Interim Phase 2 Aranesp(R) Data Suggest Major Response after 27/28 Weeks of Treatment for Anemia in Patients with Myelodysplastic Syndromes (MDS)

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Results of One of the Largest MDS Studies to Date Show Both Previously Treated and ESA-Naive Patients Responded to Aranesp Treatment

ATLANTA, Jun 03, 2006 (BUSINESS WIRE) -- Amgen (NASDAQ:AMGN), the world's largest biotechnology company, today announced that after 27/28 weeks of treatment with Aranesp(R) (darbepoetin alfa) administered every three weeks, patients with low-risk myelodysplastic syndromes who had not previously received an erythropoiesis-stimulating agent (ESA) showed a major response of 59 percent, increased hemoglobin levels and improvements in patient-reported fatigue. These updated interim data were presented at the 42nd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Atlanta. (Abstract #6564)

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 are associated with abnormal blood counts or poorly functioning blood cells and often result 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 are more prevalent in men and Caucasians and primarily occur in people older than 60.

"These results, from one of the largest MDS studies to date, are consistent with those observed at 13 weeks and provide evidence for the potential use of every-three-week dosing of Aranesp in MDS patients to reach target hemoglobin, reduce the need for blood transfusions and improve patient reported outcomes," 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.

Interim (27/28-week) results from the fully enrolled study were presented for 206 of 209 low- or intermediate-risk MDS patients with anemia (Hb less than or equal to 11 g/dL) and included erythroid response, achievement of target hemoglobin, incidence of transfusion, and patient reported fatigue. Sixty-nine percent of these patients (n=142) had not previously received an ESA.

In the group that had not previously received an ESA, 74 percent of patients had an erythroid response, with 59 percent classified as major response (greater than or equal to 2 g/dL increase in hemoglobin from baseline or transfusion independence). In addition, 74 percent of patients achieved the target hemoglobin level of 11 g/dL and no patients required a transfusion during the 27/28-week observation period.

In the group previously treated with an ESA (n=64), 50 percent experienced an erythroid response, with 30 percent classified as major. Additionally, 49 percent of patients achieved the target hemoglobin level of 11 g/dL and five percent received at least one transfusion during the 27/28-week observation period.

During the 27/28-week test period, treatment-related adverse events were reported in nine percent of patients in the group not previously treated with an ESA and in six percent of patients in the group previously treated with an ESA. Three thromboembolic events have been reported to date in this study. No pulmonary emboli have been reported.

Exploratory Analysis of Baseline Predictors of Response

Additional results of an exploratory analysis following 27/28 weeks of treatment suggest that patients not previously treated with an ESA, and baseline endogenous erythropoietin (eEPO) levels and distinct FAB (French-American-British cooperative group criteria) tissue subtypes may help predict which patients will respond to treatment with an ESA. (Abstract #6579)

"This exploratory analysis suggests that patients with lower baseline endogenous erythropoietin levels and those with refractory anemia may be more likely to achieve a major response with Aranesp treatment," said Dr. Gabrilove.

About the Phase 2 Study

This ongoing, Phase 2, single-arm, open-label, 52-week study of 209 low-risk MDS patients (those with a low risk of progressing to acute myeloid leukemia) was designed to evaluate 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) by week 13. Secondary endpoints included proportion of patients achieving an erythroid response by 27/28 weeks, changes in hemoglobin level from baseline, incidence of transfusions and impact on patient reported fatigue.

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 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, 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.

SOURCE: Amgen

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