Promore Pharma has conducted Investigator Meeting for HEAL LL-37 in Poland

STOCKHOLM, 6 September 2018 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that the company has hosted an Investigator Meeting for the HEAL study on 4-5 September 2018 in Warsaw, Poland. The clinical trial HEAL is the Phase IIb study with the company's product candidate LL-37 for treatment of venous leg ulcers.

The meeting gathered physicians, nurses and study coordinators from all clinics in Poland that will participate in the HEAL study and representatives for Promore Pharma, Clinical Research Organisation PCG Clinical Services and subcontractor EastHORN Clinical Services. Some 30 people attended the meeting which took place in Warsaw, Poland. The purpose was to meet study personnel from the participating clinics and to go through the HEAL study to ensure that the study is done in accordance with the Study protocol, guidelines and current rules.

"It is with great anticipation that we have gathered this team of world-leading scientists and physicians that will participate in our clinical trial of LL-37 for treatment of venous leg ulcers. This is one of the last preparatory steps in order to commence the enrolment of patients into this clinical study in Poland.", said Jonas Ekblom, President and CEO of Promore Pharma.

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 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 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. 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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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.