PRODUCT UPDATE

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Nelarabine Receives Accelerated Approval

The U.S. Food and Drug Administration (FDA) granted accelerated approval for nelarabine (Arranon® injection, GlaxoSmithKline, Research Triangle Park, NC), a purine nucleoside antimetabolite, for the treatment of patients with T-cell acute lymphoblastic leukemia or T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. Nelarabine is for use in pediatric and adult patients. Principal toxicities include hematologic toxicity, febrile neutropenia, laboratory abnormalities such as increased transaminases, gastrointestinal toxicity, fatigue, and asthenia (loss of strength). For pediatric and adult patients alike, neurotoxicity was dose limiting. Neurologic adverse events included headache, somnolence, hypoesthesia, sensory and/or motor neuropathy, seizures, paresthesias, tremor, and ataxia.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions, and contraindications, is available at www.fda.gov/cder/foi/label/2005/021877lbl.pdf.

Drugs being considered for accelerated approval must treat serious or life-threatening diseases and provide benefit over available therapy, and a surrogate endpoint of the studies in progress also must show likely clinical benefit. Postmarketing studies must verify clinical benefit. This means that after a drug is out on the market, studies must continue to show a benefit to patients or the drug may be pulled off the market.

Drug May Cause Complications During Cataract Surgery

Boehringer Ingelheim in Ridgefield, CT, and the FDA notified healthcare professionals of revisions to the precautions and adverse reactions sections of the prescribing information for Flomax® (tamsulosin hydrochloride). Flomax is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia. A surgical condition termed intraoperative floppy iris syndrome has been observed during phacoemulsification cataract surgery in some patients treated with alpha-1 blockers, including Flomax. Male patients being considered for cataract surgery, as part of their medical history, should be specifically questioned about whether they have taken Flomax or other alpha-1 blockers. Oncology nurses should be aware of potential drug complications when patients undergo nononcologic procedures, especially with drugs as common to patients with cancer as alpha-1 blockers.

Read the complete MedWatch 2005 safety summary at www.fda.gov/medwatch/safety/2005/safety05.htm#Flomax.

Renal Protection Drug Is Not Effective in Non-Small Cell Lung Cancer

MedImmune Oncology, Inc., in Gaithersburg, MD, is voluntarily withdrawing the indication for Ethyol® "to reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with non-small cell lung cancer (NSCLC)." The indication had received accelerated approval, but postconfirmatory studies did not verify the clinical benefit of the claim among patients with NSCLC. Ethyol's indications for renal protection in patients with ovarian cancer receiving cisplatin and for xerostomia protection in patients receiving radiation therapy are unaffected by the label change.

U.S. Food and Drug Administration Approves New Oral Chelator

Exjade® (deferasirox, Novartis Pharmaceuticals, East Hanover, NJ) tablets for oral suspension are indicated to remove iron accumulated in the heart cells and have shown efficacy in removing iron form other organs as well.

Iron accumulation in the heart can be a serious and sometimes fatal consequence of chronic blood transfusions, usually resulting from poor compliance with chelation therapy. Additional new data from a separate study in patients with sickle cell disease also confirm the efficacy of Exjade in removing excess total body and liver iron. Exjade, the first and only once-daily iron chelator administered as a drink (the tablets are dispersed in a glass of juice or water) recently was approved in the United States and Switzerland to treat iron overload that results from chronic blood transfusions in adults and children aged two and older.

To date, deferoxamine has been the standard of care for the first-line treatment of transfusional iron overload in most countries around the world. Administration of deferoxamine often requires a lengthy subcutaneous infusion; as a result, many patients may not complete chelation therapy, thus risking the toxic effects of iron overload.

Iron overload is a cumulative, potentially life-threatening, unavoidable consequence of chronic blood transfusions used to treat certain types of rare, chronic blood disorders, including thalassemia and sickle cell disease, as well as other rare anemia and myelodysplastic syndromes.

The body has no inherent mechanism to remove excess iron, so iron chelation is used as an effective treatment for transfusion-related iron overload. When iron chelation occurs, an agent binds to iron in the body and tissues and helps to remove it through the urine and/or feces.

For complete prescribing information on Exjade, visit www.exjade.com or www.exjade.com/pdf/pi-swiss.pdf.

