Aranesp Receives Positive Regulatory Opinion for Extended Dosing in Europe

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THOUSAND OAKS, Calif., Aug 5, 2004 (BUSINESS WIRE) -- Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion to expand the marketing authorization for Aranesp(R) (darbepoetin alfa) in the European Union (EU). The CHMP opinion recommends authorization of once-every-three-week Aranesp administration in the treatment of anemia in adult cancer patients with non-myeloid malignancies who are receiving chemotherapy and up to once-per-month administration in the treatment of anemia in chronic kidney disease (CKD) patients not on dialysis.

"With the majority of cancer patients receiving chemotherapy on a 21-day cycle, the opportunity to receive Aranesp once every three weeks is a significant added benefit for patients and their physicians. Once approved, patients with CKD not on dialysis, who often visit their physician monthly, can greatly benefit from an up to once-monthly Aranesp treatment regimen," said Beth Seidenberg, senior vice president of development and chief medical officer at Amgen. "Aranesp's ability to effectively correct hemoglobin with less frequent dosing than other erythropoietic agents can simplify anemia management for people with cancer receiving chemotherapy or those afflicted with CKD."

Recommendations from the CHMP are typically endorsed by the European Commission for marketing authorization within three to four months. When approved, Aranesp will be the first and only erythropoietic stimulating protein approved in the EU for once-every-three-week and once-per-month dosing.

In Europe, marketing authorization for Aranesp was granted in 2001 for the treatment of anemia associated with kidney disease. The authorization was expanded in 2002 to include patients with solid tumors and chemotherapy-induced anemia. In 2003, the approval was granted to include cancer patients with lymphoproliferative diseases. Thus, Aranesp is indicated for the treatment of anemia in adult cancer patients with non-myeloid malignancy who are receiving chemotherapy.

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 discovery of recombinant erythropoietin, epoetin alfa, which is currently marketed in the U.S. 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, 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 non-myeloid malignancies.

Aranesp is contraindicated in patients with uncontrolled hypertension. 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.

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, 2003, 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.

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.

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

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

SOURCE: Amgen Inc.

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