EU Commission Approves Updated Prescribing Information for Aranesp(R)

March 5, 2008

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--March 5, 2008--Amgen (NASDAQ: AMGN) today announced that the European Commission reached its final decision to amend the prescribing information for Aranesp(R) (darbepoetin alfa) based on the positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) in January 2008. The CHMP granted positive opinions for all centrally-authorized Erythropoiesis Stimulating Agents (ESAs) in the European Union (EU), each of which will receive European Commission Decisions. The European Commission's decision announced today is consistent with that described in Amgen's press release on Sept. 28, 2007 and the European Medicines Agency's (EMEA) announcement on Oct. 23, 2007.

A summary of key changes to the prescribing information for Aranesp are presented below. The CHMP has sought to ensure this information is consistently addressed in the Summary of Product Characteristics (SmPCs) for all ESA products in Europe.

-- Amending the SmPCs to stipulate a uniform target hemoglobin range of 10 g/dL to 12 g/dL with guidance to avoid sustained hemoglobin levels above 12 g/dL.

-- Providing guidance for dosage adjustments to maintain hemoglobin concentration between 10-12 g/dL once the therapeutic objective for an individual patient has been achieved. Patients should be monitored to ensure the lowest approved dose is used to maintain hemoglobin at a level that controls the symptoms of anemia.

-- Amending the Posology and method of administration section to recommend that Aranesp should be administered to cancer patients with symptomatic chemotherapy induced anemia (CIA) (e.g. hemoglobin concentration equal to or less than 10 g/dL (6.2 mmol/l)).

-- Amending the therapeutic indication for chronic renal failure (CRF) from "treatment of anemia associated with CRF" to "treatment of symptomatic anemia associated with CRF" in adult and pediatric patients.

-- Amending the Special Warnings to indicate ESAs have not been shown to improve overall survival or decrease the risk of tumor progression in patients with anemia associated with cancer. ESA trials have shown an unexplained excess mortality in association with high target hemoglobin concentrations (greater than 12 g/dL), including (1) shortened time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy; (2) shortened overall survival in patients with metastatic breast cancer receiving chemotherapy; (3) increased risk of death when administered to target a hemoglobin of 12g/dL (7.5 mmol/l) in patients with active malignant disease receiving neither chemotherapy nor radiation therapy. Clinical trials in patients with CKD have also observed an increased risk of death and serious cardiovascular events when ESAs were administered to target a hemoglobin of greater than 12g/dL (7.5 mmol/l).

The full Summary of Product Characteristics is available through Amgen Medical Information.

About Aranesp

Aranesp was granted marketing authorization by the European Commission in 2001 for the treatment of anemia associated with CRF, in adults and pediatric subjects 11 years of age or older. In 2002, the European Commission approved Aranesp for the treatment of anemia in adult cancer patients receiving chemotherapy with solid tumors. This patient population was subsequently expanded in 2003 to include treatment of symptomatic anemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. Approval was granted in 2004 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 up to once-per-month Aranesp administration in 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 recombinant human erythropoietin (rHuEPO) one to three times a week to Aranesp every two weeks. In 2007, the Aranesp label was updated to allow for treatment of anemia associated with CRF, in all European pediatric patients on dialysis or not on dialysis.

Aranesp was approved by the U.S. Food and Drug Administration (FDA) in September 2001 for the treatment of anemia associated with CRF for patients on dialysis and patients not on dialysis. In July 2002, the FDA approved weekly dosing of Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with nonmyeloid malignancies and in March 2006, the FDA approved every-three-week dosing in these patients.

Important EU Aranesp Safety Information

Aranesp is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic and other serious events; regional guidelines should be referred to for target and maximum hemoglobin levels, and dose adjustment rules should be performed in line with regional prescribing information.

The most commonly reported side effects in clinical trials were arthralgia, edema, injection site pain, and thromboembolic event reactions. Prescribers are recommended to consult regional prescribing information before prescribing Aranesp, including side-effects, precautions and contra-indications.

Important U.S. Aranesp Safety Information

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR and THROMBOEMBOLIC EVENTS, and TUMOR PROGRESSION

Renal failure: Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Cancer:

-- ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers when dosed to target a hemoglobin of greater than or equal to 12 g/dL.

-- The risks of shortened survival and tumor progression have not been excluded when ESAs are dosed to target a hemoglobin of less than 12 g/dL.

-- To minimize these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusions.

-- Use only for treatment of anemia due to concomitant myelosuppressive chemotherapy.

-- Discontinue following the completion of a chemotherapy course.

Aranesp is contraindicated in patients with uncontrolled hypertension.

About Amgen

Amgen discovers, develops, manufactures 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 deep and broad 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 Statements

This news release contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of March 5, 2008, and expressly disclaims any duty to update information contained in this news release.

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 safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products are affected by the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and health care cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' 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) or European Medicines Agency (EMEA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA, EMEA or comparable regulatory body 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 or EMEA 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, EMEA or comparable regulatory body can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the applicable FDA- or EMEA-approved labeling for the

products, and not the information discussed in this news release.

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