Pure Red Cell Aplasia and Severe Anemia Can Occur With Growth Factors

Revision to the warnings, precautions, adverse reactions, and dosage and administration sections of the prescribing information for Aranesp® (darbepoetin alfa, Amgen Inc., Thousand Oaks, CA), Epogen® (epoetin alfa, Amgen Inc.), and Procrit® (epoetin alfa, Ortho Biotech Products, Bridgewater, NJ) have been made to include safety information on reports of pure red cell aplasia and severe anemia, with or without other cytopenias. Cases of these conditions associated with neutralizing antibodies to erythropoietin have been reported in patients treated with Aranesp, Epogen, and/or Procrit. This has been reported predominantly in patients with chronic renal failure receiving the drugs by subcutaneous administration. Any patient who develops a sudden loss of response to any of the three drugs, accompanied by severe anemia and low reticulocyte count, should be evaluated for the etiology of loss of effect, including the presence of neutralizing antibodies to erythropoietin.

Read the complete MedWatch 2005 safety summary, including links to the Dear Healthcare Professional letters and revised prescribing information at www.fda.gov/medwatch/

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safety/2005/safety05.htm#aranesp2 and www.fda.gov/medwatch/safety/2005/safety05.htm#epoetin.

Thrombotic and Thromboembolic Events Can Result From Coagulation Factor

The prescribing information of NovoSeven® (coagulation factor VIIa, Novo Nordisk, Princeton, NJ) has been revised to include information on thrombotic and thromboembolic adverse events, which were found during clinical studies in patients without hemophilia and on postmarketing safety surveillance. A clinical study looking at older adult patients with intracerebral hemorrhage and without hemophilia indicated a potential increased risk of arterial thromboembolic adverse events with use of NovoSeven, including myocardial ischemia, myocardial infarction, cerebral ischemia, and infarction. The complete MedWatch 2005 Safety summary, including links to the Dear Healthcare Professional letter and revised prescribing information, can be found at www.fda.gov/medwatch/safety/2005/safety05.htm#NovoSeven.

NEW PRODUCTS

New Test May Detect Oral Cancer

Zila, Inc., in Phoenix, AZ, announced that it has begun a phase III clinical trial for OraTest®, its oral cancer detection drug. Zila reached an agreement with the FDA, under the special protocol assessment process, on the design and size of its new phase III clinical trial for OraTest. Severe dysplasia is recognized as a precursor to oral cancer, and Zila Tolonium Chloride, the patented active pharmaceutical ingredient in OraTest, has proven to be very sensitive to severe dysplasia in previous studies. Oral cancer is a threat to all people, not just smokers. According to statistics published by the American Dental Association, more than 30,000 people are diagnosed with the deadly disease each year in the United States, making the frequency of oral cancer greater than that of cervical, brain, or ovarian cancers. Nearly 70% of all oral cancer cases are diagnosed in later stages. However, with early detection, oral cancer has an 80% five-year survival rate, according to the American Cancer Society. More than 25% of patients with oral cancer have no predisposing risk factors. Risk factors include age older than 40, smokers or those who have used chewing tobacco in the past 10 years, and people who drink more than one alcoholic drink per day. For more information on oral cancer, visit www.cancer.org, and for more information on Zila, visit www.zila.com.

Special protocol assessment occurs when the FDA evaluates certain protocols and issues relating to them to determine whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. The assessment can happen with clinical protocols for phase III trials whose data will form the primary basis for an efficacy claim.

Pump Aids Delivery of Patient-Controlled Analgesia

The FDA has approved the Personal Therapy Manager (PTM) (Medtronic, Inc., Minneapolis, MN), which allows patients with chronic pain to use a SynchroMed® II drug pump (Medtronic, Inc.) to control delivery of physician-prescribed supplemental doses of pain medication to alleviate increased pain or activate a rescue dose. The PTM permits patients to control their pain relief without relying on a constant dose of pain medication from a pump that has been preset.

Patients use the PTM by pressing a button, triggering the delivery of a physician-prescribed dose of liquid morphine from the pump. The pump uses software to ensure that the appropriate amount of time has passed to allow for an additional dose of medication, providing a safety mechanism to prevent overdosage.

The PTM, a hand-held device about the size of a cellular phone, is used to manage all types of severe, chronic pain, including chronic cancer pain. The SynchroMed II pump is implanted just beneath the skin of the lower abdomen and delivers specially formulated medication (preservative-free morphine sulfate for chronic pain) directly to the intrathecal space, the fluid-filled area surrounding the spinal cord. The method of administration bypasses the digestive system and the blood-brain barrier, optimizing the delivery so the drug can work directly on the central nervous system.

