European Commission Approves Kepivance(TM) (Palifermin) for Oral Mucositis in Cancer Patients Undergoing Blood and Bone Marrow Transplant

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THOUSAND OAKS, Calif., Oct 28, 2005 (BUSINESS WIRE) -- Amgen (Nasdaq:AMGN), the world's largest biotechnology company, today announced that Kepivance(TM) (palifermin) has received regulatory approval in the European Union (EU). Palifermin is now authorized in the EU 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 blood and bone marrow transplant. In the EU, approximately 13,000 cancer patients undergo autologous blood and bone marrow transplant each year.

"The European Commission's approval of palifermin marks a significant advance for patients with blood cancers undergoing blood and bone marrow transplant as it is the first and only product available in the EU that will help physicians to protect patients from the devastating consequences of oral mucositis," said Willard Dere, M.D., chief medical officer and senior vice president of Global Development at Amgen. "Amgen is proud to offer this innovative medicine to address an important unmet medical need for these cancer patients."

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 one of the most debilitating side effects by patients with blood cancers undergoing blood and bone marrow transplantation. Patients suffering from these debilitating mouth sores may require high doses of narcotics, such as morphine, and intravenous feeding to receive nutrition and maintain hydration.

"Now, physicians in the EU have an option to decrease the incidence, duration and severity of oral mucositis, rather than only trying to control the pain and discomfort caused by it," said Dietger Niederwieser, M.D., elected president of the European Group for Bone and Marrow Transplantation (EBMT). "With palifermin, we can help protect patients undergoing blood and bone marrow transplant from this extremely painful side effect that can impact their ability to eat, drink and swallow."

About the Pivotal Phase 3 Study

The European Commission approval is based on a pivotal Phase 3 double-blind study that compared palifermin with placebo in the development of oral mucositis in patients with hematologic malignancies. Participants were randomized to receive palifermin 60 micro-g/kg/day (n=106) or placebo (n=106) intravenously for three consecutive days immediately before conditioning therapy (fractionated total body radiation plus high-dose chemotherapy) and for an additional three days immediately following blood and bone marrow transplant.

The incidence of the most debilitating grade of oral mucositis (grade 4) was three times less with palifermin (20 percent versus 62 percent with placebo), and the incidence of grade 3-4 mucositis where patients can only swallow liquids, if anything, was reduced by approximately one-third (63 percent versus 98 percent with placebo). Palifermin reduced the duration of painful oral mucositis (grades 2-4) by almost half or approximately one week (8 days versus 14 days with placebo).

The study found that patients treated with palifermin reported significantly less mouth and throat soreness, as well as improvements in their ability to eat, drink, swallow and talk. In addition, patients receiving palifermin required fewer days of morphine for their pain than patients receiving placebo (7 days versus 11 days, respectively).

Palifermin was shown to be effective and well-tolerated in this study. Adverse reactions seen in the study, such as rash, pruritus (itching), erythema (redness of the skin), edema, pain, fever, arthralgia (joint pain), mouth/tongue disorders and taste alteration were primarily mild-to-moderate in severity and transient.

About Kepivance

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.

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.

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.

Amgen has also received approval for Kepivance in Australia and has applied for regulatory approval in Canada and Switzerland.

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, 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.

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.

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