Promore Pharma Signs Agreement with CRO PCG Clinical Services

STOCKHOLM, 31 October, 2017 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that an agreement has been entered with PCG Clinical Services AB for the management of the LL-37 Phase IIb trial in patients with hard-to-heal leg ulcers. PCG was selected from several potential partners in a competitive process.

Promore Pharma has signed an agreement with CRO PCG Clinical Services regarding the management of Promore Pharma's LL-37 Phase IIb trial in patients with venous leg ulcers (VLU). The trial is anticipated to recruit 120 patients in Sweden and Poland in three treatment groups (two doses versus placebo). The study will have a run-in period of three weeks to rule out wounds that are not chronic, ie wounds which have failed to proceed through an orderly and timely reparative process to produce anatomic and functional integrity over a period of three months. The treatment period is twelve weeks and patient enrolment is planned to start in 2018.

"PCG Clinical Services has outstanding experience in clinical trials of advanced therapies. With strong investigator relationships, proven operational expertise and a track record of generating high-quality data, they are the ideal partner for this important trial," said Jonas Ekblom, President and CEO of Promore Pharma. "Given the initiation of our Phase II study in 2018 and that we anticipate to utilize more than 15 participating sites, we can confidently plan on providing initial efficacy data in the second half of 2019", he continued.

"PCG Clinical Services is proud to continue its long relationship with Promore, a true leader in the wound care research and development. We hope this study leads to an effective treatment for VLU and improves the lives of patients that suffer from these hard-to-heal wounds. PCG Clinical Service looks forward to advancing our partnership with Promore by performing this study." said Henrik Blombergsson, Chairman of PCG Clinical Services.

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.

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.

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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 has two projects, PXL01 and LL-37, 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 and LL-37 that is 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.

PCG Clinical Services in brief:
PCG Clinical Services is based out of Uppsala, Sweden and the company is recognized as one of the premiere CRO's in the Nordics, having extensive experience conducting clinical trials over multiple therapy areas across Phase I through Phase IV trials. PCG Clinical Services provides a wide range of clinical services, from Advisory and Project Management, through to monitoring, clinical operations, EDC, biometrics, data management, medical writing, and QA.