



Final Results of Phase 2 Clinical Trial Program Suggest Treatment of Anemia with Aranesp(R) (Darbepoetin Alfa) May Decrease Risk of Hospitalization and All-Cause Mortality in Heart Failure Patients with Anemia, Based on a Prespecified Pooled Analysis

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Results Validate Amgen's Phase 3 RED-HF(TM) Trial to Address Unmet Medical Need

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--June 19, 2006-- Amgen (Nasdaq:AMGN), the world's largest biotechnology company, announced results at the 2006 European Society of Cardiology-Heart Failure (ESC-HF) Congress from a Phase 2 study showing that, in patients with symptomatic heart failure and anemia, Aranesp(R) (darbepoetin alfa) was well tolerated and effectively raised hemoglobin (Hb) (Abstract # 60734). Amgen also announced results from a prespecified pooled analysis including these data and data from a second Phase 2 study presented in March 2006 at the American College of Cardiology (ACC) Scientific Session showing that treatment with Aranesp may decrease the risk of heart failure hospitalization and all-cause mortality, and improve symptoms (Abstract #60731). These results require confirmation from a large Phase 3 randomized controlled clinical trial.

"These results are especially encouraging because, currently, there are no approved treatments to address the debilitating effects of anemia associated with symptomatic heart failure," said Dirk J. van Veldhuisen, M.D., Department of Cardiology/Thoracic Surgery, University Medical Center, Groningen, Netherlands. "The final results of the Phase 2 program validate the importance of Amgen's recently launched large-scale Phase 3 RED-HF(TM) Trial or Reduction of Events with Darbepoetin alfa in Heart Failure Trial, which will evaluate the effect of treatment of anemia with Aranesp on morbidity and mortality in patients with symptomatic heart failure."

Heart failure affects more than 23 million people worldwide and over 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. Even though there are current, approved therapies to treat heart failure, a significant unmet medical need to treat the disease and its complications still exists.

"Despite medical advances, heart failure and its complications are a leading cause of death and hospitalization worldwide," said Willard Dere, M.D., senior vice president for Global Development and chief medical officer at Amgen. "Amgen is committed to investigating the potential that Aranesp may provide heart failure patients, who also suffer from anemia, a new treatment option through the RED-HF(TM) Trial."

About the Phase 2 Data Presented at ESC

This one-year study enrolled 319 patients with symptomatic heart failure (NYHA II-IV), left ventricular ejection fraction (LVEF) of less than or equal to 40 percent and Hb levels of 9.0 to 12.5 g/dL who were randomized to receive placebo (n=157) or Aranesp (n=162). Endpoints were change in exercise time (ET); NYHA class; Minnesota Living with Heart Failure Questionnaire (MLHFQ) score at 6 months; heart failure hospitalization and mortality at one year and safety.

Results showed that baseline characteristics of treatment groups were similar. In patients with symptomatic heart failure and anemia, treatment with Aranesp effectively raised Hb (mean (SE) 1.80 (0.10) Aranesp versus 0.45 (0.10) placebo) and showed trends suggestive of a benefit in exercise duration (adjusted mean 57.3 seconds Aranesp versus 46.5 seconds placebo) and clinical outcomes (NYHA adjusted mean -0.19 Aranesp versus -0.13 placebo; MLHFQ mean -9.3 Aranesp versus -7.1 placebo). The hazard ratio (95 percent CI) for first HF hospitalization or mortality was 0.68 (0.43, 1.08; p=0.10).

The study showed that the treatment with Aranesp was well tolerated; eight percent of patients (n=13) experienced hypertension versus six percent (n=10) in placebo, 23 percent of patients' heart failure was exacerbated (n=38) versus 29 percent (n=45) in placebo, two percent of patients (n=4) had a myocardial infarction versus three percent (n=5) placebo and no patients (n=0) in the Aranesp arm experienced deep vein thrombosis while one percent (n=2) did in the placebo arm.

About the Pooled Analysis Presented at ESC

The pooled analysis based on the two largest multicenter randomized control trials (RCTs) evaluating the safety and efficacy of Aranesp treatment in 475 patients with symptomatic heart failure and anemia, LVEF less than or equal to 40 percent and Hb levels of 9.0 to 12.5 g/dL. Patients were randomized to placebo (n=209) or Aranesp (n=266) subcutaneously every two weeks for up to one year. The endpoints were change from baseline in NYHA class; Patient's Global Assessment (PGA); MLHFQ scores at six months (individual studies); and the composite of all-cause mortality or first HF-related hospitalization, HF-related hospitalization, all-cause mortality and safety at one year.

The pooled analyses suggested that treatment with Aranesp may improve symptoms and may decrease the risk of the composite of all-cause mortality or first heart failure-related hospitalization (hazard ratio 0.67 (0.44, 1.03) p= 0.064), of heart-failure related hospitalization (hazard ratio 0.66 (0.40, 1.07) p= 0.091) and of all-cause mortality (hazard ratio 0.76 (0.39, 1.48) p= 0.418).

Adverse events were similar in both treatment groups (Aranesp versus placebo): hypertension (6 percent n=15 versus 6 percent n=12), deep vein thrombosis (zero percent n=0 versus one percent n=2), worsening heart failure (19 percent n=50 versus 25 percent n=53) and myocardial infarction (two percent n=6 versus two percent n=5).

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.

Aranesp was granted marketing authorization by the European Commission in 2001 for the treatment of anemia associated with chronic renal failure in adults and pediatric subjects 11 years of age or older. Approval was granted in 2004 for an extended dosing of up to once monthly for the treatment of anemia in CKD patients not on dialysis. In 2006 the Aranesp label was updated to allow CKD patients on dialysis to switch from EPO two to three times a week to Aranesp every two weeks.

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 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, 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 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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