The site-specific delivery targets the medication's site of action in the spinal cord, thereby minimizing the dose requirements and side effects compared to oral administration of the same drug. A clinician refills the pump by using a needle and syringe to inject the drug through the skin into the drug reservoir. For information on the PTM, visit www.ptm.medtronic.com. For more information on the SynchroMed II drug pump, visit www.medtronic.com.

Videos May Help Support Patients With Breast Cancer

The mission of WomenStories is to inspire, inform, and support patients with breast cancer by documenting and sharing survivors' experiences. WomenStories is a series of videos in which breast cancer survivors offer emotional support and advice that women need and value. An e-newsletter also is available for patient support. The videos can be ordered online and include topics such as initial diagnosis, discussions on intimacy, dealing with recurrence, and life after breast cancer. The 10 videos can be ordered separately or as a complete set. Visit www.womenstories.org for more information.

System Delivers High-Dose Chemotherapy Directly to Affected Area

Delcath Systems, Inc., in Stamford, CT, has received a Canadian patent for the Delcath system, a novel way to deliver high doses of chemotherapy to specific organs and body regions. The Delcath system has patents in the United States. The most recent indication is to treat glands with cancerous tumors, which extends the scope of the product from previously treating only organs such as the liver. The Delcath system delivers high-dose chemotherapy directly to the organ or gland affected, leaving the rest of the body free from the toxicities associated with high concentration of chemotherapy. As blood exits, special Delcath filters trap the chemotherapy, protecting the rest of the body from excessive toxicity. The procedure is repeatable and is less invasive than traditional ways of performing isolated perfusion to effect dose-directed therapy of specific body organs or regions. In May 2005, Delcath received fast-track status from the FDA for the treatment of metastatic melanoma in the liver with melphalan, an approved anticancer agent, using the Delcath system. For more information, visit www.delcath.com.

RECALL ALERTS

Novartis Recalls Seven Lots of Eye Drops

Novartis Ophthalmics in East Hanover, NJ, and the FDA notified healthcare professionals and patients of a voluntary recall because of a lack of sterility assurance of seven lots of two products, GenTeal® Gel and GenTeal GelDrops, intended for use to relieve dryness of the eyes. Although the risk of potential contamination is believed to be very low, contaminated product could cause infections in susceptible people.

The five lots of GenTeal Gel (lot Z12468, 10 ml; lot Z12900, 10 ml; lot Z12912, 3.5 ml; lot Z13161, 10 ml; and lot Z13314, 3.5 ml) include about 142,500 tubes that were distributed nationwide from March–November 2004. The two lots of GenTeal GelDrops (lot 51139, 15 ml, and lot 51283, 25 ml) include about 12,000 dropper bottles that were distributed nationwide in October 2005.

Test results for GenTeal Gel indicated the presence of mold in a small number of samples. The species of mold that is suspected generally is not harmful but has the potential to cause eye infections in susceptible people, especially those with compromised immune systems. Read the complete MedWatch 2005 safety summary at www.fda.gov/medwatch/safety/2005/safety05.htm#GenTeal.

NOTEWORTHY

Initiative Increases Awareness of Hypothermia From Infection

Arizant Healthcare Inc. in Prairie, MN, is launching its Prevent Hypothermia initiative to heighten awareness of the relationship between unintended hypothermia and surgical site infections and the simple, cost-effective ways to reduce surgical complications.

Arizant's Prevent Hypothermia campaign includes a comprehensive educational kit featuring an informational brochure, ready-to-use educational presentation, 16-month calendar, warming measurement tools, and how-to guides for the implementation of techniques to prevent surgical site infections and hypothermia. To request an educational kit, call 888-WARM-36C or visit www.preventhypothermia.org.

Genomics Will Help Researchers Understand Cancer

The National Cancer Institute and the National Human Genome Research Institute, both part of the National Institutes of Health, launched a comprehensive effort to improve the understanding of the molecular basis of cancer through the application of genome analysis technologies, especially large-scale genome sequencing. The overall effort, called the Cancer Genome Atlas, will begin with a pilot project to determine the feasibility of a full-scale effort to systematically explore the universe of genomic changes involved in all types of human cancer. The Human Genome Project has paved the way to understanding disease at the most basic level, and now researchers may be able to understand cancer and its many forms in the same way. Such understanding can provide new insights into the biologic basis of cancer, which in turn will lead to new tests, therapies, and preventive measures. For details about the Cancer Genome Atlas, including frequently asked questions, a graphic, a glossary, a brief guide to genomics, and a media library of available images, visit http://cancergenome.nih.gov.