New Phase 3 Data Show Potential Benefits of Aranesp(R) Dosed Every Three Weeks for Chemotherapy-Induced Anemia; Aranesp Treatment Achieved and Maintained Target Hemoglobin Levels and Reduced Incidence of Red Blood Cell Transfusions

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ATLANTA--(BUSINESS WIRE)--Dec. 12, 2005--Amgen (NASDAQ: AMGN), the world's largest biotechnology company, today announced results from the first multi-center, randomized, double-blind, placebo-controlled, Phase 3 trial of Aranesp(R) (darbepoetin alfa) administered every three weeks in cancer patients with chemotherapy-induced anemia. The study revealed that Aranesp increased and maintained patient hemoglobin levels to the target level of greater than or equal to 11 grams per deciliter (g/dL) and reduced the need for red blood cell transfusions by almost half compared to placebo. The data were presented at the American Society of Hematology (ASH) 47th Annual Meeting and Exposition. (Abstract #3556)

"These results on every-three-week dosing of Aranesp are encouraging," said Kerry Taylor, MD, Mater Hospital, South Brisbane, Queensland, Australia. "If approved, this extended dosing of Aranesp may allow physicians to treat anemia on the same schedule as chemotherapy, which is frequently administered every three weeks. This may reduce the number of visits patients and their caregivers need to make to the clinic."

Researchers reported results for 386 patients (n=193 per arm) treated for up to 16 weeks and found that 77 percent of patients achieved target hemoglobin levels in the Aranesp-treated group versus 55 percent in the placebo group. Additionally, from week five to the end of treatment phase, the incidence of red blood cell transfusions was significantly lower for the Aranesp-treated group (24 percent) than for the placebo group (41 percent).

The number and type of adverse events were consistent with the adverse event profile for this population of anemic cancer chemotherapy patients receiving Aranesp. Cardiovascular and thromboembolic adverse events were reported in few patients in either treatment group, and were not associated with increases in hemoglobin levels.

In May 2005, Amgen announced the submission of a supplemental biologics license application to the U.S. Food and Drug Administration (FDA) for every-three-week dosing of Aranesp for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies.

About the Phase 3 Study

This multi-center, randomized, double-blind, placebo-controlled, Phase 3 trial assessed the efficacy and safety of a fixed dose of 300 mcg of Aranesp administered every three weeks to patients with chemotherapy-induced anemia. Eligible patients had been diagnosed with anemia (hemoglobin levels less than 11g/dL) and non-myeloid malignancy with at least 12 weeks of planned chemotherapy. Patients enrolled in the study had mean hemoglobin concentrations at baseline of approximately 10 g/dL in both the Aranesp and placebo groups.

About Chemotherapy-Induced Anemia

Chemotherapy can reduce the bone marrow's ability to produce red blood cells that transport oxygen from the lungs to all of the body's muscles and organs. Anemia occurs when there are too few red blood cells and the body's tissues are "starved" of oxygen, which can make a patient feel short of breath, very weak, faint and tired.

This year, an estimated 1.3 million cancer patients will undergo chemotherapy in the United States; approximately 800,000 (67 percent) will become anemic. More than half of these patients report that fatigue associated with anemia affects their daily lives more than any other side effect of treatment, including nausea, pain and depression.

Although anemia is a common and often debilitating side effect of chemotherapy, it is often not recognized and frequently under-treated. In fact, approximately half of patients with a hemoglobin level less than the recommended target level of 11 to 12 g/dL in the National Comprehensive Cancer Network(R) (NCCN) guidelines for "Cancer and Treatment-Related Anemia" are never treated with erythropoietic therapy.

About Aranesp(R) (darbepoetin alfa)

Aranesp is a recombinant erythropoietic protein (a protein that stimulates production of red blood cells, which carry oxygen). Amgen revolutionized anemia treatment with the development of recombinant erythropoietin, Epoetin alfa. Building on this heritage, Amgen developed Aranesp, a unique erythropoiesis stimulating protein, which contains two additional sialic acid-containing carbohydrate chains compared to the Epoetin alfa molecule and remains in the bloodstream longer than Epoetin alfa because it has a longer half-life.

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, also known as chronic kidney disease (CKD), for patients on dialysis and patients not on dialysis. In July 2002, Aranesp was approved by the FDA for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies.

Important Safety Information

Aranesp is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic events and other serious events. The target hemoglobin (Hb) should not exceed 12 g/dL. If the Hb increase exceeds 1.0 g/dL in any 2-week period, dose reductions are recommended. In a study with another erythropoietic product, where the target Hb was 12 to 14 g/dL, an increased incidence of thrombotic events, disease progression, and mortality was seen.

Pure red cell aplasia (PRCA) has been observed in patients treated with recombinant erythropoietins. This has been reported predominantly in patients with chronic renal failure. Aranesp should be discontinued in any patient with evidence of PRCA and the patient evaluated for the presence of antibodies to erythropoietin products. The most commonly reported side effects in clinical trials were fatigue, edema, nausea, vomiting, diarrhea, fever, and dyspnea.

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 broad and deep 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, 2004, 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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