TrendsRx®Drug Pipeline & News

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Pipeline Highlights: October 30, 2009 – November 27, 2009 and Recent Selected Health Care News Highlights

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

fexofenadine/ pseudoephedrine (Allegra-D® 12 Hour)	**Dosage Form; Strength** **Approval Date†** **Launch Date‡** **Comments**	Oral, extended release tablet; 60 mg/120 mg April 14, 2005 November 1, 2009 The reference brand is used for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 12 years of age and older. This product is AB-rated and will be available from a single generics manufacturer.
fentanyl citrate (Actiq®)	**Dosage Form; Strengths** **Approval Date†** **Anticipated Launch Date‡** **Comments**	Oral, transmucosal lozenge; 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.2 mg, and 1.6 mg October 30, 2009 2010 The reference brand is used for the management of breakthrough cancer pain in patients 16 years of age and older with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying, persistent cancer pain. This product is AB-rated and will be available from multiple generics manufacturers.
perindopril erbumine (Aceon®)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Oral, tablet; 2 mg, 4 mg, and 8 mg November 10, 2009 November 10, 2009 The reference brand is used in patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction and for the treatment of patients with essential hypertension. This product is AB-rated and will be available from multiple generics manufacturers.
lansoprazole (Prevacid®)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Oral, capsule; 15 mg and 30 mg November 10, 2009 November 10, 2009 The reference brand is used as short-term treatment (4 weeks) for healing and symptom relief of active duodenal ulcer; treatment of patients with H. pylori infection and duodenal ulcer disease in combination with amoxicillin plus clarithromycin as triple therapy; maintenance of healed duodenal ulcers; short-term treatment (up to 8 weeks) for healing and symptom relief of active benign gastric ulcer; treatment of NSAID-associated gastric ulcer in patients who continue NSAID use; to reduce the risk of NSAID-associated gastric ulcers in patients with a history of a documented gastric ulcer who require the use of an NSAID; treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD); short-term treatment (up to 8 weeks) for healing and symptom relief of all grades of erosive esophagitis; maintenance healing of erosive esophagitis; and long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome. This product is AB-rated and will be available from multiple generics manufacturers.
tramadol ER (Ultram®)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Oral, extended release tablet; 100 mg and 200 mg November 13, 2009 November 16, 2009 The reference brand is used for the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time. This product is AB-rated and will be available from a single generics manufacturer.

Recent Product Launches[1,2*]

Intuniv™ (guanfacine) Shire Laboratories	**Dosage Form; Strengths** **Indication** **Launch Date‡**	Oral, extended release tablet; 1 mg, 2 mg, 3 mg, and 4 mg For the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years November 11, 2009
Metozolv™ ODT (metoclopramide) Salix Pharmaceuticals	**Dosage Form; Strengths** **Indications** **Launch Date‡**	Oral, disintegrating tablet; 5 mg and 10 mg For the relief of symptoms associated with acute and recurrent diabetic gastroparesis (gastric stasis) in adults and short-term (4 to 12 weeks) therapy in adults with symptomatic, documented GERD who fail to respond to conventional therapy November 16, 2009

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

Pennsaid® (diclofenac sodium)	**Dosage Form; Strength**	Topical, solution; 1.5% w/w
	Indication	For the treatment of signs and symptoms of osteoarthritis of the knee
	Approval Date	November 4, 2009
Mallinckrodt/ Nuvo Research	**Anticipated Launch Date‡**	First Quarter 2010
Lysteda™ (tranexamic acid)	**Dosage Form; Strength**	Oral, tablet; 650 mg
	Indication	For the treatment of cyclic heavy menstrual bleeding
	Approval Date	November 13, 2009
Xanodyne Pharmaceuticals	**Anticipated Launch Date‡**	Fourth Quarter 2009
Qutenza™ (capsaicin)	**Dosage Form; Strength**	Topical, transdermal patch; 8% (640 mcg/cm^2)
	Indication	For the management of neuropathic pain associated with postherpetic neuralgia
	Approval Date	November 16, 2009
NeurogesX	**Anticipated Launch Date‡**	First Half 2010

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

Byetta® (exenatide)	**Dosage Form**	Injection, subcutaneous
	Indication	For use as monotherapy, along with diet and exercise, to improve glycemic control in adults with type 2 diabetes mellitus
	Approval Date	October 30, 2009
Eli Lilly/Amylin Pharmaceuticals	**Comments**	This is a new indication for an already approved product. Refer to full Prescribing Information for a complete list of indications.
Geodon® (ziprasidone)	**Dosage Form**	Oral, capsule
	Indication	For maintenance treatment of bipolar I disorder as an adjunct to lithium or valproate in adults
	Approval Date	November 20, 2009
Pfizer	**Comments**	This is a new indication for an already approved product. Refer to full Prescribing Information for a complete list of indications.
Abilify® (aripiprazole)	**Dosage Forms**	Oral, tablet; oral, disintegrating tablet; oral, solution
	Indication	For the treatment of irritability associated with autistic disorder in pediatric patients ages 6 to 17 years, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods
	Approval Date	November 19, 2009
Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd	**Comments**	This is a new indication for an already approved product. Refer to full Prescribing Information for a complete list of indications.

