Promore Pharma reached the targeted number of patients completing treatment in the HEAL LL-37 Phase IIb clinical trial

STOCKHOLM, 24 March 2020 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announce that last patient has been dosed in the treatment phase of the company's Phase IIb-study (HEAL) with LL-37, a new candidate drug for treatment of venous leg ulcers. The company reached its target of treating 120 patients with LL-37 for three months. The company assesses that results from the study can be presented in the fourth quarter 2020 in accordance with earlier communications.

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) was that 120 patients with venous leg ulcers (VLU) in Sweden and Poland should complete the study protocol. Despite current challenges within the health care systems in Poland and Sweden following the Corona virus outbreak, the study has been carried out according to plan and 120 patients have now completed the treatment phase. Promore Pharma envisions that the study will show that treatment with LL-37 significantly increases the probability for an accelerated wound healing of chronic wounds.

"We are very grateful that we were able to complete the treatment of patients in the study in accordance with our operating plan and in retrospect it proved extremely valuable that we managed to accelerate the recruitment in the study in the end of 2019," says Jonas Ekblom, CEO of Promore Pharma. "It is satisfactory that no patients have demonstrated any serious adverse effects associated with LL-37 during the treatment period. Our intention is that we will communicate a clear timetable for the completion of the study result around mid-year, and we are anticipating to being able to present the outcome of the study during the fourth quarter," he continues.

The study, which is randomized and double blind has involved 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 have been divided into three arms, two where patients receive LL-37 in two different doses and a placebo arm. The treatment has been administered two to three times a week in connection with regular change of wound dressing and lasted for 13 weeks. The post-treatment follow-up period is four months. The study was started in October 2018 when the first patient was recruited and was fully recruited in December 2019, ahead of schedule.

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 prescription pharmaceuticals for VLUs on the traditional pharmaceutical markets. The cost for treating one VLU episode exceeds 10,000 USD. The company therefore consider that there is a great need for the candidate drug, both from the perspective of both the patients and the healthcare system.

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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.