

Phase 3 Data Show Palifermin Improves Patient Reported Outcomes in Cancer Patients and Helps Reduce Hospitalizations and Healthcare Resources

December 9, 2003

SAN DIEGO, Dec. 9 -- 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 45th 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