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

Agriflu® (influenza virus vaccine)	**Dosage Form**	Injection, intramuscular
	Indication	For the active immunization of adults 18 years of age and older for the prevention of disease caused by influenza virus subtypes A and type B contained in the vaccine
	Approval Date	November 27, 2009
Novartis Vaccines and Diagnostics Limited	**Anticipated Launch Date‡**	December 2009

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

Influenza A (H1N1) 2009 Monovalent Vaccine	**Dosage Form**	Injection, intramuscular
	Indication	For the active immunization of persons age 18 years of age and older against influenza disease caused by pandemic (H1N1) 2009 virus
	Approval Date	November 10, 2009
GlaxoSmithKline/ ID Biomedical	**Anticipated Launch Date‡**	December 2009

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Recent Prescription to OTC Switch[2,3*]

Prevacid® 24 HR (lansoprazole)	**Dosage Form; Strength**	Oral, delayed-release capsule; 15 mg
	Indication	For the treatment of frequent heartburn that occurs two or more days per week
	Approval Date	May 18, 2009
	Launch Date‡	November 12, 2009
Novartis	**Comments**	Prevacid® 24 HR will be the first OTC proton pump inhibitor (PPI) introduced into the U.S. market since Prilosec OTC® was approved in 2003.

OTC=over-the-counter

* 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.

News

Medication Safety

Information regarding selected medication safety issues can be found on the CVS Caremark Web site at www.caremark.com > Health Professional Services > Drug Safety Alerts.

FDA Issues Public Health Advisory on Plavix and Omeprazole Due to Drug Interactions[4]

As of November 17, 2009, the FDA has new data showing that omeprazole reduces the anticoagulant effect of clopidogrel (Plavix®) by about half when these two medicines are taken concurrently. Patients at risk of heart attack or stroke who use clopidogrel to prevent blood clots will not get the full effect of this medicine if they are also taking omeprazole (applicable to both prescription and non-prescription omeprazole). Subsequently, the severity level of this interaction was raised to clinically significant, and the concurrent use of these agents should be avoided. The clopidogrel label will be updated to include more details about this drug-drug interaction. The FDA made the following other points:

- Taking clopidogrel and omeprazole separately will not reduce this drug interaction.
- Other drugs that should not be combined with clopidogrel because they may have a similar interaction include esomeprazole (Nexium®), cimetidine (Tagamet® and Tagamet HB®, available with or without a prescription), fluconazole (Diflucan®), ketoconazole (Nizoral®), felbamate (Felbatol®), fluoxetine (Prozac®, Serafem®, Symbyax®), fluvoxamine (Luvox®), and ticlopidine (Ticlid®).
- At this time, the FDA does not have sufficient information about drug interactions between clopidogrel and proton pump inhibitors other than omeprazole and esomeprazole to make specific recommendations about their co-administration.
- Patients who need a medication to reduce stomach acid can use antacids and the acid reducers, Zantac® (ranitidine), Pepcid® (famotidine) and Axid® (nizatidine). The FDA does not believe these medicines will stop or limit the anticoagulant activity of Plavix®. Ranitidine and famotidine are available with or without a prescription.

Additional information is available at the FDA Web site: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191169.htm.

This medication safety issue has been reviewed and addressed by the CVS Caremark Drug Safety Alert program.

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Clinical Guidelines

Focused Update: Revised Guidelines for the Prophylactic Use of Beta Blockers[5]

On November 2, 2009, the American College of Cardiology (ACC) and the American Heart Association (AHA) released a Focused Update to the Practice Guidelines for the Prophylactic Use of Beta Blockers. The update was based on new clinical trial data highlighting the risks and benefits of using beta blockers to reduce cardiac events during noncardiac surgeries. It provides specific recommendations regarding which patients will likely benefit and patients for whom there is not enough evidence to recommend their use. Beta blockers may be considered in:

- Patients undergoing vascular surgery whose stress tests or existing coronary artery disease show them to be at high risk of heart attack or other cardiac complications
- High-risk patients undergoing intermediate-risk surgery and patients undergoing vascular surgery who have multiple risk factors for complications (e.g., diabetes, a history of heart failure, significant kidney disease)

Beta blockers should be started cautiously. They should be initiated well before the procedure and titrated up as blood pressure and heart rate allow. According to the guideline's authors, the usefulness of beta blocker prophylaxis remains uncertain in lower-risk patients and in patients undergoing lower-risk surgeries; their risks and benefits require careful consideration.

AHA/SCAI Guidelines on Percutaneous Coronary Intervention[6]

On November 18, 2009, new recommendations were released in focused updates to two guidelines: the ACC/AHA Guidelines on ST-Elevation Myocardial Infarction (STEMI) and Guidelines on Percutaneous Coronary Intervention (PCI) by the ACC/AHA/Society for Cardiovascular Angiography and Interventions. A major change was the addition of prasugrel (Effient®) to the guidelines. Prasugrel is now a recommended alternative to clopidogrel (Plavix®) in these situations. Despite an increase in bleeding, prasugrel exceeded clopidogrel in the net clinical benefit endpoint, which included all-cause mortality, ischemic events, and major bleeding events. Although prasugrel can be used for patients with STEMI undergoing PCI, it should not be used as part of dual antiplatelet therapy in patients with a history of stroke and transient ischemic attack.

References

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