PRODUCT UPDATE

Valerie Burger, RN, MA, MS, OCN®
Associate Editor

PHARMACY CORNER

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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