Amgen Announces Initiation of Phase 3 Trial to Evaluate the Impact of Treating Anemia with Darbepoetin Alfa in Patients with Heart Failure to Reduce Mortality and Hospitalization

September 2, 2005

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Sept. 2, 2005--Amgen (Nasdaq:AMGN), the world's largest biotechnology company, today announced that it will initiate a Phase 3 randomized, placebo-controlled, double-blind, multicenter, multi-national trial to evaluate the effect of anemia treatment with darbepoetin alfa on morbidity and mortality in patients with heart failure.

"Numerous epidemiological studies have consistently demonstrated that lower hemoglobin values, reflecting a condition known as anemia, are associated with increased hospitalizations and mortality in heart failure patients," said James Young, M.D., chairman of the Division of Medicine at The Cleveland Clinic Foundation, Cleveland, OH, and co-chair of the Executive Committee for this trial. "These studies have generated a very strong hypothesis that if you raise hemoglobin values with darbepoetin alfa, you can improve outcomes in this patient population. This landmark trial will test this important hypothesis."

The Executive Committee for this Phase 3 trial will be co-chaired by Karl Swedberg, professor of Medicine at Sahlgrenska University Hospital/Ostra-Goteborg University in Sweden.

"Amgen's decision to proceed with its Phase 3 trial in heart failure is driven both by results from epidemiological studies, as well as by our recently completed Phase 2 pilot studies of anemia treatment in heart failure patients which provided us with encouraging results," said Willard Dere, M.D., senior vice president for Global Development and chief medical officer at Amgen. "We are excited at the potential for darbepoetin alfa to help heart failure patients, especially given the grievous nature of this illness. Despite the use of various currently available treatment options, the morbidity and mortality associated with heart failure remains high, and we hope that darbepoetin alfa will help address this important unmet medical need."

According to the American Heart Association, approximately five million Americans and over four million Europeans suffer from heart failure. Over twenty three million suffer from heart failure worldwide.(1) Heart failure is the leading cause of hospitalization for people over the age of 65 years and causes almost one million hospitalizations each year.(2) This condition results in decreased oxygen delivery to the body due to a poorly functioning heart. Anemia reduces the oxygen content of the blood. When both heart failure and anemia occur together, oxygen delivery is further hampered, leading to a worsened condition for the patient. Although anemia is a common condition in heart failure patients, physicians caring for them have typically overlooked anemia in the absence of definitive studies suggesting that it should be treated.

Results from Amgen's Phase 2 pilot studies of anemia in heart failure patients will be released in early 2006. More information about Amgen's Phase 3 trial in heart failure is available at www.amgentrials.com.

About Aranesp(R) (darbepoetin alfa)

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 a recombinant erythropoietin, epoetin alfa, which is currently marketed in the U.S. by Amgen as EPOGEN(R) (Epoetin alfa)(3) and by Ortho Biotech Products, LP, as Procrit(R) (Epoetin alfa)(4). Building on this heritage, Amgen developed Aranesp, which contains two additional sialic acid-containing carbohydrate chains than the Epoetin alfa molecule, resulting in more activity, with the added benefit of less-frequent administration.

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 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 nonmyeloid malignancies.

Aranesp is contraindicated in patients with uncontrolled hypertension and patients with known hypersensitivity to the active substance or any of the excipients. Erythropoietic therapies may increase the risk of thrombotic and other serious events; dose reductions are recommended if the hemoglobin increase exceeds 1.0 g/dL in any two-week period. The most commonly reported side effects in Aranesp trials were fatigue, edema, nausea, vomiting, diarrhea, fever and dyspnea.

The Aranesp dosage should be adjusted for each patient to achieve and maintain a target hemoglobin not to exceed 12 g/dL. Doses must be individualized to ensure that hemoglobin is maintained at an appropriate level for each patient.

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 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.

Full prescribing information for Aranesp(R) is available at 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.

(1)American Heart Association. Heart Disease and Stroke Statistics: 2005 Update, Dallas, TX: American Heart Association; 2005.

(2)Ansari M, Massie BM. Heart failure: how big is the problem? Who are the patients? What does the future hold? Am Heart J. 2003;146:1-4.

(3)EPOGEN(R) is a registered trademark of Amgen, Inc.

(4)PROCRIT(R) is a registered trademark of Ortho Biotech Products, L.P.

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