TrendsRx® Drug Pipeline & News

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Pipeline Highlights: November 20, 2009 – December 29, 2009 and Recent Selected Health Care News Highlights

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

norethindrone acetate/ethinyl estradiol (femhrt®)	**Dosage Form; Strength** **Approval Date†** **Anticipated Launch Date‡** **Comments**	Tablet, oral; 1 mg/0.005 mg November 6, 2009 TBD The reference brand is indicated for • the treatment of moderate to severe vasomotor symptoms associated with menopause • the prevention of postmenopausal osteoporosis for women at significant risk of osteoporosis. This product is AB-rated and will be available from a single generics manufacturer.
valacyclovir (Valtrex®)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Tablet, oral; 500 mg and 1 g January 31, 2007 November 27, 2009 The reference brand is indicated for • the treatment of cold sores (herpes labialis) in adults • the treatment of initial and recurrent episodes of genital herpes in immunocompetent adults • chronic suppressive therapy of recurrent episodes of genital herpes in immunocompetent and in HIV-infected adults • the reduction of transmission of genital herpes in immunocompetent adults • the treatment of herpes zoster (shingles) in immunocompetent adults • the treatment of cold sores in pediatric patients ≥12 years of age • the treatment of chickenpox in immunocompetent pediatric patients 2 to <18 years of age This product is AB-rated. Ranbaxy Laboratories will have a 180-day exclusivity period to market generic valacyclovir.
azelastine (Optivar®)	**Dosage Form; Strength** **Approval Date†** **Launch Date‡** **Comments**	Ophthalmic solution; 0.05% March 23, 2009 December 1, 2009 The reference brand is indicated for the treatment of itching of the eye associated with allergic conjunctivitis This product is AT-rated and will be available from multiple generics manufacturers.
nizatidine (Axid®)	**Dosage Form; Strength** **Approval Date†** **Launch Date‡** **Comments**	Solution, oral; 15 mg/mL November 18, 2009 January 4, 2010 The reference brand is indicated in adults for the treatment of active duodenal ulcer; as maintenance therapy for duodenal ulcer patients at a reduced dosage after healing of an active duodenal ulcer; for the treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis and associated heartburn due to GERD; and for the treatment of active benign gastric ulcer. The reference brand is indicated for the treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis, and associated heartburn due to GERD in children aged 12 years and older. This product is AA-rated and will be available from a single generics manufacturer.
oxcarbazepine (Trileptal®)	**Dosage Form; Strength** **Approval Date†** **Launch Date‡** **Comments**	Suspension, oral; 300 mg/5 mL June 26, 2009 December 11, 2009 The reference brand is indicated as monotherapy or adjunctive therapy in the treatment of partial seizures in adults; as monotherapy in the treatment of partial seizures in children aged 4 years and above with epilepsy; and as adjunctive therapy in children aged 2 years and above with epilepsy. This product is AB-rated and will be available from a single generics manufacturer.
donepezil ODT (Aricept® ODT)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Disintegrating tablet, oral; 5 mg and 10 mg December 11, 2009 Fourth quarter 2010 The reference brand is indicated for the treatment of dementia of the Alzheimer's type This product is AB-rated and will be available from a single generics manufacturer.
budesonide (Pulmicort Respules®)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Inhalation, suspension; 0.25 mg/2 mL and 0.5 mg/2 mL November 2008 December 15, 2009 Teva Pharmaceutical Industries Ltd. received FDA approval for its generic version of Pulmicort Respules in November 2008. The company immediately started shipping product but had to halt sales because the product was launched prior to patent expiration. The patent infringement case was adjudicated in December 2009. This product is AN-rated and will be available from multiple generics manufacturers.

