Promore Pharma is granted a patent for LL-37 in Japan

STOCKHOLM, 27 August 2019 – Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that the company was granted a patent in Japan for the usage of LL-37 for treating chronic wounds.

The Japanese patent authority has formally granted the patent "*New Treatment of Chronic Ulcers*" with LL-37. The patent is valid until 19 November 2034. Patents within the same patent family have previously been granted in the USA. In the territories Europe, Russia, Canada, South America , other Asia and South Africa the patent review is in an early stage.

"This is an important step in our continuous work to secure an optimum protection for our innovative candidate drug. The ultimate purpose is to secure exclusivity for our products on the market after launch for a period that is as long as possible," said Jonas Ekblom President and CEO of Promore Pharma.

HEAL LL-37 is the company's ongoing clinical phase IIb trial, which 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. The aim is that 120 patients should complete the study protocol.

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.