Promore Pharma has enrolled first patient in HEAL LL-37 in Poland

STOCKHOLM, 1 October 2018 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that the first patient has been enrolled in the company's Phase II-study (HEAL) with the company's product candidate LL-37 for treatment of venous leg ulcers. The patient is treated at Klinika Flebologii in Warsaw.

Promore Pharma's phase IIb study with LL-37, HEAL (A Study in Patients with **H**ard-to-Heal Venous Leg Ulcers to Measure **E**fficacy **a**nd Safety of **L**ocally Administered LL-37) is anticipated to recruit 120 patients in Sweden and Poland with venous leg ulcers (VLU). 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 for LL-37.

"I am very pleased that the first patient has been enrolled in the HEAL study" said Associated Professor Jan Apelqvist, at the Diabetic Foot Center, department of Endocrinology at the University Hospital of Lund and Malmö (SUS) and Coordinating Investigator for the HEAL study. "There are few approved drug products available for these patients and current therapies for managing VLUs are unsatisfactory. There is therefore an urgent need to develop new strategies and treatments of chronic ulcers, to help these patients and reduce the burden of care in an efficient and cost-advantageous way" he continued.

The study begins with a run-in period of three weeks, in order to identify patients who are under treated and thus do not have a chronic wound. Thereafter, patients are divided into three arms, two where patients receive LL-37 in two different doses 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 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. In Europe alone the costs for VLUs are estimated to exceed 15 billion EUR annually.

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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 09.00 CET on 1 October 2018.

Promore Pharma in brief

Promore Pharma is a biopharmaceutical company specialized in the development of therapeutic peptides. The company's aim is to develop first-in-category pharmaceuticals for indications where very few efficacious prescription pharmaceuticals are available, thus, addressing high unmet medical needs. Promore Pharma's two projects are in late stage clinical development phase and have a very strong safety profile since they are based on innate substances that are administered locally. The leading project, 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 has initiated a clinical phase IIb study in patients with venous leg ulcers (VLU). The product candidates can also be deployed for other indications, such as preventing dermal scarring, adhesions after other surgical procedures and treatment of diabetic foot ulcers. The company is listed on Nasdaq First North.

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.