Kepivance(TM) (palifermin) Receives Positive Regulatory Opinion for Approval in Europe

July 28, 2005

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--July 28, 2005--Amgen (Nasdaq:AMGN) today announced that the European Committee for Medicinal Products for Human Use (CHMP), which is the scientific advisory panel to the European Medicines Agency (EMEA), has issued a positive opinion to approve marketing authorization for Kepivance(TM) (palifermin) in the European Union (EU). The CHMP opinion recommends authorization of palifermin to decrease the incidence, duration and severity of oral mucositis (mouth sores) in patients with hematologic (blood) cancers undergoing myeloablative therapy associated with a high incidence of severe oral mucositis, and requiring autologous bone marrow transplant.

"Before palifermin, the best we could hope for in managing oral mucositis was to control the patient's pain with narcotics and oral rinses," said Jean-Luc Harousseau, M.D., head of the department of clinical hematology in the University Hospital of Nantes and former palifermin investigator. "With the potential approval of palifermin, physicians may be able to help protect transplant patients with hematologic malignancies from severe oral mucositis and may decrease their pain and discomfort."

In patients with oral mucositis, the cells lining the mouth and throat are damaged by the chemotherapy drugs and/or radiation used in cancer treatment. Oral mucositis can be extremely painful and can have a devastating impact on patients. In fact, oral mucositis has been rated as the most debilitating side effect by patients with blood cancers undergoing bone marrow transplantation. Patients suffering from these debilitating mouth sores may require longer hospitalization, high doses of narcotics, such as morphine, and intravenous feeding to receive nutrition and maintain hydration. In the EU, approximately 13,000 cancer patients undergo autologous bone marrow transplant each year.

"Palifermin is an innovative medicine that helps meet a significant medical need for these cancer patients," said Willard Dere, M.D., senior vice president of global development and chief medical officer at Amgen. "Oral mucositis can be extremely painful for these patients and can impact their everyday lives. Once approved, palifermin will be the first and only therapy available in the EU that will enable physicians to focus on helping to protect these patients from oral mucositis by decreasing its incidence, duration and severity."

Recommendations from the CHMP are typically endorsed by the European Commission for marketing authorization within three to four months.

About Kepivance

Kepivance was approved by the U.S. Food and Drug Administration (FDA) in December 2004. In the U.S., Kepivance is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic cancers undergoing high-dose chemotherapy, with or without radiation, followed by a bone marrow transplant. The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. Amgen has also applied for regulatory approval in Australia, Canada and Switzerland.

Kepivance, a recombinant human keratinocyte growth factor, reduces the incidence and duration of severe oral mucositis by helping to protect existing epithelial cells that line the mouth and throat from the damage caused by chemotherapy and radiation, and stimulating the growth and development of new epithelial cells to build up the mucosal barrier. By reducing the incidence and duration of severe mouth sores, Kepivance helps patients continue normal daily activities, like eating, drinking, swallowing and talking.

In patients with hematologic malignancies, the most common serious adverse reaction in clinical trials attributed to Kepivance was skin rash reported in less than one percent of patients. Other serious adverse reactions occurred at a similar rate in patients who received Kepivance or placebo with the most frequent being fever, gastrointestinal events, and respiratory events. The most commonly reported adverse reactions attributed to Kepivance were rash, erythema, edema, pruritus, dysesthesia, mouth/tongue thickness/discoloration, and taste alteration.

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 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.

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