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Pergamum announces final data from Phase I/II study of LL-37 in patients with chronic leg ulcers

STOCKHOLM – October 10, 2013. Pergamum AB, which is a portfolio company of Karolinska Development AB, announced today that it has finalized the Clinical Study Report of a randomized Phase I/II trial of LL-37 for treatment of venous leg ulcers. Patients treated with LL-37 had a statistically significant improved healing rate compared with placebo and no safety or tolerability concerns were noted, confirming the positive preliminary data reported in July this year.

Chronic leg ulcers are often defined as those that fail to heal after six weeks or more of appropriate treatment. Venous leg ulcers are the most common type of hard-to-heal leg wounds, accounting for >70% of all cases in the developed world.

LL-37 is a human peptide that is involved in acute wound healing. Data from independent research groups suggest that chronic wounds have a relative deficit of LL-37 and should benefit from therapeutic, exogenous application of the peptide.

Jonas Ekblom, CEO of Pergamum commented: “This was primarily a safety study but the data also show that LL-37 has an effect in this difficult to treat patient group, which has been lacking access to new innovative pharmaceutical products. Pergamum’s candidate drug has the potential to become the first in a new class of pharmaceuticals for chronic leg ulcers, a major medical problem. The worldwide wound care market today is worth over EUR 10bn.”

In a double blind multicenter study, 34 patients with venous leg ulcers received either placebo or one of three different doses of LL-37 (0.5, 1.6, and 3.2 mg/ml) of Pergamum’s potential first-in-class therapeutic peptide LL-37 in a gel formulation. The primary objective of the trial was to assess the safety and tolerability and the data demonstrate that there are no safety concerns with LL-37. The investigational drug was well tolerated when it was applied to venous leg ulcers at the two lower doses (0.5 mg/mL and 1.6 mg/mL). However, an increased incidence of local reactions at the treated wounds was observed in the highest dose group (3.2 mg/ml).

The results also show that the healing rate for the patients who received the lowest dose (0.5 mg/ml) and the middle dose (1.6 mg/ml) of LL-37 were approximately 6 and 3-fold higher respectively, compared to the patients who received placebo ($p=0.003$ for 0.5 mg/mL and $p=0.088$ for 1.6 mg/ml). There was no improvement in healing rate in the highest dose group. The clinical trial report thereby confirms the positive top-line data reported earlier this year.

”The fact that statistically verifiable clinical performance of an investigational drug can be demonstrated in a relatively small study is rare. This is especially so in the treatment of venous leg ulcers. These findings suggest that LL-37, in conjunction with compression, could be a very promising new treatment”, said Richard White, Professor of Tissue Viability, Institute of Health & Society, University of Worcester.

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"Now that the clinical trial report has been finalized, Pergamum will focus its efforts on finding the right industrial partner to bring this novel treatment concept to market", said Torbjörn Bjerke, CEO of Karolinska Development AB and Chairman of the Board of Pergamum.

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TO THE EDITORS

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 several therapeutic peptides of which three programs are 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 universities, delivers a continuous flow of innovations. Today, the portfolio consists of 35 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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