twice the risk of suicidal behavior or ideation compared to those receiving placebo.
- The relative risk for suicidality was higher in those patients diagnosed with epilepsy compared to patients who were given one of the drugs in the class for psychiatric or other conditions.
- Results were generally consistent among the eleven drugs studied.
- The FDA expects that the increased risk of suicidality and subsequent labeling changes will apply to the entire therapeutic class.

This medication safety issue has been reviewed by the Caremark Drug Safety Alert (DSA) program. Caremark is prepared to answer inquiries from participants and has sent an iScribe® notification to physicians.

Revised Labeling for Chantix® (varenicline)[4]

On February 1, 2008, the FDA announced changes to the WARNINGS and PRECAUTIONS sections of the Chantix package insert regarding serious neuropsychiatric symptoms in patients treated with Chantix.

- Symptoms include changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide.
- Symptoms were seen both during and following withdrawal of Chantix treatment.

This medication safety issue has been reviewed by the Caremark DSA program. Caremark is prepared to respond to inquiries regarding this safety issue.

Early Communication about Botox®, Botox® Cosmetic (Botulinum toxin Type A), and Myobloc® (Botulinum toxin Type B)[5]

On February 7, 2008, the FDA issued an early communication regarding an ongoing safety review of Botox and Botox Cosmetic. Reports received by the FDA involve systemic adverse reactions suggestive of botulism.

- Reactions include respiratory compromise and death following the use of botulinum toxins type A and B for both FDA-approved and unapproved uses.
- The most serious cases had outcomes that included hospitalization and death, and occurred mostly in children treated for cerebral palsy-associated limb spasticity, a use of botulinum toxins that is unapproved in the United States.

This medication safety issue has been reviewed by the Caremark DSA program. Physician notification has been sent out regarding this issue; Caremark is prepared to respond to participant concerns.

Nationwide Recall of Duragesic® 25 mcg/hr (fentanyl transdermal system) CII Pain Patches[6]

On February 15, 2008, PriCara and Sandoz Inc. announced a nationwide recall of all lots of 25 mcg/hr Duragesic Patches sold in the United States.

- Drug reservoir on the patches may be compromised, exposing patients or caregivers to fentanyl gel. Patches with a cut edge should not be used.
- Fentanyl is a Schedule II opioid medication and exposure may lead to respiratory depression and possible overdose that may be fatal.
- Recalled patches have expiration dates on or before December 2009 and are all manufactured by ALZA Corporation.

This medication safety issue has been reviewed by the Caremark Drug Safety Alert (DSA) program. Caremark is prepared to answer inquiries from participants and has sent an iScribe® notification to physicians.

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Nationwide Recall of Fentanyl transdermal system CII Patches[7]

On February 19, 2008, Actavis Inc. announced a nationwide recall of certain lots of Fentanyl transdermal system CII Patches sold in the United States and labelled with an Abrika or Actavis label.

- The product may have a fold-over defect which can cause the patch to leak and expose patients or caregivers directly to the fentanyl gel.
- Exposure to fentanyl gel may lead to respiratory depression and possible overdose, which may be fatal.
- Lots covered by this recall include doses of 25 mcg/hr, 50 mcg/hr, 75 mcg/hr and 100 mcg/hr and are listed in the firm's press release.

This medication safety issue has been reviewed by the Caremark Drug Safety Alert (DSA) program. Caremark is prepared to answer inquiries from participants and has sent an iScribe® notification to physicians.

Clinical Guidelines

Updated Osteoporosis Guidelines by the National Osteoporosis Foundation[8]

The National Osteoporosis Foundation (NOF) released a new Clinician's Guide to Prevention and Treatment of Osteoporosis that addresses the way health care providers approach fracture risk assessment and treatment in people with low bone mass or osteoporosis. Selected 2008 recommendation updates from NOF include

- Expanded guidelines to include non-Caucasian, postmenopausal women, as well as men 50 years of age and older
- Incorporation of the algorithm on absolute fracture risk (FRAX®) by the World Health Organization
- Better identification of people who are at high risk for developing osteoporosis and fractures and when treatment is medically appropriate
- Updated recommendations on daily calcium and vitamin D intake

Revised Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents[9]

On January 29, 2008, the Department of Health and Human Services issued revisions to the December 2007 guidelines for the use of antiretroviral agents. Revisions include

- Recommendations on what combination regimen to initiate for treatment in antiretroviral-naïve patients
- Recent data on short-term and long-term treatment interruption
- New information on acute HIV infection
- Discussion and recommendation on *Mycobacterium tuberculosis* disease or latent tuberculosis infection with HIV coinfection

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