

## FDA News Flash January 23, 2012

### FDA REGULATORY NEWS

- On Friday, FDA allowed marketing of the STRATIFY JCV™ Antibody ELISA test, the first test designed to help determine the risk of a rare brain infection called progressive multifocal leukoencephalopathy (PML) in people using the drug Tysabri to treat multiple sclerosis (MS) or Crohn's Disease (CD). The STRATIFY JCV Antibody ELISA test, when analyzed in light of other clinical factors of the patient, can allow physicians and patients to assess the risk for developing PML, and provide better insight into the benefits of continuing Tysabri treatment in these patients. In a separate but related action, FDA announced approval of updates to the drug label for Tysabri which identifies a positive test for anti-JCV antibodies as a risk factor for developing PML. [[FDA Press Release](#)] (FDA.gov)
- FDA's Reproductive Health Drugs Advisory Committee voted 13 to 4 against recommending approval of Columbia Laboratories and Watson Pharmaceuticals' progesterone gel 8% for the prevention of pre-term birth in women with short cervixes. Committee members cited insufficient evidence of efficacy provided by the results of the US pivotal trial, and similarly, decided that the overall risk/benefit profile of the drug was not acceptable to support approval for the proposed indication. (The Pink Sheet Daily)
- According to comments from Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research (CDER), the agency has not used the accelerated pathway for drug products to its full potential, and believes that this pathway could be more consistently and effectively used to qualify drug candidates if FDA issues both internal and external guidance to clarify the process. Better implementation of the accelerated approval may serve as a potential alternative to the implementation of a new "Progressive" or "Exceptional" approval process to expedite approval of potentially breakthrough drugs in specific circumstances. (The Pink Sheet)

### FDA COMPLIANCE NEWS

- The Mini Sentinel study, a pilot project for FDA's Sentinel Initiative, has gained access to electronic healthcare data on 126M individuals, surpassing the goal of 100M established in the FDA Amendments Act of 2007 (FDAAA). According to Dr. Robert Temple, Deputy Center Director for Clinical Science at CDER, this data could augment investigations prompted by FDA's adverse events reporting system (AERS), and could serve as important comparison information for drug safety event investigations. (The Pink Sheet)

### CLIENT NEWS

- CareFusion opens office in Dubai (Trade Arabia)
- Carestream Health names Barry Canipe as Chief Financial Officer and Jianqing Bennett as Vice President of Global Medical Sales and Services (Rochester Democrat and Chronicle)

- Covidien appoints Stacy Enxing Seng as President of Vascular Therapies Global Business Unit (BusinessWire)
- Medtronic receives 510(k) clearance for the Aquamantys SBS 5.0 Sheathed Bipolar Sealer (BusinessWire)
- Quest Diagnostics receives market authorization for the STRATIFY JCV Antibody ELISA testing service (PRNewswire)

For additional information, please respond to [dailydose@becker-consult.com](mailto:dailydose@becker-consult.com).

## MEETINGS

### Next week

- Pediatric Advisory Committee. January 30, 2011. Discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act for Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein), Cervarix (Human Papillomavirus Bivalent (Types 16 and 18) vaccine, recombinant, Focalin XR (dexamethylphenidate), Daytrana (methylphenidate), Seroquel (quetiapine), Pancreaze (pancrelipase), Zenpep (pancrelipase), Creon (pancrelipase), Xerese cream 5%/1% (acyclovir and hydrocortisone), Xolair (omalizumab), Benicar (olmesartan medoxomil), Atacand (candesartan cilexetil), Mirena (levonorgestrel—releasing intrauterine system), Plan B One Step (levonorgestrel), and Flomax (tamsulosin). [\[FR Notice\]](#)

### Next 30 days

- Oncologic Drugs Advisory Committee. February 8, 2012. Discuss supplemental biologics license application 125320/28 for XGEVA (denosumab) injection, application submitted by Amgen, Inc. The proposed indication for this product is for the treatment of men with castrate-resistant prostate cancer at high risk of developing bone metastases, or spread of cancer to the bones. Amgen, Inc., (NASDAQ:AMGN). [\[FR Notice\]](#)
- Oncologic Drugs Advisory Committee. February 9, 2012. Discuss supplemental new drug application (NDA) 21790/010 for DACOGEN (decitabine) for injection, application submitted by Eisai, Inc. The proposed indication for this product is for the treatment of acute myelogenous leukemia (AML) in adults 65 years of age or older who are not considered candidates for induction chemotherapy. Discuss NDA 022481, with the proposed trade name PIXUVRI (pixantrone dimaleate) injection, application submitted by Cell Therapeutics, Inc. The proposed indication for this product is as a single agent treatment for patients with relapsed or refractory, aggressive Non-Hodgkin's Lymphoma who received two or more prior lines of therapy. Cell Therapeutics, Inc., (NASDAQ:CTIC). [\[FR Notice\]](#)
- Anesthetic and Analgesic Drug Products Advisory Committee. February 9, 2012. Discuss the available efficacy and safety data for supplemental new drug application (sNDA) 22395/S-013, QUTENZA (capsaicin 8%) Patch, by NeurogesX, Inc., for the proposed indication of management of neuropathic pain (nerve pain) related to HIV-associated peripheral neuropathy. NeurogesX, Inc., (NASDAQ:NGSX). [\[FR Notice\]](#)
- Neurological Devices Panel of the Medical Devices Advisory Committee. February 10, 2012. Discuss and make recommendations regarding the possible reclassification of cranial electrotherapy stimulator (CES) devices. [\[FR Notice\]](#)

