Amgen Submits Supplemental Biologics License Application for Aranesp Extended Dosing; Phase 3 Study Evaluated Aranesp Dosed Once Every Three Weeks in Patients with Chemotherapy-Induced Anemia

May 6, 2005

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--May 6, 2005--Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for Aranesp(R) (darbepoetin alfa). The sBLA is based on Phase 3 data that Amgen believes will demonstrate Aranesp administered every three weeks is safe and effective in the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies. If approved, Aranesp will be the first therapy indicated in the United States for once every three week dosing in the treatment of anemia in these patients.

"As the first company to clone erythropoietin and develop recombinant EPO as a therapy, Amgen is deeply committed to improving the chemotherapy experience for cancer patients and their families," said Willard Dere, M.D., chief medical officer and senior vice president of global development at Amgen. "Since chemotherapy is most commonly given to patients every three weeks, an extended dosing schedule for Aranesp has the potential to reduce the amount of patient, physician and caregiver time required for anemia therapy."

About Chemotherapy-Induced Anemia

Chemotherapy can reduce the bone marrow's ability to produce red blood cells that transport oxygen from the lungs to all of the body's muscles and organs. Anemia occurs when there are too few red blood cells and the body's tissues are "starved" of oxygen, which can make a patient feel short of breath, very weak, faint and tired.

This year, an estimated 1.3 million cancer patients will undergo chemotherapy in the United States; approximately 800,000 (67 percent) will become anemic. More than half of these patients report that fatigue associated with anemia affects their daily lives more than any other side effect of treatment, including nausea, pain and depression.

Although anemia is a common and often debilitating side effect of chemotherapy, it is often not recognized and frequently under-treated. In fact, 42 percent of patients with a hemoglobin (Hb) level less than the recommended target level of 11 to 12 g/dL in the National Comprehensive Cancer Network(R) (NCCN) guidelines for "Cancer and Treatment-Related Anemia" are never treated with erythropoietic therapy.

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, which is currently marketed in the United States by Amgen as EPOGEN(R) (Epoetin alfa)(i) and by Ortho Biotech Products, LP, as Procrit(R) (Epoetin alfa)(ii). 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. By virtue of its longer half-life, Aranesp should be administered less frequently than Epoetin alfa in patients with chronic kidney disease (CKD).

Aranesp is approved for multiple indications with varying dosage instructions in both the United States and in Europe. Aranesp was approved by the FDA in September 2001 for up to every two week dosing 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 weekly dosing for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies. In 2004, the European Committee for Medicinal Products for Human Use approved Aranesp for extended dosing intervals of once every three weeks in the treatment of anemia in adult cancer patients with non-myeloid malignancies who are receiving chemotherapy and monthly in the treatment of anemia associated with CKD.

Important Safety Information

Aranesp(R) 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.

Pure red cell aplasia (PRCA) has been observed in patients treated with recombinant erythropoietins. This has been reported predominantly in patients with CRF. Aranesp(R) 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 clinical trials 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 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 U.S. Food and Drug Administration (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.

(i) EPOGEN(R) is a registered trademark of Amgen, Inc.
(ii) Procrit(R) is a registered trademark of Ortho Biotech Products, L.P.

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