ORTHO BIOTECH

August 13, 2004

Dear Health Care Professional:

Ortho Biotech Products, LP ("Ortho Biotech"), wishes to advise you of important changes to the safety information and dosing sections of the product labeling for PROCRIT® epoetin alfa. To ensure consistency with labeling for other products in this class, changes to hemoglobin rate of rise and target have been made.

Hemoglobin rise

The newly revised prescribing information for PROCRIT® in its cancer chemotherapy indication recommends dosing interruption and modification if the rate of rise of hemoglobin exceeds 1 gram per deciliter over a 2-week period. The goal of treatment (hemoglobin target level) should be individually determined for each patient, and this target may range from 10 up to 12 grams per deciliter. Importantly, the new prescribing information recommends that the target hemoglobin in patients with cancer should not exceed 12 grams per deciliter in men and women. The dose should be withheld if the hemoglobin is 13 grams per deciliter, or above. This guidance applies whether patients are treated with PROCRIT three times weekly or with the newly approved once weekly dosing regimen (see below).

The new recommendations result from recent investigational studies, some with erythropoietin products other than PROCRIT, and conducted outside of the US, where patients with cancer were treated to high hemoglobin target levels, beyond the correction of anemia. These studies permitted or required dosing to achieve hemoglobin levels of greater than 12 grams per deciliter. An increased frequency of adverse patient outcomes, including increased mortality and thrombotic vascular events was reported in these studies. Additional details of these studies are included in the following sections of the revised Prescribing Information: See WARNINGS - Thrombotic Events and Mortality and PRECAUTIONS - Tumor Growth Factor Potential.

Since all erythropoietin products share similarities in mechanism of action, Ortho Biotech deems this information to be relevant for prescribers and patients to help ensure the safe and effective use of PROCRIT®.

Dosage and Administration:

Previously, the only dosing regimen specified in PROCRIT® labeling for the cancer chemotherapy indication was 150 IU per kilogram SC TIW. Recently, another dosing regimen, 40,000 IU SC weekly, has been approved for use in this patient population. The revised product labeling includes the following guidance regarding once weekly dosing of PROCRIT:

- The starting dose is 40,000 Units SC weekly. If after 4 weeks of therapy, the hemoglobin has not increased by ≥ 1 g/dL, in the absence of RBC transfusion, the PROCRIT® dose should be increased to 60,000 Units weekly.
- If patients have not responded satisfactorily to a PROCRIT® dose of 60,000 Units weekly after 4 weeks, it is unlikely that they will respond to higher doses of PROCRIT®.

Ortho Biotech is committed to providing you with the most current product information for PROCRIT®. You can report adverse events to Ortho Biotech at Medical Information at 1-800-325-7504, prompt #2. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-0178), the MedWatch website at www.fda.gov/medwatch, or mailed to MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787. Both healthcare professionals and consumers should use Form 3500 (available at the MedWatch website) for reporting adverse events.

A copy of the revised prescribing information for PROCRIT® is enclosed. Should you have any questions or require further information regarding the use of PROCRIT®, please contact the Ortho Biotech Medical Information at 1-800-325-7504, prompt #2.

Sincerely,

Marc Kamin, M.D.,
Vice President, Ortho Biotech Clinical Affairs, LLC.