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

Revatio® (sildenafil)	**Dosage Form; Strength**	Injection, intravenous; 10 mg (12.5 mL) single-use vial
	Indication	For the treatment of adult patients with pulmonary arterial hypertension (WHO Group I) to improve exercise ability and delay clinical worsening
	Approval Date	November 18, 2009
	Anticipated Launch Date‡	TBD
Pfizer Inc.	**Comments**	New formulation
Nexcede (ketoprofen)	**Dosage Form; Strength**	Oral, soluble film; 12.5 mg
	Indications	For the temporary relief of minor aches and pains due to headache, toothache, backache, menstrual cramps, the common cold, muscular aches, minor pain of arthritis, and the temporary relief of fever.
	Approval Date	November 25, 2009
	Anticipated Launch Date‡	Fourth Quarter 2009
Novartis Consumer Health, Inc.	**Comments**	The new formulation will be marketed over the counter.
Omeprazole/sodium bicarbonate/ magnesium hydroxide	**Dosage Form; Strengths**	Tablet, oral, immediate-release; 20 mg/750 mg/343 mg and 40 mg/750 mg/343 mg
	Indications	**20 mg/750 mg/343 mg:** • Short-term treatment of active duodenal ulcer • Treatment of heartburn and other symptoms associated with gastroesophageal reflux disease • Short-term treatment of erosive esophagitis that has been diagnosed by endoscopy • Maintenance of healing of erosive esophagitis **40 mg/750 mg/343 mg:** • Short-term treatment of active benign gastric ulcer
	Approval Date	December 4, 2009
	Anticipated Launch Date‡	2010
	Comments	This is a new formulation of an already approved product.
Santarus Inc.		Although the drug has been approved, the FDA has not yet approved the trade name. The company expects the FDA to complete its review of the trade name approval request within 180 days of the drug's approval.
Clonidine ER	**Dosage Forms; Strengths**	Tablet, oral, once-daily; 0.17 mg and 0.26 mg Suspension, oral, once-daily; 0.09 mg/mL
	Indication	For the treatment of hypertension
	Approval Date	December 3, 2009
	Anticipated Launch Date‡	2010
Tris Pharma	**Comments**	These are new formulations of an already approved product. They were developed using Tris Pharma's proprietary OralXR+™ platform technology.
Zyprexa® Relprevv™ (olanzapine) For Extended Release Injectable Suspension	**Dosage Form; Strengths**	Injection, deep intramuscular gluteal; 210 mg/vial, 300 mg/vial, and 405 mg/vial
	Indication	For the treatment of schizophrenia in adults
	Approval Date	December 11, 2009
	Anticipated Launch Date‡	TBD
Eli Lilly and Company		

Recent Product Launches[1,2*]

Chenodal™ (chenodiol)	**Dosage Form; Strength**	Oral, tablet; 250 mg
	Indication	For the treatment of patients with radiolucent stones in well-opacifying gallbladders in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age.
Manchester Pharmaceuticals	**Launch Date‡**	November 20, 2009
Cervarix® (Human Papillomavirus Bivalent [Types 16 and 18] Vaccine, Recombinant)	**Dosage Form; Strength**	Injection, intramuscular; 0.5-mL suspension for injection as a single-dose vial or prefilled syringe
	Indications	For the prevention of cervical cancer, cervical intraepithelial neoplasia (CIN) grade 2 or worse, adenocarcinoma in situ, and CIN grade 1 caused by oncogenic human papillomavirus types 16 and 18 in females 10 through 25 years of age
	Launch Date‡	December 1, 2009
GlaxoSmithKline Biologicals		
Berinert® (C1 esterase inhibitor [human])	**Dosage Form; Strength**	Injection, intravenous; 500 units lyophilized concentrate in a single-use vial
	Indication	For the treatment of acute abdominal or facial attacks of hereditary angioedema in adult and adolescent patients
	Launch Date‡	December 11, 2009
CSL Behring GmbH		

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

Cymbalta® (duloxetine HCl)	**Dosage Form**	Oral, capsule
	Indication	For the maintenance treatment of generalized anxiety disorder
	Approval Date	November 19, 2009
	Comments	This is a new indication for an already approved product.
Eli Lilly/Amylin Pharmaceuticals		Refer to full Prescribing Information for a complete list of indications.
Selzentry™ (maraviroc)	**Dosage Form**	Oral, tablet
	Indication	For the treatment of therapy-naïve adults infected with CCR5-tropic HIV-1 virus in combination with other antiretroviral agents
	Approval Date	November 20, 2009
	Comments	This is a new indication for an already approved product.
Pfizer Inc.		Refer to full Prescribing Information for a complete list of indications.
Seroquel XR® (quetiapine fumarate)	**Dosage Form**	Tablet, oral, extended-release
	Indication	As adjunctive treatment of major depressive disorder
	Approval Date	December 2, 2009
	Comments	This is a new indication for an already approved product.
AstraZeneca Pharmaceuticals LP		Refer to full Prescribing Information for a complete list of indications.
Seroquel® (quetiapine fumarate)	**Dosage Form**	Tablet, oral
	Indications	For the treatment of: • Schizophrenia in adolescents 13 to 17 years of age • Acute treatment of manic episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex in children and adolescents ages 10 to 17
	Approval Date	December 2, 2009
	Comments	This is a new indication for an already approved product.
AstraZeneca Pharmaceuticals LP		Refer to full Prescribing Information for a complete list of indications.
Zyprexa® (olanzapine)	**Dosage Form**	Tablet, oral
	Indications	For the acute treatment of: • Schizophrenia in adolescents 13 to 17 years of age • Manic or mixed episodes associated with bipolar I disorder and maintenance treatment of bipolar I disorder in adolescent patients aged 13 to 17 years of age
	Approval Date	December 4, 2009
	Comments	This is a new indication for an already approved product.
Eli Lilly and Company		Refer to full Prescribing Information for a complete list of indications.
Spiriva® HandiHaler® Capsules (tiotropium bromide inhalation powder)	**Dosage Form**	Capsules for oral inhalation (for use with HandiHaler device)
	Indication	For the reduction of exacerbations in patients with chronic obstructive pulmonary disease
	Approval Date	December 17, 2009
	Comments	This is a new indication for an already approved product.
Boehringer Ingelheim		Refer to full Prescribing Information for a complete list of indications.

