

## **Promore Pharma receives approval for Phase IIb trial with LL-37 in Poland**

**STOCKHOLM, 22 August 2018 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, announces today that The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland has approved the company's application to start a Phase IIb study (HEAL) with LL-37 for treatment of venous leg ulcers.**

Promore Pharma's phase IIb study with LL-37, HEAL (*A Study in Patients with Hard-to-Heal Venous Leg Ulcers to Measure Efficacy and Safety of Locally Administered LL-37*) is anticipated to recruit 120 patients with venous leg ulcers (VLU) in Sweden and Poland. The company has previously announced that an approval was received from the Swedish Medical Products Agency. Now an approval has been received by The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland.

"With this approval Promore Pharma has all the authority approval applied for to start the recruitment of patients in this bi-national HEAL study. This means we can start the recruitment in the next few months, according to the plan previously announced", says Jonas Ekblom, President and CEO of Promore Pharma.

"A new product for treatment of venous leg ulcers would mean a huge step forward within the gigantic therapeutic area that is wound and trauma", he continued.

HEAL is anticipated to recruit 120 patients with VLUs with a size up to 40 square centimeters. Patients are divided into three arms, two where patients receive LL-37 and a placebo arm. The treatment will be ongoing for thirteen weeks, two to three times a week in connection with regular change of wound dressing. The study is randomized and double blind. The primary end point is the proportion of patients that have complete healed wounds, which is what regulatory authorities require for market approval. In addition, the effect of LL-37 on venous leg ulcer healing is studied based on several secondary endpoints, as well as local tolerability and safety of LL-37. The post-treatment follow-up period is four months.

VLU constitutes the largest category of all chronic, or hard-to-heal, ulcers and represent significant challenges to patients and healthcare systems since they are frequent, costly to manage, recurring, and may persist for months or years. There are an estimated 13-18 million patients in the traditional pharmaceutical markets. Standard treatment consists of compression bandaging and there are no approved pharmaceutical products for VLUs. Only in Europe the costs for VLUs are estimated to exceed 15 billion EUR annually.

### **For additional information, please contact**

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*This information is information that Promore Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 09:30 CET on 22 August 2018.*

#### **Promore Pharma in brief**

Promore Pharma is a biopharmaceutical company specialized in the development of therapeutic peptides for the bioactive wound care market. The company's aim is to develop two first-in-category products for indications where very few efficacious prescription pharmaceuticals are available, thus, addressing high unmet medical needs. Promore Pharma's two projects, PXL01 and LL-37, are in late stage clinical phase. PXL01, that will be used for prevention of post-surgical adhesions and scars, is being prepared for clinical Phase III-studies in patients undergoing tendon repair surgery in the hand. LL-37 is being prepared for a clinical Phase IIb study in patients with venous leg ulcers. The product candidates can also be deployed for other indications, such as preventing dermal scarring and treatment of diabetic foot ulcers. The company is listed on Nasdaq First North with Redeye AB as Certified Adviser.

#### **About LL-37:**

LL-37 is based on a human antimicrobial peptide, structurally derived from the C-terminal part of human cathelicidin antimicrobial protein 18 (hCAP18), and stimulates the function of several cell types involved in wound healing, including skin keratinocytes and fibroblasts. In the Phase IIa study conducted by Promore Pharma in VLU patients, LL-37 showed, in the most effective dose, an increase in healing rate of relative wound area reduction of over 75% after one month treatment, suggesting a significantly higher efficacy than what has been reported for any other treatment in chronic wounds. No serious adverse events that were deemed to be caused by the investigational product occurred in the trial. The product candidate can be combined with the standard wound care treatments and can be applied by nurses or potentially by the patient alone. The development of LL-37 focuses initially on venous leg ulcers but the company sees good potential in developing LL-37 for also diabetic foot ulcers.