# Promore Pharma has recruited half of the patients in HEAL LL-37

***STOCKHOLM, 20 June 2019 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that half of the patients have been enrolled and started the treatment in the company's Phase II-study (HEAL) with the company's product candidate LL-37 for treatment of venous leg ulcers. With the same pace in recruitment all patients should be included and randomized in the beginning of 2020.***

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 with venous leg ulcers (VLU) in Sweden and Poland. Promore Pharma received approval from the medical product agencies in Sweden and Poland in the third quarter 2018 and could announce that the first patient was recruited in October 2018.

"I am happy and satisfied that we have reached enrolment of half of the patients that should be recruited in the HEAL study," said Jonas Ekblom President and CEO of Promore Pharma. "We have actively worked with the clinics to support our plan. The recruitment rate has varied from month to month, which is usually the case in all clinical trials, but overall, we have kept our timetable. It is also very satisfactory that we have not seen any safety issues and that very few patients have dropped out from the trial" he continued.

The study is randomized and double blind. The primary endpoint is the proportion of patients that have completely healed wounds. 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 study begins with a run-in period of three weeks, in order to identify patients who are under-treated and therefore 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 is administered two to three times a week in connection with regular change of wound dressing and will be ongoing for 13 weeks. The post-treatment follow-up period is four months.

On the traditional pharmaceutical markets, there are an estimated 13-18 million patients with VLUs and these wounds constitutes the largest category of all chronic, or hard-to-heal, ulcers. VLU represent significant challenges to patients and healthcare systems since they are frequent, costly to manage, recurring, and may persist for months or years. 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. 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.