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

Kalbitor® (ecallantide)	**Dosage Form**	Injection, subcutaneous
	Indication	For the treatment of acute attacks of hereditary angioedema in patients 6 years of age and older.
	Approval Date	December 1, 2009
Novartis Vaccines and Diagnostics Limited	**Anticipated Launch Date‡**	First quarter 2010
Fluzone® High-Dose (influenza virus vaccine)	**Dosage Form**	Injection, intramuscular; 0.5 mL (formulated to contain a total of 180 mcg [60 mcg of each strain] of influenza virus hemagglutinin)
	Indication	For active immunization of persons 65 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine
	Approval Date	December 23, 2009
Sanofi Pasteur, Inc.	**Anticipated Launch Date‡**	2010

* 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.

‡ A launch date/anticipated launch date may not reflect the actual availability of this medication. Due to circumstances beyond the control of CVS 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.

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News

Health News

FDA Advisory Committee Votes to Allow Expanded Use of the Cholesterol Drug Crestor® [4-6]

The Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin (JUPITER) trial, which was published in November 2008, was conducted to determine whether healthy people with relatively normal lipid levels and increased C-reactive protein levels would experience fewer adverse cardiovascular events when treated with 20 mg once-daily Crestor® (rosuvastatin, AstraZeneca). The results showed a statistically significant reduction in time to major cardiovascular events defined as the composite of death, heart attack, stroke, hospitalization and revascularization in the group that had received rosuvastatin. Based on these results, AstraZeneca is seeking FDA approval to expand Crestor's indication to include prevention of cardiovascular disease in individuals having an increased risk by virtue of elevated C-reactive protein.

On December 15, 2009, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) declared that AstraZeneca had established sufficient benefit to offset observed risks to support the use of Crestor in individuals meeting the following criteria:

- Men ≥ 50 years, women ≥ 60 years;
- hsCRP ≥ 2.0 mg/L; fasting LDL < 130 mg/dL; triglycerides < 500 mg/dL; and
- No prior history of cardiovascular or cerebrovascular events or coronary heart disease risk equivalent as defined by NCEP ATP-III guidelines.

AstraZeneca has noted that it will look into performing additional studies and/or follow-up analyses suggested by the EMDAC to gain FDA approval of the expanded indication.

Clinical Guidelines

New Clinical Practice Recommendations Promote HbA1c as a Diagnostic Test for Diabetes[7]

The American Diabetes Association will publish new Clinical Practice Recommendations as a supplement to the January 2010 issue of Diabetes Care. The new guidelines call for adding a glycosylated hemoglobin (HbA1c) test to the existing protocol of fasting plasma glucose and oral glucose tolerance as a means of diagnosing diabetes and identifying pre-diabetes. The HbA1c test is a simple blood test that does not require fasting, unlike the current diagnostic tests. The convenience of the HbA1c test may encourage more people to be tested for Type II diabetes, promote early detection, and help reduce the number of people who go undiagnosed each year.

References:

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5. Clinical Briefing Document, Endocrine and Metabolic Drugs Advisory Committee December 15, 2009 Meeting. New Drug Application 21-366/S016: CRESTOR® (rosuvastatin calcium). Food and Drug Administration Web site. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm193829.htm. December 11, 2009. Accessed December 30, 2009.
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