

# Kepivance®: Improving the Quality of Life for Cancer Patients

National Cancer Institute, National Institutes of Health

Cancer is the second largest cause of mortality in the US, 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 the progress in our fight against cancer has come at a heavy price in the form of devastating side effects. While they are meant to kill cancer cells, most cancer drugs also destroy normal tissues. 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 narcotics such as morphine, 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. Rubin and his collaborators at 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 FDA in 2004 and sold under the brand name Kepivance®, this is a first of its kind of 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 by this treatment to their patients, 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 in prescribing them and new uses are developed.

Primary Contact : Dr. Jeffrey S. Rubin, Senior Investigator, National Cancer Institute, National Institutes of Health, Building 37, Room 2042, 37 Convent Drive, Bethesda, MD 20892, Phone: 301-496-4265, Fax: 301-496-8479, E-mail: RubinJ@mail.nih.gov

Other Inventors:                      Dr. Paul W. Finch, Scientific Consultant  
    Dr. Stuart A. Aaronson, Professor and Chairman  
    Mount Sinai School of Medicine

	FLC Representative Making Nomination	Nominee(s)' Supervisor	ORTA Representative Technology Transfer Program Manager	Lab Director
Name:	Krishna Balakrishnan	Robert Wilttrout MD	Karen Maurey	Andrew Von Eschenbach, MD
Address:	6011 Executive Blvd., #325	Bldg. 428, Rm. 46 P.O. Box B	6120 Executive Blvd., Suite 450	31 Center Drive, MSC 2580
City:	Rockville	Frederick	Rockville	Bethesda
State/Zip:	MD 20852	MD 21702-1201	MD 20852	MD 20892-2580
Phone:	301-435-3888	301.846.1258	301/496-0477	301.496.5615
Fax:	301-402-0220		301/402-2117	
E-mail	balki@nih.gov	wilttrou@mail.nih.gov	maureyk@mail.nih.gov	vonescha@mail.nih.gov