Promore Pharma receives approval for Phase IIb trial with LL-37

STOCKHOLM, 3 July 2018 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, announces that the Swedish Medical Products Agency has approved the company's application to start a Phase IIb study with LL-37 for treatment of venous leg ulcers (HEAL).

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) with a size up to 40 square centimeters. 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 (0.5 and 1.6 mg/mL) 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 of LL-37. The post-treatment follow-up period is four months.

"This is an important step in our ambition to develop a new treatment for this common disease. The Swedish Medical Products Agency´s approval means we can start recruitment of patients in the coming months, in line with what we have previously communicated", says Jonas Ekblom, President and CEO of Promore Pharma. "A new product for treatment of venous leg ulcers would mean a huge step forward within the gigantic therapeutic area that is wound and trauma", he continues.

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. Only in the US the costs for VLUs are estimated at a minimum of USD 14 billion 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.