New Phase 2 Data Suggest Treatment of Anemia with Aranesp(R) (Darbepoetin Alfa) May Provide Clinical Benefits in Heart Failure Patients

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ATLANTA--(BUSINESS WIRE)--March 13, 2006-- Amgen's Phase 3 RED-HF(TM) Trial Will Evaluate the Clinical Effect of Treating Anemia in Patients with Symptomatic Heart Failure

Amgen (Nasdaq:AMGN), the world's largest biotechnology company, announced results from a Phase 2 study that showed that treating anemia with Aranesp(R) (darbepoetin alfa) in patients with symptomatic heart failure was well-tolerated, effectively raised hemoglobin and improved patients' symptoms as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ). The results were presented today at the 2006 American College of Cardiology (ACC) Scientific Session.

"There is increasing evidence of a link between anemia and heart failure, and of the potential that treating anemia in heart failure patients may be beneficial over time," said Dirk J. van Veldhuisen, M.D., Ph.D., FESC, FACC, Department of Cardiology/Thoracic Surgery, University Medical Center, Groningen, Netherlands. "These data are encouraging and support the need for a large-scale, definitive trial to determine the effect of treating anemia in heart failure patients."

Based on the evaluation of the results of the Phase 2 program and observational studies, Amgen has initiated the Phase 3 RED-HF(TM) (Reduction of Events with Darbepoetin alfa in Heart Failure) Trial, a randomized, double-blind, placebo-controlled, multicenter, multinational trial that will evaluate the effect of treatment of anemia with Aranesp on morbidity and mortality in patients with symptomatic heart failure.

"Despite medical advances, heart failure and its complications are a leading cause of death and hospitalization worldwide, and there remains a significant unmet medical need for effective treatments for these patients," said Willard Dere, M.D., senior vice president for Global Development and chief medical officer at Amgen. "Amgen is committed to investigating Aranesp's potential to help heart failure patients who also suffer from anemia through the RED-HF Trial."

About the Phase 2 Study

This 26-week study enrolled 165 patients with symptomatic heart failure (New York Heart Association (NYHA) II-IV; HF duration greater than or equal to 3 months), left ventricular ejection fraction (LVEF) less than or equal to 40 percent and hemoglobin (Hb) levels of 9.0 to 12.5 g/dL. Patients were randomized to receive Aranesp subcutaneously every two weeks at starting doses of 0.75 mcg/kg (n=56) or 50 mcg (fixed dose; n=54) or placebo (n=55) to achieve and maintain a target Hb of 14.0 +/- 1.0 g/dL. The primary endpoint was the rate of Hb rise per week during the titration period. Other endpoints included change from baseline to month six in six-minute walk distance, Patient's Global Assessment (PGA), Minnesota Living With Heart Failure Questionnaire (MLHFQ), KCCQ and safety.

Investigators concluded that in patients with symptomatic heart failure and anemia, treatment with Aranesp effectively raised Hb levels, significantly improved KCCQ total symptom score (Aranesp 8.2 vs. placebo 1.5; p = 0.027) and had a similar adverse event profile as previously seen in clinical trials with Aranesp. Statistically nonsignificant improvements in PGA (Aranesp 65 percent vs. placebo 49 percent; p = 0.057), MLHFQ total score (Aranesp -10.1 vs. placebo -7.4; p = 0.413) and 6-minute walk distance (Aranesp 34.2 m vs. placebo 11.4 m; p = 0.074) were observed. Fixed dosing was as effective as weight-based dosing in raising Hb levels (difference: 0.05 g/dL/wk; 95 percent CI 0.01, 0.09), and no change was observed in NYHA class (Aranesp -0.30 vs. placebo -0.23; p = 0.473). The number of adverse events was similar across treatment groups.

Amgen Cardiovascular Clinical Trials Program

Amgen has initiated an extensive clinical trials program to study the effect of treating anemia or chronic kidney disease (CKD) complications on cardiovascular outcomes in different patient populations. In addition to the RED-HF Trial, Amgen initiated TREAT (Trial to Reduce Cardiovascular Events with Aranesp Therapy), an ongoing trial in diabetic patients with chronic kidney disease and anemia not requiring dialysis and will initiate a trial that will study the effect of treating the CKD complication, secondary hyperparathyroidism, with Sensipar(R)/Mimpara(R) (cinacalcet HCl) in end stage renal disease (ESRD) patients on dialysis on cardiovascular outcomes.

Anemia and Heart Failure

Heart failure and its complications are a leading cause of death and hospitalization worldwide, affecting over 23 million people worldwide and five million people in the U.S. Heart failure alone is the leading cause of hospitalization for people over the age of 65 years and causes almost one million hospitalizations every year. Approximately 20 to 30 percent of people diagnosed with heart failure also suffer from anemia, resulting in increased risk of morbidity and mortality versus patients who suffer from heart failure without anemia. Despite current, approved therapies to treat heart failure, a significant unmet medical need to treat the disease and its complications still exists.

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 the treatment of anemia 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 indicated for the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.

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 chronic renal failure (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, Aranesp and other erythropoietic proteins should be withheld. 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 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 it 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.

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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