FDA Approves Kepivance for Severe Oral Mucositis in Cancer Patients Undergoing Bone Marrow Transplant; Pivotal Phase 3 Study Published in This Week's New England Journal of Medicine

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THOUSAND OAKS, Calif., Dec 15, 2004 (BUSINESS WIRE) -- Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that following priority review, the U.S. Food and Drug Administration (FDA) has approved Kepivance(TM) (palifermin), the first and only therapy to decrease the incidence and duration of severe oral mucositis (mouth sores) in patients with hematologic (blood) 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.

"Until now, severe painful oral mucositis has been considered an unmet medical need for which no effective therapies existed to reduce either its incidence or duration. The most we could do for our patients was to give them ice chips and narcotics to try and manage their pain," said Patrick Stiff, M.D., director of the Cardinal Bernardin Cancer Center, Loyola University Health System and professor of Hematology/Oncology, Loyola University Chicago Stritch School of Medicine, Maywood, Ill., and one of the lead investigators in the Kepivance pivotal trial. "We are excited to have a new option that will enable physicians to focus on helping to protect their patients with hematologic malignancies from this complication rather than solely managing its consequences."

"As a science-based, patient-focused organization, Amgen works to discover and develop innovative therapies to treat grievous illnesses," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of research and development at Amgen. "We are excited that Kepivance is now available to transplant patients with hematologic malignancies who suffer from severe oral mucositis. We are also investigating the safety and efficacy of Kepivance in other cancer treatment modalities."

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. Severe mouth sores can make patients' everyday activities, such as eating, drinking, swallowing and talking, difficult or impossible. 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.

Approximately 11,000 adult Americans with hematologic malignancies, including non-Hodgkins lymphoma, Hodgkin's disease, leukemia and multiple myeloma undergo bone marrow transplantation each year. Bone marrow transplantation is a procedure in which a patient's bone marrow is destroyed by anticancer drugs or radiation and is then replaced. Bone marrow transplants make it possible to use more effective, very high doses of chemotherapy that would otherwise be impossible, and nearly all patients undergoing this treatment suffer from oral mucositis. In fact, oral mucositis is rated as the most debilitating side effect by patients undergoing this cancer treatment.

Pivotal Phase 3 Study Published in This Week's New England Journal of Medicine

The pivotal phase 3 double-blind study published in this week's New England Journal of Medicine, compared Kepivance with placebo in the development of oral mucositis in patients with hematologic malignancies. Participants were randomized to receive Kepivance 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). Then all patients received bone marrow transplantation, followed by an additional three days of either Kepivance or placebo.

The incidence of the most debilitating grade of mucositis (grade 4) was three times less with Kepivance (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). Kepivance 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 Kepivance reported significantly less mouth and throat soreness, as well as improvements in their ability to eat, drink, swallow and talk. In addition, patients receiving Kepivance required fewer days of morphine for their pain than patients receiving placebo (7 days versus 11 days, respectively).

Kepivance was shown to be safe and well-tolerated in this study. Adverse events seen in the study, such as rash, pruritus (itching), erythema (redness of the skin), paresthesia (tingling skin), mouth/tongue disorders and taste alteration were mild-to-moderate and transient.

About Kepivance

Kepivance is a recombinant human keratinocyte growth factor that works at the cellular level to help protect patients with hematologic malignancies undergoing high-dose chemotherapy and/or radiation followed by bone marrow transplant from severe oral mucositis. Kepivance reduces the incidence and duration of severe oral mucositis in these patients by protecting the epithelial cells that line the mouth and throat from the damage caused by chemotherapy and radiation and by stimulating the growth and development of new epithelial cells to build up the mucosal barrier.

The most common serious adverse reaction in clinical trials attributed to Kepivance was skin rash reported in less than 1% of patients. Other serious adverse reactions occurred at a similar rate in patients who received Kepivance or placebo. The most frequently reported serious adverse event in Kepivance and placebo-treated patients were fever, gastrointestinal events, and respiratory events. The most commonly reported adverse reactions were rash, erythema, edema, pruritus, dysesthesia, mouth/tongue thickness/discoloration, and taste alteration.

For more information about ongoing Kepivance clinical trials, please visit www.amgentrials.com.

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 US 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 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

The Kepivance prescribing information, a product photo and other media tools are available at www.amgen.com. Prescribing information is also available via fax by calling 800-772-6436.

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.

SOURCE: Amgen Inc.

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