

**Profit from Innovation** 



# Pergamum reports positive Phase II data from clinical trial in outer ear infections

STOCKHOLM – December 21, 2012. Pergamum AB announced today that the primary endpoint was met in the randomized Phase II trial of DPK-060 for treatment of acute external otitis. Karolinska Development AB is the majority owner of Pergamum AB.

"The study results announced today, clearly shows the potential for DPK-060 to play a significant role in the future treatment of outer ear infections. We estimate that more than 10 million people in the US, EU and Japan seek medical care for this disease, causing a considerable workload at otolaryngology departments", said Jonas Ekblom, CEO of Pergamum AB. "There is a clear medical need to avoid rapidly increasing global prevalence of antibiotics resistance that limits the therapeutic value of conventional products."

The completed study is a Phase II double-blind, randomized, placebo-controlled, multi-center trial in patients with acute external otitis. The primary objective of the trial was to assess local tolerability and safety of 2% DPK-060 ear drops in infections caused by bacterial or fungal pathogens. The trial enrolled 69 patients. After top-line analysis of the study data, it was concluded that DPK-060 is safe and tolerable for topical treatment in the outer auditory channel. In addition, secondary endpoints showed a complete cure in 85% - 94% (depending on which rating scale is utilized) of the patients after 10 days of treatment with DPK-060, and the difference compared to placebo was statistically significant.

External otitis, also frequently called swimmer's ear is one of the most common ear, nose and throat infections treated in out-patient settings. The clinical signs of the condition can range from mild inflammation and discomfort to life-threatening symptoms. DPK-060 is a novel anti-microbial peptide, which is unlikely to evoke antibiotic resistance.

"The data from this randomized study demonstrate that topical treatment with DPK-060 is safe and well tolerated. Furthermore, a sizable fraction of the patients that received DPK-060, demonstrated complete clinical cure after 10 days of treatment. As a consequence, we will start searching for a corporate partner for this program in 2013", said Torbjörn Bjerke, CEO of Karolinska Development AB and Chairman of Pergamum AB.

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#### TO THE EDITORS

#### **About DPK-060**

DPK-060 is a novel anti-microbial peptide which is structurally derived from the endogenous human protein kininogen. It has a broad-spectrum action on bacteria such as *Staphylococcus aureus*, including multidrugresistant strains, as well as fungi such as *Candida* and *Malassezia*. Studies from several independent investigators suggest that peptides such as DPK-060 do not evoke conventional antibiotic resistance. Previously, DPK-060 has shown positive data in a clinical Phase II study in atopic dermatitis and has the potential to treat many other dermatological conditions where these microorganisms constitute a major problem.

# **About Pergamum**

Pergamum is a biopharmaceutical company specialized in the development of therapeutic peptides for local application in infections and wounds. The company's vision is to develop a portfolio of unique development programs representing high medical value that ultimately, through global partnerships, will result in first-in-class and first-in-category products. The current development pipeline includes three therapeutic peptides in clinical development, with potential for use in several medical applications. Please visit our web site: www.pergamum.com.

### **About Karolinska Development AB**

Karolinska Development aims to create value for patients, researchers, and investors by developing innovations from world class science into products that can be sold or out-licensed with high returns. The business model is to: SELECT the most commercially attractive medical innovations; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading Nordic universities, delivers a continuous flow of innovations. Today, the portfolio consists of 34 projects, of which 15 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

Karolinska Development is listed on NASDAQ OMX. Karolinska Development may be required to disclose the information provided herein pursuant to the Securities Markets Act.