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Trends Rx® Drug Pipeline & News
A bi-weekly publication highlighting recent events in the pharmaceutical industry

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News Highlights from February 14 – February 25, 2005

PIPELINE

Recent NDA Approvals[1]

Drug Name	Indication(s)	Drug Class	Approval Date	Route of Administration
Vanos™ (fluocinonide) Cream, 1%; manufactured by Medicis Pharmaceutical	The treatment of plaque-type psoriasis	Corticosteroid	02/14/2005	Topical
Ammonul®; manufactured by Medicis Pharmaceutical	The adjunctive treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle	Ammonia scavenger	02/18/2005	Injection-Intravenous infusion
Vaccinia Immune Globulin Intravenous (VIGIV); manufactured by DynPort Vaccine	The treatment of rare adverse reactions to smallpox vaccination	Immune Globulin	02/18/2005	Injection-Intravenous

Recent Product Launches[1]

Drug Name	Indication(s)	Drug Class	Launch Date	Route of Administration	Comments
Tev-Tropin™ (somatropin (rDNA origin) for injection); manufactured by Savient Pharmaceuticals/Teva Pharmaceutical Industries	The treatment of children with short stature due to growth hormone deficiency	Recombinant human growth hormone	02/11/2005	Injection-Subcutaneous	
Zegerid™ (omeprazole) Powder for Oral Suspension 40 mg; manufactured by Santarus	For the reduction of risk of upper GI bleeding in critically ill patients and the short-term treatment (four to eight weeks) of active benign gastric ulcers	Proton pump inhibitor (PPI)	02/22/2005	Oral Powder for oral suspension; once-daily, immediate-release formulation	Zegerid is the first and only immediate-release oral proton pump inhibitor approved for this indication.
Eligard® 45 mg (leuprolide acetate for injectable suspension); manufactured by Sanofi-Aventis	The palliative treatment of advanced prostate cancer	Luteinizing hormone-releasing hormone (LHRH) agonist	02/17/2005	Injection-Subcutaneous Six-month dosing regimen	New formulation of an already marketed product.

First Generic Approvals/Launches[1]

Generic Drug Name	Reference Brand	Dosage Form/Strength(s)	Approval Date	Launch Date
carboplatin injection	Paraplatin® for Injection	10 mg/mL; packaged in 600 mg/60 mL single-dose vials	11/ 23/ 2004	02/22/2005

DRUG SAFETY

Phenergan® (promethazine) Labeling Changes[2] On January 21, 2005, Wyeth Pharmaceuticals notified healthcare professionals of labeling changes to the *Contraindications*, *Warnings/Use in Pediatric Patients*, and *Dosage and Administration* sections of the Phenergan prescribing information. Phenergan tablets and suppositories are contraindicated for use in pediatric patients less than two years of age because of the potential for fatal respiratory depression. When administering Phenergan to pediatric patients two years of age and older, caution should be exercised.

Gabitril® (tiagabine) Labeling Changes[3] On February 14, 2005, Cephalon Inc. notified healthcare professionals of labeling changes to the *Warnings* section of the Gabitril prescribing information regarding the risk of seizures in patients without epilepsy on Gabitril therapy. Cephalon will engage in an educational campaign to discourage off-label use of Gabitril therapy.

FDA Panel Makes Recommendations On COX-2 Inhibitors[4] On February 18, 2005, an FDA advisory committee recommended that Celebrex® (celecoxib) remain on the market with new labeling warnings, including a black box warning about the increased risk of cardiovascular events. With a 31-1 vote, the FDA's Arthritis Drugs and Drug Safety & Risk Management Advisory Committees voted that the overall risk/benefit profile of Celebrex supports the continued marketing of Celebrex in the United States. The final vote on Bextra® (valdecoxib) (with two abstentions) was 17-13; the committee's vote was also split on Vioxx® (rofecoxib), with a 17-15 vote. The FDA is not required to accept the recommendations of this advisory panel, although it often does so.

References

1. Caremark: RxPipeline Insider. Full Content available with subscription at: www.rxpipelineinsider.com. Accessed on: February 18, 2005 and February 25, 2005.
2. U.S. Food and Drug Administration. MedWatch: Phenergan (promethazine hydrochloride). Available at: http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#phenergan. Accessed on: February 17, 2005.
3. U.S. Food and Drug Administration. MedWatch: Gabitril (tiagabine). Available at http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Gabitril. Accessed on: February 22, 2005.
4. Celebrex Should Stay on the Market, FDA Panel Says, But Splits on Vioxx, Bextra. F-D-C Reports --- *The Pink Sheet.* 2005; 67(8): 3. Available with subscription at: www.thepinksheet.com. Accessed on: February 25, 2005.