Aranesp(R) ``145 Study'' Shows No Difference in Survival in Patients with Small-Cell Lung Cancer

April 19, 2007

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--April 19, 2007--Amgen (NASDAQ: AMGN) today announced the results of the "145 study", a randomized, double-blind, placebo-controlled, multicenter Phase 3 study of Aranesp(R) (darbepoetin alfa) in 600 previously untreated patients with extensive-stage small-cell lung cancer (SCLC) receiving platinum-containing chemotherapy. The study demonstrated no statistically significant difference in risk of death (overall survival Aranesp compared to placebo Hazard Ratio (HR): 0.93, 95% CI: 0.78 to 1.11) or investigator determined progression-free survival (HR: 1.02, 95% CI: 0.86 to 1.21).

The study demonstrated a significant change in hemoglobin concentration from baseline in favor of Aranesp (a co-primary endpoint). Aranesp-treated patients also experienced a significantly lower risk of blood transfusions (HR: 0.40, 95% CI: 0.29 to 0.55). The overall safety profile, including thromboembolic events, was consistent with that described in the U.S. label.

"The 145 study is a component of Amgen's ongoing pharmacovigilance program designed to evaluate the effect of Aranesp on long-term survival in patients with chemotherapy-induced anemia. This study had higher initiation and maintenance hemoglobin targets (Hb less than or equal to 13 g/dl) than in the U.S. label," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "These results contribute to the growing body of evidence on ESA safety, reinforcing the neutral impact of ESAs on survival in cancer patients suffering from chemotherapy-induced anemia."

Amgen initiated the SCLC study in 2002 after results from a previous Phase 3 study showed a trend towards improved survival in patients with lung cancer. The 145 study was designed to evaluate whether increasing or maintaining hemoglobin concentrations with Aranesp, when administered with platinum-containing chemotherapy in patients with previously untreated extensive-stage SCLC, increased survival.

In this study, patients were randomized 1:1 to receive Aranesp 300 mcg or placebo every week (QW) for the first 4 weeks, followed by once every three week (Q3W) dosing (commencing on week 5) for the remainder of the 24-week treatment period. Patients were treated to a target Hb of 13 g/dL, which is higher than indicated by the FDA-approved product label, with dose withholding at 14 g/dL.

Conference Call Information

Amgen will discuss the results of the 145 study during a conference call to review the Company's first quarter financial results with the investment community at 2:00 PM, Pacific Time, Monday, April 23, 2007. Live audio of the conference call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public. The conference call, including the question and answer session, is expected to last approximately one hour.

The webcast of the conference, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found on Amgen's Web site, www.amgen.com, under Investors. Information regarding presentation times, webcast availability, and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay 72 hours after the event.

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 anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy, and in March 2006, the FDA approved every-three-week dosing in these patients.

Important Safety Information including boxed WARNING

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.

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.

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 or radiation therapy. ESAs are not indicated for this population.

Patients receiving ESAs pre-operatively for reduction of allogeneic red blood cell transfusions: A higher incidence of deep venous thrombosis was documented in patients receiving Epoetin alfa who were not receiving prophylactic anticoagulation. Aranesp is not approved for this indication.

Aranesp is contraindicated in patients with uncontrolled hypertension. Aranesp and other erythropoietic therapies increase the risk of serious arterial and venous thromboembolic events, including myocardial infarction, stroke, congestive heart failure, and hemodialysis graft occlusion. A rate of

hemoglobin rise of greater than 1 g/dL over 2 weeks may also contribute to these risks. To reduce cardiovascular risks, the hemoglobin (Hb) concentration should not exceed 12 g/dL, the rate of hemoglobin increase should not exceed 1 g/dL in any 2-week period.

Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin have been reported in patients treated with Aranesp. This has been reported predominantly in patients with CRF receiving Aranesp by subcutaneous administration. A sudden loss of response to Aranesp, accompanied by severe anemia and low reticulocyte count, should be evaluated. If anti-erythropoietin antibody-associated anemia is suspected, withhold Aranesp and other erythropoietic proteins. Aranesp should be permanently discontinued in patients with antibody-mediated anemia. Patients should not be switched to other erythropoietic proteins as antibodies may cross-react.

The most commonly reported side effects in clinical trials in patients with CRF were infection, hypertension, hypotension, myalgia, headache, and diarrhea. The most commonly reported side effects in clinical trials in patients with chemotherapy-induced anemia were fatigue, edema, nausea, vomiting, diarrhea, fever and dyspnea.

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.

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SOURCE: Amgen