Aranesp(R) Phase 3 Study in Patients with Active Cancer Not Receiving Concurrent Chemotherapy or Radiotherapy Presented at AACR Annual Meeting

April 16, 2007

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--April 16, 2007--Amgen (Nasdaq:AMGN) today presented the results from a randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy and safety of Aranesp(R) (darbepoetin alfa) for the treatment of anemia in patients with active cancer not receiving chemotherapy or radiotherapy ("the 103 study"). Aranesp is not approved for use by the FDA or EMEA in these patients. These results were presented in an oral session at the 2007 American Association for Cancer Research (AACR) annual meeting in Los Angeles, Calif. (AACR Abstract #LB-3).

As reported in January, the study did not meet its primary endpoint of reducing red blood cell (RBC) transfusions in the Aranesp treatment group. Transfusion occurrences from weeks 5 to 17 favored Aranesp but were not statistically significant between the groups (hazard ratio: 0.85, p=0.32). Among those receiving Aranesp, there was a significantly higher proportion of patients with a hemoglobin response (p less than 0.0001), hemoglobin correction (p less than 0.001), and hematopoietic response (p=0.002) compared with placebo.

The adverse event rate was similar between the groups. However, the overall number of deaths was greater in the Aranesp group (48.5 percent versus 46 percent in placebo; hazard ratio: 1.29; p=0.006). In post-hoc analyses adjusting for stratification factors at randomization and sex, stage IV disease, prior chemotherapy use and prior radiotherapy use, there remained a significant difference in survival between the groups. However, hazard ratios and statistical significance diminished when the analyses were further adjusted for known prognostic factors including baseline ECOG status, tumor type, tumor stage, baseline FACT-F cutoff at median and baseline Hb (hazard ratio: 1.17, p=0.11).

"This study evaluated ESA treatment for patients with active cancer, not receiving chemotherapy or radiation, who are anemic due to the cancer itself. Unfortunately, the benefit of ESA treatment was not observed in these gravely ill patients," said John Glaspy, M.D., professor, David Geffen School of Medicine, University of California at Los Angeles. "Since this was not designed as a survival study and statistical significance diminished when the analyses were adjusted for known prognostic factors, there is no clear explanation for the increase of deaths in the Aranesp group."

About the Study

This Phase 3 study was designed to evaluate the efficacy and safety of Aranesp 6.75 mcg/kg administered every four weeks for the treatment of anemia in cancer patients not receiving chemotherapy or radiotherapy. The study was conducted in 21 countries, including sites in Western Europe, Central and Eastern Europe, Australia and North America. The majority of patients (60 percent) were from Central and Eastern Europe.

Patient eligibility included: greater than or equal to 18 years, nonmyeloid malignancy (with active disease), hemoglobin (Hb) less than or equal to 11 g/dL, and no chemotherapy or radiotherapy treatment within four weeks of screening or during the study. Patients (n=985) were randomized to Aranesp 6.75 mcg/kg or placebo every four weeks, with an end of study visit at week 19, and two years of follow up to evaluate survival. Patients were stratified by screening Hb (less than 10 g/dL or greater than or equal to 10 g/dL), geographic region (Europe versus rest of world), RBC transfusion in the prior 12 weeks, tumor type/treatment (specifically, diagnoses of chronic lymphocytic leukemia or low grade lymphoma, ongoing hormonal or antibody therapy versus all other eligible patients), and ECOG status (0-1, 2).

Demographics were broadly similar between the groups. The mean (SD) age was 64.1 (11.6) years; the most common cancers were non-small cell lung (18 percent), breast (13 percent), and prostate (11 percent); most patients had disease stage III or IV (82 percent) and an ECOG status of 0 or 1 (72 percent); and baseline Hb was 9.5 g/dL in each group.

However, there were more men in the Aranesp group (56 percent) compared to the placebo group (47 percent) and overall survival was worse for men than women (hazard ratio: 1.38 versus 0.99, respectively). More patients received prior chemotherapy in the Aranesp group (73 percent versus 66 percent in placebo). The mean (SD) number of days between prior chemotherapy and first study drug dose was 262 (572) days for the Aranesp group compared to 315 (660) for the placebo arm.

About Aranesp

Aranesp was approved by the U.S. Food and Drug Administration (FDA) in September 2001 for the treatment of anemia associated with chronic renal failure (CRF), also known as chronic kidney disease (CKD), for patients on dialysis and patients not on dialysis. In July 2002, the FDA approved weekly dosing of Aranesp for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies and in March 2006, the FDA approved every-three-week dosing in these patients.

Important Safety Information

Use the lowest dose of Aranesp that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion (see DOSAGE and ADMINISTRATION in the prescribing information).

Aranesp and other erythropoiesis-stimulating agents (ESAs) increased the risk for death and for serious cardiovascular events when administered to target a hemoglobin of greater than 12 g/dL (see WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events).

Cancer Patients: Use of ESAs

-- shortened the time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target a hemoglobin of greater than 12 g/dL;

-- shortened overall survival and increased deaths attributed to disease progression at 4 months in patients with metastatic breast cancer receiving chemotherapy when administered to target a hemoglobin of greater than 12 g/dL;

-- increased the risk of death when administered to target a hemoglobin of 12 g/dL in patients with active malignant disease receiving neither chemotherapy nor radiation therapy. ESAs are not indicated for this population.

(See WARNINGS: Increased Mortality and/or Tumor Progression in the prescribing information).

The Aranesp prescribing information, including important safety information and boxed warning, may be accessed at www.aranesp.com.

About Amgen

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

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, 2006, 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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify side effects or manufacturing problems with Amgen's products after they are on the market.

In addition, sales of Amgen's 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 U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. In addition, Amgen competes with other companies with respect to some of Amgen's marketed products as well as for the discovery and development of new products. Amgen believes that some of the newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen 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 Amgen routinely obtains patents for Amgen's products and technology, the protection offered by Amgen's patents and patent applications may be challenged, invalidated or circumvented by Amgen's competitors and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for Amgen's products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of Amgen's existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of Amgen's products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's 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 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.

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SOURCE: Amgen