Interim Data Suggest Major Response with Aranesp(R) in Anemic Patients with Myelodysplastic Syndromes (MDS)

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THOUSAND OAKS, Calif., Jul 06, 2005 (BUSINESS WIRE) -- Amgen Inc. (NASDAQ:AMGN), the world's largest biotechnology company, today announced new interim data from a Phase 2 study evaluating the use of 500 mcg of Aranesp(R) (darbepoetin alfa) every three weeks to treat anemia in patients with a bone marrow disorder known as myelodysplastic syndromes (MDS). The data were presented at the 17th International Symposium of the Multinational Association of Supportive Care in Cancer (MASCC) in Geneva. (Abstract #02-007)

"The majority of MDS patients develop clinically significant anemia during the course of their disease, which often leads to fatigue and increased red blood cell transfusions," said Janice Gabrilove, M.D., professor of medicine, hematology and medical oncology at Mount Sinai School of Medicine, New York and the study's lead investigator. "In this study, low risk MDS patients receiving Aranesp every three weeks, who had no prior erythropoietic therapy, exhibited an overall response of 77 percent, increased hemoglobin levels and improvements in patient reported fatigue."

Results of an interim analysis were presented from the first 100 patients of an approximately 200 patient, Phase 2, single arm study of low risk MDS patients (those with a low risk of progressing to acute myeloid leukemia) with anemia and treated with Aranesp 500 mcg administered every three weeks. Of the 100 patients evaluated, 63 percent had no prior erythropoietic agent use. 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.

Results were presented for all 100 patients for incidence of transfusion and patient reported fatigue and 90 patients were evaluated for erythroid response and target hemoglobin. In the group who had no previous treatment with an erythropoietin (n=57), 77 percent of patients had an erythroid response with 47 percent classified as major (greater than or equal to 2 g/dL increase from baseline hemoglobin or transfusion independence). In the previously erythropoietin treated group (n=33), 36 percent experienced an erythroid response with 21 percent classified as major. Two-thirds of patients achieved hemoglobin levels above 11 g/dL, the target range for patients with chemotherapy-induced anemia. Eighteen percent in the erythropoietin-naive group had a least one transfusion during the 13-week observation period.

"In these interim results MDS patients who have never been treated for their anemia responded to Aranesp and those who had prior erythropoietic therapy continued to respond," added Gabrilove. "There are currently no recombinant erythropoietic products approved by the FDA for the treatment of anemia in MDS patients. These interim data are encouraging and we look forward to the final results."

During the 13-week test period, 74 percent of patients experienced at least one adverse event. Sixteen percent (n=16) of patients experienced a serious adverse event, with anemia, neutropenia and chest pain as the most common. Five percent (n=5) had treatment-related adverse events, with injection-site pain as the most common. No thrombotic events have been reported to date in this study.

About MDS

Myelodysplastic Syndromes (MDS), also known as pre-leukemia or "smoldering" leukemia, encompass a group of disorders in which the bone marrow does not produce enough blood cells. MDS causes 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

Aranesp is a recombinant erythropoietic protein (a protein that stimulates production of oxygen-carrying red blood cells). 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 than 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.

Aranesp was initially granted marketing authorization by the European Medicines Agency (EMEA) in 2001 for the treatment of anemia associated with chronic renal failure in adults and pediatric subjects 11 years of age or older. In 2002, the EMEA approved Aranesp for the treatment of anemia in adult cancer patients receiving chemotherapy with solid tumors. This patient population was subsequently expanded in 2003 to include all adult cancer patients with non-myeloid malignancies receiving chemotherapy. In 2004, Aranesp was approved by the EMEA for every-three-week dosing in patients with chemotherapy-induced anemia and up to once-per-month dosing in the treatment of anemia in chronic kidney disease patients not on dialysis.

Important Safety Information

Aranesp is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic and other serious events. Seizures have occurred in patients with chronic renal failure participating in clinical trials. Regional guidelines should be referred to for target and maximum hemoglobin levels, and dose adjustment rules should be performed in line with regional prescribing information. In a study of Epoetin alfa-treated hemodialysis patients with clinically evident cardiac disease, where the target Hct was 42% (Hb =14 g/dL), an increased incidence of thrombotic events and mortality was seen. The reason for increased mortality observed in this study is unknown. In an oncology 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 Aranesp trials for chronic renal insufficiency were infection, hypertension, hypotension, myalgia, headache, and diarrhea. The most commonly reported side effects in Aranesp trials for chemotherapy-induced anemia were fatigue, edema, nausea, vomiting, diarrhea, fever, and dyspnea.

About Amgen

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

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 we project. 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 us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. We develop 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 we may have believed at the time of entering into such relationship. Also, we or others could identify side effects or manufacturing problems with our products after they are on the market. In addition, sales of our 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 our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our 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 we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, the discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our 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 Inc.

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