



Amgen Receives Complete Response Letter for Extended Dosing of Aranesp(R) for Patients with Chronic Kidney Disease and Anemia

October 13, 2006

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Oct. 13, 2006--Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter, commonly referred to as an "approvable" letter, for Aranesp(R) (darbepoetin alfa) de novo once every-two-week and maintenance once-monthly dosing regimens for chronic kidney disease (CKD) patients with anemia not on dialysis.

In December 2005, Amgen submitted a biologics license supplement to the FDA for these Aranesp dosing regimens for CKD patients with anemia not on dialysis. The FDA has requested additional clinical data for the once-monthly dosing regimen, including an additional clinical study. The FDA has also requested additional label language and clarification of submitted data for the de novo once every-two-week dosing regimen. Amgen is committed to working closely with the FDA to resolve these questions in a timely and efficient manner.

About Anemia and Chronic Kidney Disease (CKD)

According to the National Kidney Foundation, CKD affects 20 million Americans (one in nine adults) and more than 20 million others are at increased risk for developing kidney disease. CKD is an irreversible condition characterized by kidney damage and impaired function that often progresses over time. Patients with CKD often suffer from serious complications such as anemia, which occurs when failing kidneys no longer produce sufficient erythropoietin, a hormone that stimulates the production of oxygen-carrying red blood cells. Red blood cells contain hemoglobin, a red, iron-rich protein that carries oxygen from the lungs to all of the body's tissues. Oxygen provides the energy the body needs for normal activities. Anemia occurs when the number of red blood cells (or the hemoglobin in them) falls below normal (12 to 18 g/dL of blood). Therefore, the body gets less oxygen and does not have enough energy to function properly.

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 CKD, for patients on dialysis and patients not on dialysis. In 2002, Aranesp was approved for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies in the U.S. and European Union (EU). Today, Aranesp is the only erythropoiesis-stimulating protein approved in the U.S. and EU for weekly and every-three-week administration, which allows physicians to synchronize anemia treatment with the majority of chemotherapy schedules. Since its introduction in 2001, more than 2 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. Seizures have occurred in patients with Chronic Kidney Disease. 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 of Epoetin alfa treated hemodialysis patients with clinically evident cardiac disease, where the target hematocrit (Hct) was 42% (Hb = 14 g/dL), an increased incidence of thrombotic events and mortality was seen. The reason for increased mortality observed in this study is unknown. In a study with another erythropoietic product, in women with metastatic breast cancer receiving chemotherapy, 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 in patients with CRF were infection, hypertension, hypotension, myalgia, headache, and diarrhea. The most commonly reported side effects in clinical trials in patients with chemotherapy-induced anemia 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 <http://www.aranesp.com>

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