



Phase 3 Data Suggest Palifermin Significantly Reduces the Duration and Incidence of Oral Mucositis in Cancer Patients

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FOR IMMEDIATE RELEASE

-- Debilitating and Painful Condition Can Interrupt Chemotherapy Schedule --

CHICAGO, IL, June 1, 2003 - Amgen (Nasdaq:AMGN), the world's largest biotechnology company, today announced data from a Phase 3 study showing that Palifermin, Amgen's proprietary recombinant human keratinocyte growth factor (rHuKGF) molecule, significantly reduced the duration and incidence of severe oral mucositis in patients with hematologic malignancies undergoing high-dose chemotherapy and radiotherapy and total body irradiation followed by hematopoietic stem cell support compared to placebo. 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 percent vs 20 percent). Results were presented by the study's lead investigator, Ricardo Spielberger, MD, City of Hope National Medical Center, Duarte, CA, at the 39th American Society of Clinical Oncology (ASCO) Annual Meeting.

Mucositis is a painful and debilitating condition in which patients experience severe mouth ulcerations that can make everyday activities such as eating, swallowing and talking difficult or impossible. The pain from severe ulcerations can prevent a patient's intake of food and fluids, leading to malnutrition and dehydration that requires hospitalization. Patients with the most severe form of oral mucositis may not be able to tolerate either a solid or liquid diet and must receive total parenteral nutrition (TPN), which is given intravenously. This line remains throughout treatment until the pain from the mucositis stops and the patient is able to eat again.

"Severe oral mucositis is rated by patients themselves as one of the most debilitating side effects of bone marrow or peripheral blood progenitor cell transplants. Severe mucositis is not only extremely painful but it can also lead to serious infections, particularly in this patient population whose natural defenses have been diminished by the high-dose cytotoxic treatment," said Dr. Spielberger. "At this time, there are no approved therapies to treat or prevent mucositis in cancer patients. This study shows that palifermin both protects and heals the cells that line the mouth and gut from the damage of high-dose chemotherapy and radiotherapy. We are very excited about these results."

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 peripheral blood progenitor cell transplantation, followed by an additional three days of either palifermin or placebo.

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). Furthermore, palifermin-treated patients reported 60 percent less soreness of the mouth and throat, required lower doses of painkillers and less total parenteral nutrition use (11 percent versus 40 percent with placebo). [ASCO Abstract #3642]

Palifermin was well tolerated. 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 rHuKGF recipients than in placebo recipients, although the difference was not statistically significant.

Natural keratinocyte growth factor stimulates the growth and development of epithelial cells, which include those that line the mouth and gastrointestinal tract. Amgen is studying palifermin for protection and healing of epithelial cells injured by anti-tumor treatments such as radiation and chemotherapy.

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

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For more information, please contact:

Media: 805-447-4587

Investors: 800-84-AMGEN