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## ***News Release***

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### **PHASE 3 DATA SHOW PALIFERMIN IMPROVES PATIENT REPORTED OUTCOMES IN CANCER PATIENTS AND HELPS REDUCE HOSPITALIZATIONS AND HEALTHCARE RESOURCES**

SAN DIEGO, (December 9, 2003) – Amgen (Nasdaq:AMGN), the world's largest biotechnology company, today announced additional data from a Phase 3 study demonstrating that treatment with palifermin (recombinant human keratinocyte growth factor or rHuKGF), an investigational product, was associated with a statistically significant and clinically meaningful improvement in mouth and throat soreness as reported by patients with hematological malignancies undergoing high dose chemotherapy and radiotherapy with peripheral blood progenitor cell (PBPC) transplants. Mouth and throat soreness is caused by the severe mouth ulcerations characteristic of oral mucositis, a painful and debilitating side effect of some cancer treatments. The results were presented by the study's lead investigator, 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, in an oral presentation at the 45<sup>th</sup> American Society of Hematology (ASH) Annual Meeting. [ASH Abstract # 676]

"These findings are especially exciting because there are currently no approved therapies for the treatment or prevention of oral mucositis," Stiff said. "In this trial, patients given palifermin experienced improvements in their ability to eat, drink, talk, swallow and sleep, as well as their overall functional well being."

Patients enrolled in the study (n=212) reported daily how sore their mouths and throats were, as well as their limitation in carrying out daily activities. On average, patients receiving palifermin reported a reduction in soreness of 54 percent compared to the placebo arm of the study (p=0.0001). This reduction in soreness translated into, on average, a 40 percent improvement in palifermin-treated patients' ability to eat, drink, swallow, sleep and talk (p<0.001).

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Patients in the study were randomized to receive either palifermin (106 patients) 60 mcg/kg/day or placebo (106 patients) for three days prior to high-dose chemotherapy and total body irradiation (TBI). Then all patients received PBPC transplantation, followed by an additional three days of either palifermin or placebo.

Patients undergoing PBPC transplants rate severe mucositis as one of the most debilitating side effects of this treatment. Everyday activities like eating, swallowing and talking can become difficult or impossible leading to malnutrition and dehydration that often requires hospitalization. In addition, the pain from severe ulcerations often requires morphine-based analgesics, which can lead to hallucinations and patients feeling loss of control. Patients with the most severe form of oral mucositis are unable to swallow anything at all and may need total parenteral nutrition (TPN) administered intravenously until the pain from the mucositis recedes, and the patient is able to swallow again.

In addition to a lower incidence of severe oral mucositis, patients receiving palifermin had almost one week less severe mucositis compared to those receiving placebo (10.4 days vs. 3.7 days). In particular, palifermin helped protect patients from the most severe form of oral mucositis (grade 4) with three times fewer palifermin-treated patients getting this painful and debilitating side effect, compared to placebo-treated patients (62 vs. 20 percent). [ASCO 2003 Abstract #3642]

### **Further Analysis Shows Palifermin May Help Reduce Health Utilization Costs**

Additional data from the same trial was presented in a second oral session by Christos Emmanouilides, M.D., University of California, Los Angeles Medical Center, and demonstrated that by reducing the severity and duration of oral mucositis in this patient population, palifermin also reduced health resource utilization in terms of number of days of hospitalization, analgesic use and parenteral nutrition. Patients receiving palifermin spent fewer days in the hospital than those on placebo (15.3 vs. 17.3 days), required less narcotic analgesics and were significantly less likely to need parenteral nutrition (11 vs. 43 percent of patients). [ASH Abstract # 883]

Adverse events included mild/moderate skin and oral erythema with/without edema. Transient, asymptomatic increases in serum amylase and lipase were also observed and occurred more frequently in palifermin recipients than in placebo recipients, although the difference was not statistically significant.

### **About Palifermin**

Natural keratinocyte growth factor has been shown in preclinical studies to stimulate the growth and development of epithelial cells, which include those that line the mouth and gastrointestinal tract. Amgen is studying palifermin (rHuKGF) for protection and healing of epithelial cells injured by anti-tumor treatments such as radiation and chemotherapy.

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## **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, 2002, 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.

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