

Kepivance[®]: Improving the Quality of Life for Cancer Patients

Department of Health
and Human Services
National Institutes of Health
National Cancer Institute

Cancer is the second largest cause of mortality in the U.S., but researchers have made tremendous progress in developing new and effective treatments to reduce these mortalities. The National Cancer Institute's 2015 challenge goal is to turn cancer from a killer into a chronic disease in the next ten years. Thus far, progress in the fight against cancer has come at a heavy price in the form of devastating side effects. While meant to kill cancer cells, most cancer drugs also destroy normal tissue.

Mucositis (painful sores and ulcers in the lining of the mouth) is a common complication of chemotherapy and/or radiation, affecting approximately 80% of patients who undergo this intensive treatment prior to bone marrow transplantation. In this condition, the cells lining the mouth and throat are damaged, making the patients' everyday activities, such as eating, drinking, swallowing and talking, difficult or impossible. They require longer hospitalization, high doses of painkillers,

and intravenous feeding. Prior to Kepivance[®], there was no treatment for this condition.

This invention describes the use of Palifermin, a recombinant human keratinocyte growth factor (KGF) that can be used to reduce the incidence and duration of oral mucositis in cancer patients. Dr. Jeffrey Rubin and his collaborators at the National Institutes of Health (NIH) discovered the original molecule, realized its importance, and filed for patent protection in 1989. Amgen was then chosen as a commercial partner to develop a useful therapeutic with this molecule, because they had worked with other growth factors such as PDGF and G-CSF. Convinced that KGF would fit well in Amgen's product development strategy, NIH granted them an exclusive license to the invention in 1992.

Approved by the Food and Drug Administration in 2004 and sold under the



From left: Dr. Paul Finch, Dr. Jeffrey Rubin, Dr. Stuart Aaronson

brand name Kepivance[®], this is a first-of-its-kind medicine that directly and effectively addresses the issue of a cancer patient's quality of life, and it is bound to inspire other drug developers to introduce such valuable products. Currently, this drug benefits approximately 11,000 adult Americans with hematologic malignancies who undergo bone marrow transplantation each year. As other indications are pursued and the medical community realizes the value provided to their patients by this treatment, the number of people benefiting from Kepivance[®] is bound to multiply. First-of-a-kind drugs generally see a delayed but rather dramatic upswing in usage as practitioners become more comfortable prescribing them and as new uses are developed.

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