- Cellular, Tissue, and Gene Therapies Advisory Committee. February 10, 2012. Hear updates of the research programs in the Cellular and Tissue Branch, Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research, FDA. [[FR Notice](#)]
- Public Workshop. February 15, 2012. Ethical and Regulatory Challenges in the Development of Pediatric Medical Countermeasures. Plenaries and breakout sessions on the ethical and regulatory challenges in the development of medical countermeasures for the pediatric population. [[FR Notice](#)]

### **Next 90 days**

- Endocrinologic and Metabolic Drugs Advisory Committee. February 22, 2012. Discuss the safety and efficacy of new drug application (NDA) 22-580, proposed trade name QNEXA (phentermine/topiramate) Controlled-Release Capsules, manufactured by VIVUS, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) equal to or greater than 30 kilograms (kg) per square meter or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related comorbidities. VIVUS, Inc., (NASDAQ:VVUS). [[FR Notice](#)]
- Cardiovascular and Renal Drugs Advisory Committee. February 23, 2012. Discuss the new drug application (NDA) 203202, proposed trade name NORTHERA (droxidopa capsules), submitted by Chelsea Therapeutics, Inc., for the treatment of symptomatic neurogenic orthostatic hypotension in patients with primary autonomic failure (Parkinson's Disease, Multiple System Atrophy, and Pure Autonomic Failure), Dopamine Beta-Hydroxylase Deficiency, and Non-Diabetic Autonomic Neuropathy. Chelsea Therapeutics, Inc., (NASDAQ:CHTP). [[FR Notice](#)]
- Dermatologic and Ophthalmic Drugs Advisory Committee. February 27, 2012. Comment on the following topics related to the use of ophthalmic drug products: Appropriate types of clinical evidence for developing anti-inflammatory drugs for the treatment of postoperative drugs and reduction of ocular pain in patients who have undergone ocular surgery; and the appropriateness of marketing a single bottle of ophthalmic product for use in both eyes for postsurgical indications as it relates to the potential risk for infection. [[FR Notice](#)]
- FDA Rare Disease Patient Advocacy Day. March 1, 2012. Meeting to enhance the awareness of the rare disease community as to FDA's roles and responsibilities in the development of products (drugs, biological products, and devices) intended for the diagnosis, prevention, and/or treatment of rare diseases or conditions. [[FR Notice](#)]
- Public Workshop. March 7-8, 2012. FDA Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice. Co-sponsored by the FDA Los Angeles District Office and the Society of Clinical Research Associates (SoCRA). Aid the clinical research professional's understanding of the mission, responsibilities, and authority of the FDA and to facilitate interaction with FDA representatives; focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). [[FR Notice](#)]
- Arthritis Advisory Committee Meeting. March 12, 2012. Discuss the anti-nerve growth factor (Anti-NGF) drug class that is currently under development and the safety issues possibly related to these drugs. [[FR Notice](#)]
- Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting. March 14, 2012. Discuss the clinical pharmacology aspects of pediatric clinical trial design and dosing to optimize pediatric drug development. [[FR Notice](#)]

- Public Workshop. May 3, 2012. Clinical Development Programs for Sedation Products. Solicit information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups as FDA develops guidance on clinical development programs for sedation products. [[FR Notice](#)]
- Public Workshop. April 12, 2012. Role of Naloxone in Opioid Overdose Fatality Prevention. [[FR Notice](#)]
- **POSTPONED:** Immunology Devices Panel. TBD. Discuss, make recommendations, and vote on a premarket approval application for the ProgenSA PCA3 assay, which is indicated to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended based on current standard of care, before consideration of PCA3 assay results. Gen-Probe, Inc., (NASDAQ:GPRO). [[FR Notice](#)]

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