



## Analysis of Head-to-Head Studies Shows That Aranesp(R) Dosed Every Two Weeks Offers Similar Results With Less Frequent Administration Compared to Epoetin Alfa

December 7, 2003

These results support the recently published National Comprehensive Cancer Network Guidelines on Cancer and Treatment Related Anemia

SAN DIEGO, Dec. 7 - Amgen (Nasdaq: AMGN), the world's largest biotechnology company, today presented data from head-to-head trials suggesting that Aranesp (darbepoetin alfa) dosed 200 mcg once every two weeks provided similar results to epoetin alfa dosed 40,000 units once weekly in boosting hemoglobin and reducing the need for blood transfusions in cancer patients undergoing chemotherapy. The results were presented by the study's lead investigator, Dr. Lee Schwartzberg, medical director of The West Clinic, Memphis, Tenn., at the American Society of Hematology (ASH) Annual Meeting. (Abstract #1878)

"This analysis should provide the oncology community with further trial data that Aranesp can treat anemia and offer the benefit of less frequent dosing. Fewer injections can translate into less office visits, which is a meaningful benefit for patients and caregivers. Studies have shown that, on average, a simple injection requires two or more hours of a patient's day and more than an hour of a caregiver's day," said Schwartzberg.

The interim analysis evaluated the first 210 patients enrolled in three identical, randomized, open-label, multi-centered studies in patients with breast, lung, and gynecologic cancers. Patients in both arms of the studies had similar hemoglobin responses, hematopoietic responses, transfusion rates and mean change in hemoglobin. In addition, the results were analyzed based upon the outcome hemoglobin targets defined within the new National Comprehensive Cancer Network (NCCN) guidelines on cancer and treatment-related anemia.

The NCCN guidelines set an important standard for clinical oncology practice stating that physicians should initiate therapy when hemoglobin is less than 11 g/dL and target treatment to maintain patients' hemoglobin between 11-12 g/dL for optimal care. These guidelines are the first to recognize the use of Aranesp dosed at 200 mcg every other week.

More than 90 percent of Aranesp patients in the analysis reached the NCCN guideline target range (11-12g/dL) and almost all of the patients were maintained successfully. The time to reaching target range was comparable in both treatment groups. Further studies to confirm these findings are planned.

For the analysis, there were 105 patients in each arm with a mean baseline hemoglobin of 10.4 g/dL. The mean change in hemoglobin after 17 weeks of treatment was similar between the treatment groups (1.4 g/dL for the Aranesp group and 1.5 g/dL for the epoetin alfa group, using the intent-to-treat approach (missing values or values within 28 days of a transfusion were imputed using the last-value-carried-forward method)). No difference in the incidence of severity of adverse events was observed between treatment groups.

### 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(R)(i) and by Ortho Biotech Products, LP, as Procrit(R) (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.

### About Amgen

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

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended December 31, 2002, and in Amgen's periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, sales growth of recently launched products, difficulties or delays in manufacturing its products, and regulatory developments (domestic or foreign) involving current and future products and manufacturing facilities. In addition, sales of Amgen's products are affected by reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify side effects or manufacturing problems with its products after they are on the market. In addition, Amgen competes with other companies with respect to some of

its marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. In addition, while Amgen routinely obtain patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third party suppliers.

Aranesp prescribing information can be accessed by calling 800-772-6436 or by logging onto [www.aranesp.com](http://www.aranesp.com).

CONTACT: Amgen, Thousand Oaks  
Kelly Stoddard, (805) 447-0821 (media)  
Cary Rosansky, (805) 447-1060 (investors)

(i) EPOGEN(R) is a registered trademark of Amgen Inc.

(ii) Procrit(R) is a registered trademark of Ortho Biotech Products, L.P.

NOTE TO EDITORS: An electronic version of this news release may be accessed via our Web site at [www.amgen.com](http://www.amgen.com) . Journalists and media representatives may sign up to receive all news releases electronically at time of announcement by filling out a short form in the Media section of the Web site.