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CONTACT:
Valerie Johns
Senior Marketing Manager
SAGE Publications
Tel: 805-410-7778
Email: media.inquiries@sagepub.com

**STUDY IN THE JOURNAL OF CLINICAL PHARMACOLOGY
LOOKS AT THE EFFECTS OF PALIFERMIN IN PATIENTS WITH IMPAIRED KIDNEY FUNCTION**

Los Angeles, London, New Delhi, and Singapore (November 30, 2006) - Chemotherapy and radiation for the treatment of various malignancies often result in damage to mucus membranes. Patients suffer ulcerations, pain and an increase risk of infection. Palifermin (Kepivance) is approved for use to decrease the chances of developing severe mucositis or injury to the cells lining the mouth, as well as shorten the time of severe mucositis in patients with cancer. Up to now, it had not been known whether patients with impaired kidney function required any different dosing.

In a recent study published in the December issue of *The Journal of Clinical Pharmacology* by SAGE Publications, Dr. B. Gillespie and colleagues from Amgen Inc. in Thousand Oaks, CA, conducted a study that assessed the effects of renal function on the pharmacokinetics, safety and tolerability of palifermin after a single IV injection.

The clinical trial consisted of 31 participants with varying degrees of renal function, from normal to end-stage renal disease requiring hemodialysis.

Each participant received a single dose of the drug, palifermin. Noone discontinued the study due to adverse events, although 26 subjects reported at least 1 adverse event, mild to moderate in severity which included fatigue and headaches. One subject, who had insulin-dependent diabetes, experienced a significant abnormal glucose level, however, this was not considered related to the study.

The authors concluded that 'these findings indicate that a subject's level of renal function does not appear to affect palifermin clearance or tolerability. Therefore, dose adjustment of palifermin is not indicated for patients with renal impairment.'

The article "Effect of Renal Function on the Pharmacokinetics of Palifermin" can be accessed at no-charge for a limited time at *The Journal of Clinical Pharmacology's* web site at www.jclinpharm.org/cgi/reprint/46/12/1460.

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