



Aranesp(R) Study Showing No Negative Impact on Survival in SCLC Presented at World Conference on Lung Cancer

September 6, 2007

Amgen Oncology Presents New Lung Cancer Data for AMG 706 in Combination with Chemotherapy and Vectibix(TM)

SEOUL, Korea--(BUSINESS WIRE)--Sept. 6, 2007--Amgen (NASDAQ:AMGN) presented the results from a randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy and safety of Aranesp(R) (darbepoetin alfa) in previously untreated patients with extensive-stage small-cell lung cancer (SCLC) receiving chemotherapy ("the 145 study") on Monday, Sept. 3 at the 2007 World Conference on Lung Cancer in Seoul, Korea. The study demonstrated no statistically significant difference in risk of death (overall survival Aranesp compared to placebo Hazard Ratio (HR): 0.93, 95 percent CI: 0.78 to 1.11) or investigator assessed progression-free survival (HR: 1.02, 95 percent CI: 0.86, 1.21). (WCLC Poster #PD6-3-6)

This study is a component of Amgen's ongoing pharmacovigilance program designed to evaluate the effect of Aranesp on long-term survival in anemic patients undergoing concomitant chemotherapy. The study was completed three months ahead of Amgen's post-marketing commitment, and the results were publicly announced and primary data were provided to the U.S. Food and Drug Administration (FDA) in April 2007. Additionally, Amgen presented the results at the FDA's Oncologic Drug Advisory Committee meeting in May 2007.

As reported in April, the "145 study" demonstrated that Aranesp maintained hemoglobin (Hb) levels at a higher level than placebo and significantly reduced red blood cell (RBC) transfusions relative to placebo. The estimated difference in Hb change between the two groups was 0.84 g/dL (95 percent CI: 0.53 g/dL, 1.15 g/dL). A total of 52 Aranesp patients (17 percent) had at least one red blood cell transfusion during the study treatment compared to 116 patients (39 percent) in the placebo group (HR: 0.40, 95 percent CI: 0.29, 0.55).

Overall, 493 of 596 patients died during the treatment period or long-term follow up through a pre-specified cut off date. In the Aranesp group, 242 patients (81 percent) died and 251 patients (84 percent) died in the placebo group. Median survival time to death was 40 weeks for both groups.

"These study results show no statistically significant difference in overall survival or investigator assessed progression-free survival when Aranesp is used in patients with extensive-stage small-cell lung cancer receiving chemotherapy," said Robert Pirker, M.D., Medical University of Vienna, Vienna, Austria. "This study is particularly important as it was conducted in a homogeneous population, receiving platinum-containing chemotherapy and the treatment arm received higher than usual doses of erythropoiesis stimulating agents (ESAs). It's important to note that this tumor type was one of the first to be reported as expressing a putative EPO receptor although subsequent rigorous studies have invalidated methodologies employed and there is at this time no conclusive evidence to indicate that the EPO receptor is in any way involved in the malignant process."

The adverse event rate was similar between the two groups. A total of 138 Aranesp patients (46 percent) and 121 patients in the placebo group (41 percent) experienced a serious adverse event. Cardiovascular and thromboembolic events occurred at a moderately higher rate in the Aranesp group (22 percent) than in the placebo group (15 percent), primarily due to embolisms/thromboses (9 percent Aranesp versus 5 percent placebo).

About the Aranesp Study

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 with a baseline Hb greater than or equal to 9 g/dL and less than or equal to 13 g/dL were randomized 1:1 to receive Aranesp 300 mcg or placebo every week (QW) for the first four 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.

Demographics and baseline disease characteristics were generally similar between the treatment groups. Most patients were men (63 percent Aranesp, 66 percent placebo), and all subjects were white. The mean (SD) age was 61 years and was similar between the groups, and similar percentages of patients in each group were greater than or equal to 65 years of age (36 percent Aranesp, 34 percent placebo). Most patients had an ECOG performance status of less than 2 (78 percent Aranesp, 79 percent placebo), and the median time since initial diagnosis was 15 days in both treatment groups. Mean (SD) Hb values at baseline were 12.03 g/dL (1.07 g/dL) in the Aranesp group and 11.86 g/dL (1.03) in the placebo group.

AMG 706 in Combination with Chemotherapy and/or Vectibix Results (WCLC Poster #PD3-3-7)

Additionally, Phase 1b data were presented on Wednesday, Sept. 5, on AMG 706 administered in combination with carboplatin/paclitaxel (C/P) and/or Vectibix(TM) (panitumumab) for the treatment of patients with advanced non-small cell lung cancer (NSCLC). Data suggest that treatment with 125 mg daily of AMG 706 is tolerable when combined with C/P and/or Vectibix, with little effect on the compound's pharmacokinetic activity, warranting further investigation. Forty-five patients were enrolled and received greater than or equal to 1 dose of AMG 706. There were three dose limiting toxicities across arms of the trial. Treatment-related adverse events (grades 3 or higher) included fatigue (22 percent), hypertension (22 percent), pulmonary embolism (13 percent) and diarrhea (4 percent).

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) 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 Aranesp Safety Information

Use the lowest dose of Aranesp(R) 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.

About AMG 706

AMG 706 is an investigational, highly selective, oral agent that is being evaluated for its ability to inhibit angiogenesis by targeting vascular endothelial growth factor receptors 1, 2 and 3 (VEGFR1-3). It is also under investigation for its potential direct anti-tumor activity by targeting platelet-derived growth factor receptor (PDGFR), and stem cell receptor (c-kit) signaling, which may also confer direct anti-tumor activity. AMG 706 has been studied in Phase 2 studies for both gastrointestinal stromal tumors and thyroid cancer. Currently, there are trials enrolling patients in non-small cell lung and breast cancer as well as in other solid tumors.

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.

CONTACT: Amgen, Thousand Oaks
Ashleigh Koss, 805-313-6151 (media)
Arvind Sood, 805-447-1060 (investors)

SOURCE: Amgen