Promore Pharma announces positive results from Phase IIb study of ropocamptide in the treatment of venous leg ulcers

STOCKHOLM, 19 November 2020 -- Promore Pharma AB today announces the results of the company's phase IIb clinical trial of ropocamptide (LL-37), which is a new candidate drug for the treatment of venous leg ulcers. Patients with larger leg ulcers (≥10 cm2), which is the group most in need of new treatment methods, show a notable and statistically significant improvement compared with placebo, while no statistically verifiable differences could be detected for the total study group. The improvement resulting from ropocamptide treatment was more pronounced in the group of patients receiving 0.5 mg/ml, which confirms the dose-response findings of the company's former Phase II trial.

The results from Promore Pharma's clinical trial HEAL LL-37, where a total of 144 patients were treated with two different doses of ropocamptide (0.5 mg/ml and 1.6 mg/ml) or placebo, have now been analyzed. The study show that larger wounds (≥10cm2) healed significantly faster among patients treated with ropocamptide as compared with placebo. Patients treated with the most effective dose of ropocamptide, which is 0.5 mg/ml, demonstrated a more than three-fold higher frequency of completely healed wounds. At an aggregated level, where wounds of all sizes included in the study were analyzed, no significant differences can be noted at the whole group level between the three treatment groups.

In patients with larger wounds that were treated with 0.5 mg/ml ropocamptide, 28.1% achieved complete wound healing, in the group treated with 1.6 mg/ml ropocamptide 19.6%, whereas only 8.1% of patients in the placebo group showed complete healing. This difference is statistically significant ($p < 0.05$) for the most effective dose group. When analyzing the proportion of patients who achieved 70% healing of their wounds, a statistically significant advantage could be demonstrated for both dose groups of ropocamptide compared to placebo ($p<0.05$). The mean reduction in wound size after discontinuation of treatment was 33.7% for patients treated with placebo, and 56.3% for patients treated with the most effective dose of ropocamptide (0.5 mg / ml). Regarding safety and tolerability, no serious side events have been noted that can be considered related to the trial drug.

"These findings are promising and suggest a treatment value of ropocamptide for patients with large venous leg ulcers, the patient population most difficult to treat with today's medical devices, and give us the necessary information for planning of confirmatory trials to come," said Margit Mahlapuu, CSO of Promore Pharma.

Ropocamptide, that is a naturally occurring peptide in humans, has been formulated as a viscous hydrogel that is administered locally in conjunction with regular dressing changes. The study, which is randomized and double-blind, began with a three-week placebo treatment to exclude patients who are undertreated and thus do not have a chronic wound. Thereafter, the patients were divided into three arms, two arms where the patients received ropocamptide in two different doses and a placebo arm. The treatment was administered twice a week in connection with regular wound dressing changes and lasted for a total of thirteen weeks. Despite current challenges in the healthcare system, in both Poland and Sweden, as a consequence of the COVID-19 pandemic, the study has been completed according to plan and the goal of reaching 120 patients that have undergone the entire study protocol could be achieved.

"It is very satisfying that we have been able to conclude the HEAL LL-37 trial with high quality and that we have been able demonstrate a clear-cut efficacy of ropocamptide in larger wounds in yet another clinical study, where current treatment alternatives generally are insufficient," says Jonas Ekblom, CEO of Promore Pharma. "We will now assess the outcome of the study further and based on our conclusions, define the optimal development path of ropocamptide," he continues.

On the traditional pharmaceutical markets, there are an estimated 13-18 million patients with hard-to-heal wounds and venous leg ulcers (VLUs) constitute the largest subcategory of these wounds. Of these, large wounds (≥10 cm2) constitute approx. 20% - 30%. Not least due to longer treatment times, larger wounds are considerably more costly for the healthcare system.

VLUs 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 for the healthcare system. The company therefore consider that there is a great need for the candidate drug, both from the perspective of 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, ensereptide (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. Ropocamptide (LL-37) has recently been evaluated in 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 ropocamptide (LL-37):

Ropocamptide 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, ropocamptide 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 ropocamptide focuses initially on venous leg ulcers but the company sees good potential in developing ropocamptide for also diabetic foot ulcers.

This information is information that Promore Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2020-11-19 14:37 CET.

Attachments

Promore Pharma announces positive results from Phase IIb study of ropocamptide in the treatment of venous leg ulcers