



Totality of Available Data Reaffirms PROCRT® (Epoetin alfa) Safe and Effective When Used Appropriately As Labeled to Treat Chemotherapy-Induced Anemia

BRIDGEWATER, NJ (March 11, 2008) -- The totality of scientific data submitted in recent months to the U.S. Food and Drug Administration (FDA) in preparation for the March 13th Oncologic Drugs Advisory Committee Meeting (ODAC) reaffirms that erythropoiesis-stimulating agents (ESAs) are safe and effective when used according to the product label to treat chemotherapy-induced anemia (CIA). ESAs are an important treatment option for CIA patients as the only proven therapeutic alternative to blood transfusions.

"ESA use within the label has not been associated with increased risk of mortality or disease progression," said Craig Tendler, M.D., Vice President, Medical Affairs, Oncology/Nephrology, Ortho Biotech Products, L.P. "Ortho Biotech looks forward to Thursday's ODAC meeting, at which we hope that responsible recommendations will be made based on the totality of available evidence, including a substantial body of scientific data submitted to the FDA over the past several months."

At the ODAC meeting, Ortho Biotech will:

- Present the totality of data requested by the FDA at the May 2007 ODAC meeting, including follow-up survival data submitted over the last four months from studies accounting for approximately 50 percent of the 7,444 patients in the company's database;
- Suggest that vascular thrombotic events (VTEs) are the most plausible explanation for increased mortality with ESAs in cancer patients seen in some studies with high hemoglobin targets;
- Recommend additional research to address outstanding issues; and
- Propose risk minimization strategies to reduce the risk of VTEs and ensure safe and appropriate use.

The company has provided to the FDA all available clinical data from relevant, randomized controlled trials of ESAs to treat CIA. "The known risks of ESA use are prominently displayed in the current product labeling, and we will continue to support direction to healthcare professionals to use the lowest dose of ESAs that will gradually increase the hemoglobin concentration to a level that will avoid the need for blood transfusion," Dr. Tendler said.

In addition to working closely with the FDA, Ortho Biotech, along with independent investigators and other ESA manufacturers, have provided data to the independent Cochrane Collaboration to facilitate a patient-level analysis of all data from appropriately designed and conducted controlled clinical studies. This project will create a database of more than 15,000 patients, making it the largest combined analysis of ESA safety data ever undertaken. The company also has proposed unrestricted funding to support independent research through the National Cancer Institute to evaluate potential mechanisms that may mediate adverse outcomes when ESAs are used to treat CIA.

About PROCRT (Epoetin alfa)

PROCRT is used for the treatment of anemia in patients with most types of cancer receiving chemotherapy, with chronic renal failure who are on dialysis and those who are not on dialysis, who are being treated with zidovudine for HIV infection, and to reduce the need for transfusion in anemic patients who are scheduled for elective noncardiac, nonvascular surgery. Depending on the country in which Epoetin alfa is marketed, these indications may differ.

Important U.S. Safety Information for PROCRT

Boxed WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR and THROMBOEMBOLIC EVENTS, and TUMOR PROGRESSION

Renal failure: Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Cancer:

- **ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers when dosed to target a hemoglobin of ? 12 g/dL.**

- The risks of shortened survival and tumor progression have not been excluded when ESAs are dosed to target a hemoglobin of < 12 g/dL.
- To minimize these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusions.
- Use only for treatment of anemia due to concomitant myelosuppressive chemotherapy.
- Discontinue following the completion of a chemotherapy course.

Perisurgery: PROCRIT® increased the rate of deep venous thromboses in patients not receiving prophylactic anticoagulation. Consider deep venous thrombosis prophylaxis.

Contraindications

PROCRIT is contraindicated in patients with uncontrolled hypertension or with known hypersensitivity to albumin (human) or mammalian cell-derived products.

Additional Important Safety Information

- The dose of PROCRIT should be titrated for each patient to achieve and maintain the following hemoglobin levels:
 - Chronic renal failure patients - hemoglobin levels between 10 to 12 g/dL. If a patient does not attain hemoglobin levels of 10 to 12 g/dL despite 12 weeks of appropriate PROCRIT therapy, see DOSAGE and ADMINISTRATION in the PROCRIT Prescribing Information.
 - Cancer or HIV patients - the lowest hemoglobin level sufficient to avoid transfusion and not to exceed 12 g/dL.
- Monitor hemoglobin regularly during therapy, more frequently following a dosage adjustment or until hemoglobin becomes stable.
- Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin have been reported in patients with chronic renal failure receiving PROCRIT by subcutaneous administration. If any patient develops a sudden loss of response to PROCRIT, accompanied by severe anemia and low reticulocyte count, and anti-erythropoietin antibody-associated anemia is suspected, withhold PROCRIT and other erythropoietic proteins. Contact ORTHO BIOTECH (1-888-2ASKOBI or 1-888-227-5624) to perform assays for binding and neutralizing antibodies. If erythropoietin antibody-mediated anemia is confirmed, PROCRIT should be permanently discontinued and patients should not be switched to other erythropoietic proteins.
- The safety and efficacy of PROCRIT therapy have not been established in patients with a known history of a seizure disorder or underlying hematologic disease (e.g., sickle cell anemia, myelodysplastic syndromes or hypercoagulable disorders).
- In some female patients, menses have resumed following PROCRIT therapy; the possibility of pregnancy should be discussed and the need for contraception evaluated.
- Prior to and regularly during PROCRIT therapy monitor iron status; transferrin saturation should be 20% and ferritin should be 100 ng/mL. During therapy absolute or functional iron deficiency may develop and all patients will eventually require supplemental iron to adequately support erythropoiesis stimulated by PROCRIT.
- During PROCRIT therapy, blood pressure should be monitored carefully and aggressively managed, particularly in patients with an underlying history of hypertension or cardiovascular disease.
- In studies, the most common side effects included fever (pyrexia), diarrhea, nausea, vomiting, swelling of hands or feet (edema), lack or loss of strength or weakness (asthenia, fatigue), shortness of breath, high blood pressure, headache, joint pain (arthralgias), abnormal skin sensations (as tingling or tickling or itching or burning; paresthesia), rash, constipation and upper respiratory infection.

Please visit www.procrit.com for the full Prescribing Information, including the Boxed WARNINGS.

About Ortho Biotech Products, L.P.

Ortho Biotech Products, L.P. is a leading biopharmaceutical company devoted to helping improve the lives of patients with cancer and with anemia due to multiple causes, including chronic kidney disease. Since it was founded in 1990, Ortho Biotech and its worldwide affiliates have earned a global reputation for researching, manufacturing and marketing innovative products that enhance patients' health. Located in Bridgewater, N.J., Ortho Biotech is an established market leader in Epoetin alfa therapy for anemia management. The company also markets treatments for recurrent ovarian cancer, rejection of transplanted organs and other serious illnesses. For more information, visit www.orthobiotech.com.

Forward-Looking Statement

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown

risks or uncertainties materialize, actual results could vary materially from Johnson & Johnson's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of the Company's Annual Report on Form 10-K for the fiscal year ended December 30, 2007. Copies of this Form 10-K, as well as subsequent filings, are available online at <http://www.sec.gov>, www.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statements as a result of new information or future events or developments.

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