PRODUCT UPDATE

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New Form of Paclitaxel Is Approved

Abraxis Oncology in Schaumburg, IL, announced that Abraxane™, a new form of paclitaxel, has been approved for the treatment of metastatic breast cancer after failure of combination chemotherapy or for relapse within six months of adjuvant chemotherapy. This new form of paclitaxel is suspended in albumin rather than a solvent. As described in the package insert, Abraxane had fewer instances of severe neutropenia and hypersensitivity reactions but a higher incidence of nerve damage, severe muscle and joint pain, and gastrointestinal toxicities. In a clinical trial of 460 patients, tumors shrank in 21.54% of women treated with Abraxane compared with 11.1% of those treated with paclitaxel. For more information, visit www.abraxane.com or call 800-564-0216.

New Combination Pain Medication Approved for Short-Term Treatment of Acute Pain

Combunox™ tablets (Forest Pharmaceuticals, Inc., New York, NY) combine oxycodone (5 mg) with ibuprofen (400 mg) for the short-term treatment of moderate to severe pain. The most common indications for this new combination will be acute pain caused by injury or surgery. The U.S. Food and Drug Administration (FDA) approval was based on three double-blind trials that demonstrated that Combunox was significantly more effective in relieving pain than either drug alone or placebo. The most common side effects of this drug include nausea, vomiting, somnolence, dizziness, and headache. For more information, visit www.combunox.com or call 800-678-1605, ext. 7301.

New Formulation of Alemtuzumab Has Several Advantages

Berlex, Inc., in Montvale, NJ, has announced a new concentrated formation of alemtuzumab (Campath®). The old formulation was 30 mg in 3 ml. The new concentration is 30 mg in 1 ml. The new concentration also is available packaged in a vial rather than in ampoules. The vial contents do not need to be filtered before use. Several advantages to the new packaging and new formulation include longer shelf life, increased convenience, and increased safety. Nurses and pharmacists need to be aware of the higher concentration to prevent medication errors. For more information, visit www.campath.com or call 800-473-5832.

Manufacturer Issues Safety Alert for Darbepoetin Alfa

The FDA and Amgen Inc. in Thousand Oaks, CA, have notified healthcare providers about revisions to the warnings and precautions sections of the prescribing information for darbepoetin alfa (Aranesp®). Darbepoetin alfa is indicated for the treatment of chemotherapy-induced anemia in patients with nonhematologic malignancies. This safety alert concerns adverse events seen during off-label use of other products in the same class (epoetin alfa and epoetin beta). Two recent investigational studies conducted outside the United States and using higher-than-usual doses to increase hemoglobin levels to greater than 12 g/dl found increased mortality and thrombotic vascular events. Amgen, in its letter to providers, reminded them that the target hemoglobin level should not exceed 12 g/dl.

New Contraindication Added for Anagrelide Hydrochloride

Anagrelide hydrochloride (Agrylin®, Shire Pharmaceuticals, Wayne, PA) is an oral medication used to treat thrombocythemia related to myeloproliferative disorders. The FDA has issued a notice that the contraindications and warnings sections of the prescribing information for anagrelide now include a contraindication to the use of anagrelide in patients with severe hepatic impairment. The prescribing information advises dose reduction in patients with moderate hepatic impairment and close monitoring of these patients for cardiovascular effects. New information also is included in the prescribing information about use in patients who are renally impaired and those also taking aspirin, as well as the effects of taking the drug with food. For more information, visit www.fda/gov/medwatch/SAFETY/2005/safety05.hrm#Agrylin. For full prescribing information, visit www.agrylin.com.

FDA Renews Nationwide Alert on IV Flush Brand of Heparin and Saline

In February, the FDA reissued an alert for all IV Flush brand of heparin and sodium chloride flushes. The FDA cautions not to use them and to immediately return them to the original distributor. *Pseudomonas fluorescens* infections have been reported in patients who received these products. Some of these flushes may have been provided to patients for home use. They can be identified by the syringe label that has the words "IV Flush Dallas, TX." For any questions, contact the company at 972-463-7389. To report any concerns to the FDA regarding these products, contact the Medwatch office at 800-FDA-1088. Clinicians with patients possibly infected by these products should report suspected cases to their state or local health department and to the FDA.

Voriconazole Approved for Treatment of Serious Fungal Infections in Non-Neutropenic Patients

Vfend® (voriconazole, Pfizer Inc., New York, NY) was developed to provide more effective treatment options with fewer side effects for patients with serious fungal infections. Vfend is currently approved in the United States as first-line treatment of invasive aspergillosis and esophageal candidiasis and as salvage therapy for fungal infections caused by *Scedosporium apiospermum* and *Fusarium* species. In December 2004, Pfizer announced that Vfend had been approved for the treatment of *Candida* infections in nonneutropenic patients, including those with infections in the skin, abdomen, kidneys, and bladder wall, as well as in wounds. This approval came following the results of a randomized, multicenter study that involved 422 patients worldwide. Patients received Vfend or amphotericin B followed by fluconazole. The investigator concluded that Vfend was as effective as amphotericin B in removing *Candida* from the blood and had a lower incidence of treatment-related side effects. The adverse reactions that were most likely

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