Updated Interim Aranesp(R) Phase 2 Data Suggest Major Response in Anemic Patients with Myelodysplastic Syndrome (MDS); Patients with Bone Marrow Disorder Also Showed Improvements in Hemoglobin Levels and Fatigue

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ATLANTA, Dec 11, 2005 (BUSINESS WIRE) -- Amgen (NASDAQ:AMGN), the world's largest biotechnology company, today announced updated interim data from a Phase 2 study evaluating the use of 500 mcg of Aranesp(R) (darbepoetin alfa) administered every three weeks to treat anemia in patients with a bone marrow disorder known as myelodysplastic syndrome (MDS). Low-risk MDS patients receiving Aranesp every three weeks, who had no prior erythropoietic therapy, exhibited an overall response of 70 percent, increased hemoglobin levels and improvements in patient-reported fatigue. The data were presented at the American Society of Hematology (ASH) 47th Annual Meeting in Atlanta. (Abstract #2541)

"During the course of their disease, the majority of MDS patients develop clinically significant anemia, which can lead to fatigue and the need for red blood cell transfusions," said Janice Gabrilove, MD, professor of medicine, hematology and medical oncology at Mount Sinai School of Medicine, New York and the study's lead investigator. "Currently, there are no recombinant erythropoietic products approved for the treatment of anemia in MDS patients. These results are encouraging."

Results for the 13-week test period were presented for 189 of 209 patients enrolled and included erythroid response, achievement of target hemoglobin, incidence of transfusion and patient reported fatigue. Sixty-nine percent of these patients (n=130) had no prior erythropoietic agent use.

In the group that had no previous treatment with an erythropoietic agent, 70 percent of patients had an erythroid response, with 49 percent classified as major response (defined as greater than or equal to 2 grams per deciliter (g/dL) increase from baseline hemoglobin or transfusion independence). Sixty-seven percent of patients achieved the target hemoglobin level of 11 g/dL. Nineteen percent in the erythropoietin-naive group had at least one transfusion during the 13-week observation period.

In the group previously treated with an erythropoietic agent (n= 59), 44 percent experienced an erythroid response, with 24 percent classified as major. Forty-five percent of patients achieved the target hemoglobin level of 11 g/dL, and 29 percent had at least one transfusion.

During the 13-week test period, 78 percent of patients experienced at least one adverse event. Seventeen percent (n=33) of patients experienced a serious adverse event, with fatigue, asthenia, and diarrhea as the most common. Six percent (n=12) had treatment-related adverse events, with injection-site pain and diarrhea the most common (n=2 for each). No thrombotic events have been reported to date in this study.

About the Phase 2 Study

This Phase 2, single-arm study of approximately 200 low-risk MDS patients (those with a low risk of progressing to acute myeloid leukemia) was designed to assess treatment of anemia in this patient population with Aranesp 500 mcg administered every three weeks. The primary endpoint of the study was the proportion of patients achieving an erythroid response (defined in accordance with the International Working Group Response Criteria) during the 13-week test period. Secondary endpoints included changes in hemoglobin level from baseline, incidence of transfusions and impact on patient reported fatigue.

About MDS

Myelodysplastic Syndrome (MDS), also known as pre-leukemia or "smoldering" leukemia, encompasses a group of disorders in which the bone marrow does not produce enough blood cells. MDS is associated with abnormal blood counts or poorly functioning blood cells and often results in anemia (low red blood cell count), neutropenia (low white blood cell count) and thrombocytopenia (low blood platelet count). Approximately 21,000 new cases of MDS are diagnosed each year in the United States. MDS is more prevalent in men and Caucasians, and primarily occurs in people older than 60.

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. In May 2005, Amgen announced the submission of a biologics license supplement to the FDA for every- three-week dosing in the treatment of chemotherapy-induced anemia.

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.

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.

SOURCE: Amgen

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