# Randomized Head-to-Head Trial Shows Aranesp Dosed Every Two Weeks is Comparable to Epoetin Alfa Dosed Once a Week in Breast Cancer Patients

December 11, 2004

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Dec. 11, 2004--Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that data from a head-to-head study show that 200 mcg of Aranesp(R) (darbepoetin alfa) dosed once every two weeks has similar efficacy to 40,000 U of Epoetin alfa dosed once every week in boosting hemoglobin and reducing the need for blood transfusions in breast cancer patients with chemotherapy-induced anemia. The results were presented by one of the study's lead investigators, Lee Schwartzberg, M.D., FACP, medical director of The West Clinic, Memphis, Tenn., at the 27th annual San Antonio Breast Cancer Symposium (SABCS). (SABCS Abstract #6030)

"In this trial, no differences in the ability to achieve, in the time to achieve or in the ability to maintain the target hemoglobin range were observed between the two treatment groups," said Dr. Schwartzberg. "These findings are important as they suggest that Aranesp is effective in correcting anemia when administered every two weeks, which is potentially more convenient than every week administration for patients and caregivers."

The results were analyzed based upon the achievement and maintenance of target hemoglobin threshold (greater than or equal to 11 g/dL) and range (11-13 g/dL, which is based on the American Society of Hematology (ASH)/American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) guidelines for cancer and treatment-related anemia). In the multi-center trial, 141 breast cancer patients were randomized to receive either 200 mcg of Aranesp dosed every two weeks (n=72) or 40,000 U of Epoetin alfa dosed once a week (n=69).

More than 90 percent of patients in both groups achieved hemoglobin levels of greater than or equal to 11 g/dL (93 percent in Aranesp group and 90 percent in Epoetin alfa group). The median time to reach the target hemoglobin level was three weeks in the Aranesp group and four weeks in the Epoetin alfa group. After achieving the target hemoglobin level, 93 percent of patients in the Aranesp group remained in the target hemoglobin range compared to 91 percent in the Epoetin alfa group.

During the study, a lower proportion of patients treated with Aranesp (six percent) required a blood transfusion compared with patients treated with Epoetin alfa (16 percent). At the beginning of the trial, mean baseline hemoglobin was 10.5 g/dL for the Aranesp group and 10.6 g/dL for the Epoetin alfa group. At the end of treatment, mean change in hemoglobin was 1.9 g/dL for Aranesp and 1.7 g/dL for Epoetin alfa.

Both Aranesp and Epoetin alfa had similar safety profiles in this study. During the treatment period, 15 percent of Aranesp patients and 24 percent of Epoetin alfa patients had one or more serious adverse events. These events were consistent with those observed in cancer patients receiving chemotherapy and included general disorders, administration site conditions and gastrointestinal disorders. No thrombotic events occurred.

About Aranesp

In July 2002, Aranesp was approved by the U.S. Food and Drug Administration (FDA) for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies. 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)(1) and by Ortho Biotech Products, LP, as Procrit(R)(2). 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 (for example, where Epoetin alfa is administered three times a week, Aranesp should be administered weekly).

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.

The Aranesp dosage should be adjusted for each patient to achieve and maintain a target hemoglobin not to exceed 12 g/dL. Doses must be individualized to ensure that hemoglobin is maintained at an appropriate level for each patient.

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.

Forward Looking Statement

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, 2003, 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. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly or sometimes even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify side effects or manufacturing problems with our products after they are on the market. In addition, sales of our products are affected by the availability of reimbursement and the

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 US legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of our products.

In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, the discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Further, the scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (FDA) for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses. Only the FDA can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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

EDITOR'S NOTE: An electronic version of this news release may be accessed via our Web site at 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.

(1) Epogen(R) is a registered trademark of Amgen, Inc.

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

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