Amgen Submits Biologics License Application for FDA Approval of Palifermin

June 24, 2004

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--June 24, 2004--Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced submission of a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for palifermin, a first-in-class investigational compound in development by Amgen for oral mucositis (mouth sores). The potential therapeutic indication is to reduce the incidence, duration and severity of oral mucositis in patients with hematologic malignancies undergoing high-dose chemotherapy, with or without irradiation, followed by a bone marrow transplant.

Approximately 11,000 Americans with hematologic malignancies, including non-Hodgkins lymphoma, Hodgkin's disease, leukemia and multiple myeloma, undergo bone marrow transplants each year.

The BLA was submitted under the FDA's Fast Track designation program, which is designed to expedite FDA review of an investigational therapy for an unmet medical need. If approved, palifermin will be the first therapy indicated to reduce the incidence, duration and severity of oral mucositis in bone marrow transplant patients.

"Palifermin is a first-in-class, innovative biologic that protects the epithelium of the mouth and gastrointestinal tract from damage caused by anti-cancer therapy," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development at Amgen. "The palifermin BLA filing is an important milestone for Amgen and our commitment to advance innovative molecules that address unmet need in grievous illnesses."

In patients with oral mucositis, the sensitive cells (mucosa) lining the mouth and digestive tract are damaged by the drugs or radiation used in cancer treatment. Severe mucositis is extremely painful (often requiring opioid-like analgesics), interferes with alimentation (process of providing nutrition), increases the chance of serious infection and can force hospitalization. In addition, painful mouth sores can make everyday activities like eating, swallowing, talking and sleeping difficult or impossible.

The BLA filing contains data from the Phase 3 pivotal study of palifermin which demonstrated that patients with hematologic malignancies undergoing high-dose chemotherapy, with or without irradiation, and bone marrow transplant support who received palifermin suffered less ulcerative oral mucositis (grades 2-4) compared to those receiving placebo (15.7 days vs. 8.4 days). In addition, palifermin helped protect patients from the most severe form of oral mucositis (grade 4) with 20 percent of palifermin-treated patients experiencing this painful and debilitating side effect, compared to 62 percent of placebo-treated patients.

Serious adverse events occurred at the same rate in patients who received palifermin or placebo (21 percent). The most frequently reported serious adverse events in both groups were fever, gastrointestinal and respiratory related.

Most adverse events were attributable to the underlying malignancy, cytotoxic chemotherapy, or total body irradiation and occurred at similar rates in patients who received palifermin or placebo. Other adverse events were consistent with the pharmacologic action of palifermin on skin and oral epithelium and included rash, pruritus (itching), erythema (redness), edema (swelling), mouth/tongue thickness or discoloration, and taste disorders. These events were mild to moderate in severity and were reversible.

About Palifermin

Palifermin (a recombinant human keratinocyte growth factor) is a first-in-class investigational compound in development by Amgen for mucositis throughout the gastrointestinal tract. Like endogenous keratinocyte growth factor, palifermin targets epithelial cells lining the mouth and gastrointestinal tract by binding to certain epithelial cell-surface receptors. This binding stimulates epithelial cell proliferation, differentiation and upregulation of cytoprotective mechanisms.

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 Statements

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.

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