



Aranesp Dosed Once Every Two Weeks Increases Hemoglobin Levels, Improves Fatigue And Reduces Need For Transfusions In Patients With Chemotherapy-Induced Anemia

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FOR IMMEDIATE RELEASE

CHICAGO, IL, June 1, 2003 - Amgen (Nasdaq:AMGN), the world's largest biotechnology company, presented data on Aranesp® (darbepoetin alfa) dosed once every two weeks and once every three weeks in the management of anemia in patients with chemotherapy-induced anemia. Results from seven studies, including the large-scale SOAR (Successful Outcomes in Anemia Research) trial, further enhance the wide body of data supporting the benefits of extended dosing with Aranesp® compared to other currently available anemia treatments.

Lee Schwartzberg, MD, an Aranesp® investigator and medical director of The West Clinic, Memphis, TN, commented, "We continue to study ways to better manage chemotherapy-induced anemia to raise hemoglobin levels, improve quality of life and reduce dependence on blood transfusions in cancer patients. These data support what I've often seen with my patients, that Aranesp® effectively can be dosed less often than other anemia therapies."

Three presentations from the SOAR trial reported on the effectiveness of Aranesp® in 1,173 patients with chemotherapy-induced anemia dosed once every two weeks. The first of these presentations was presented by Douglas W. Blayney, MD, Wilshire Oncology Medical Group, Pomona, CA, and colleagues who reported that Aranesp® 3.0 mcg/kg (200 mcg for the average patient) administered once every two weeks provided a clinically significant increase in hemoglobin (> 2 g/dL from baseline) in 71 percent of patients in the study and a hematopoietic response (> 2 g/dL increase from baseline or hemoglobin > 12 g/dL) in 84 percent of patients. [ASCO Abstract #3003]

In the second presentation, the role of Aranesp® in improving energy levels and reducing fatigue in patients with chemotherapy-induced anemia was examined by Saroj Vadhan-Raj, MD, University of Texas, M.D. Anderson Cancer Center, Houston, TX. Preliminary data from this ongoing study of 1,173 patients showed that treatment with Aranesp® dosed once every two weeks resulted in clinically significant improvements in both patient-reported fatigue and energy scores. [ASCO Abstract #2942]

"In addition to the improvement in fatigue and energy levels, the benefits of fewer injections for patients should not be underestimated," said Dr. Vadhan-Raj, lead investigator of the Aranesp® study. "Fewer injections mean fewer trips to physician's offices and clinics, less disruption of daily living, fewer reminders of the disease and overall improved quality of life. These things mean a lot to people dealing with an already burdensome treatment like chemotherapy."

The third presentation by Barry C. Mirtsching, MD, Center for Oncology Research & Treatment, Dallas, TX, focused on a comparison of the SOAR data with data from patients treated with Epoetin alfa in other clinical trials. These analyses suggest that the clinical outcomes in treating anemia associated with chemotherapy (specifically hematopoietic response, mean hemoglobin change after both four and 12 weeks, and proportion of patients requiring red blood cell transfusions) were similar between Aranesp® dosed every two weeks compared with once-weekly or three times per week dosing of Epoetin alfa and required fewer injections. [ASCO Abstract #2944]

The most frequently reported adverse events were consistent with those previously observed with darbepoetin alfa in this patient population (i.e., gastrointestinal and constitutional symptoms associated with chemotherapy).

About Aranesp®

Aranesp® was approved by the U.S. Food and Drug Administration (FDA) in July 2002 for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies. Aranesp® was approved by the FDA in September 2001 for the treatment of anemia associated with chronic renal failure, also known as chronic kidney disease, for patients on dialysis and patients not on dialysis.

Aranesp® is a recombinant erythropoietic protein (a protein that stimulates production of oxygen-carrying red blood cells). Amgen revolutionized anemia treatment with the discovery of recombinant erythropoietin, Epoetin alfa, which is currently marketed in the U.S. by Amgen as EPOGEN®ⁱ and by Ortho Biotech Products, LP, as Procrit®ⁱⁱ. Building on this heritage, Amgen developed Aranesp®, which contains two additional sialic acid-containing carbohydrate chains than the Epoetin alfa molecule resulting in more activity with the added benefit of less-frequent administration.

Aranesp® is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic and other serious events; dose reductions are recommended if the hemoglobin increase exceeds 1.0 g/dL in any two-week period. The most commonly reported side effects in Aranesp® trials were fatigue, edema, nausea, vomiting, diarrhea, fever, and dyspnea.

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

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ⁱ EPOGEN® is a registered trademark of Amgen Inc.

ⁱⁱ Procrit® is a registered trademark of Ortho Biotech Products, L.P.

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Aranesp® prescribing information can be accessed by calling 800-772-6436 or by logging onto www.aranesp.com.

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