Promore Pharma has finalized recruitment of patients in HEAL LL-37 early

STOCKHOLM, 10 December 2019 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announce that all patients in the company's Phase IIb-study (HEAL) with LL-37 for treatment of venous leg ulcers have been recruited. Results from the study are expected to be available in the fourth quarter 2020.

The aim with 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 that 120 patients with venous leg ulcers (VLU) in Sweden and Poland should complete the study protocol. Now all patients that are assessed to be required have been recruited at 15 clinics in Poland and Sweden. Promore Pharma hope that the study will show that treatment with LL-37 significantly increases the probability for an accelerated wound healing of chronic wounds.

"I am extremely content that we have successfully recruited all patients in the HEAL study earlier than anticipated. It is very uncommon for recruitment to go faster than planned and I would like to give a great deal of credit to those within the company, and the clinics, that have accomplished this", says Jonas Ekblom, president and CEO of Promore Pharma. "We expect to be able to communicate a clear timetable for the completion of the study result in connection with the finalization of the statistical analysis plan at the turn of the half-year. We aim to be able to communicate data from the study, in connection with our interim report for the third quarter of 2020, at the latest" he continues.

The study, which is randomized and double blind begins with a run-in period of three weeks, in order to eliminate 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. The company announced that the first patient was recruited to the study in October 2018 and that half of the required patients were recruited and randomized in June 2019.

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. The cost for treating one VLU episode is over 10,000 USD. The company therefore consider that there is a great need for the candidate drug, both from the patient's and society's perspective.

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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 is performing 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 Growth Market.

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.