New Phase 2 Data Show Promise of Aranesp(R) Treatment for Anemia of Cancer

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Monthly Aranesp Treatment Improved Hematopoietic Response In Cancer Patients Not Receiving Chemotherapy or Radiation Therapy

ORLANDO, Fla.--(BUSINESS WIRE)--Dec. 9, 2006--Amgen (NASDAQ:AMGN) today announced final results of a 17-week randomized, double-blind, placebo-controlled, Phase 2 study evaluating Aranesp(R) (darbepoetin alfa) administered every four weeks for the treatment of anemia in cancer patients not undergoing chemotherapy and/or myelosuppressive radiotherapy, a condition known as anemia of cancer. Patients receiving Aranesp were nearly three times more likely to achieve a hematopoietic response than patients receiving a placebo (69 percent vs. 24 percent, respectively). These results were presented at the American Society of Hematology (ASH) 48th annual meeting in Orlando, Fla. (Abstract # 1304)

Although anemia is increasingly recognized as the most common side effect of chemotherapy, a growing body of evidence demonstrates that as many as 475,000 cancer patients also can become vulnerable to anemia due to the cancer itself. To combat anemia symptoms, anemia of cancer patients often receive a blood transfusion, which can be a tiring and invasive procedure. Despite its prevalence, anemia of cancer in patients is under-recognized and often not treated.

"Patients with cancer who are not receiving chemotherapy or myelosuppressive radiotherapy may have infrequent clinic visits," said David H. Gordon, M.D., clinical professor, University of Texas Health Science, and the study's lead investigator. "This study evaluated the effectiveness of extended dosing and the results suggest that this may be a potential treatment option for such patients."

Researchers reported results for 218 patients treated with Aranesp (n=162) or placebo (n=56) for up to 17 weeks. The study's primary endpoint was the percentage of patients with a hematopoietic response (greater than or equal to 2g/dL hemoglobin rise from baseline or achievement of hemoglobin greater than or equal to 12g/dL without a red blood cell transfusion during the preceding 28 days). Sixty-nine percent of Aranesp-treated patients had a hematopoietic response versus 24 percent in the placebo group (p less than 0.0001). In addition, 85 percent of the patients in the Aranesp group reached the target hemoglobin of greater than or equal to 11g/dL compared to 50 percent of the placebo group (p less than 0.001). Additionally, patients with hemoglobin levels less than 10 g/dL and who were treated with Aranesp received fewer red blood cell transfusions versus those patients with hemoglobin levels less than 10g/dL in the placebo group (15 percent vs. 29 percent, respectively).

The number and type of adverse events were consistent with those previously observed in patients receiving Aranesp. Four patients (2 percent) in the Aranesp arm experienced serious thromboembolic events.

About the Phase 2 Study

This randomized, double-blind, placebo-controlled, Phase 2 study assessed the efficacy of Aranesp administered every four weeks to anemia of cancer patients not undergoing chemotherapy and/or myelosuppressive radiotherapy within 30 days of screening or during the study. Eligible patients had been diagnosed with anemia of cancer (hemoglobin levels less than 11g/dL) and non-myeloid malignancy. The primary tumor types of the patients included in the study were breast, hematologic, and prostate. Patients were randomized 3:1 to Aranesp (6.75 mcg/kg) or placebo.

About Anemia of Cancer

Anemia is a serious and under-treated condition characterized by a reduction in the normal volume of red blood cells in the blood. Major symptoms of anemia include: extreme fatigue, weakness, shortness of breath, confusion, dizziness, rapid heartbeat, extreme skin pallor, difficulty staying warm and depression. Currently, there are no U.S. Food and Drug Administration (FDA)-approved treatments for chronic anemia of cancer, which is caused by the cancer itself and is unrelated to chemotherapy.

About Aranesp

Amgen revolutionized anemia treatment with the development of Epoetin alfa, a recombinant erythropoietin (a protein that stimulates the production of oxygen-carrying red blood cells). Building on this heritage, Amgen developed Aranesp, a unique erythropoiesis-stimulating protein that can be dosed less frequently.

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. With the addition of the every-three-week dosing, Aranesp, the only erythropoiesis-stimulating protein approved by the FDA for every-three-week administration, can allow physicians to synchronize anemia treatment with weekly and every-three-week chemotherapy, which are the majority of chemotherapy schedules. Since its introduction in 2001, more than 1.7 million CKD and chemotherapy patients with anemia have received treatment with Aranesp.

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 - 14 g/dL, an increased incidence of thrombotic events, disease progression, and mortality was seen.

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 predominately 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.

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 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, 2005, 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.

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.

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