Clarification of outcome in the clinical trial HEAL LL-37

Stockholm 20 November 2020 – On 19 November 2020, Promore Pharma reported results from the clinical trial with ropocamptide for the treatment of venous leg ulcers, HEAL LL-37, and the company hereby wants to make some clarifications regarding the study execution and the results from the trial.

- **Subgroup analysis:** Besides analysis of the total study population, a subgroup analysis has been performed in the HEAL LL-37 trial, where patients have been grouped based on wound size (<10 cm2 or ≥10 cm2). This subgroup analysis regarding efficacy was not part of the original statistical analysis plan, but has been performed in accordance with the analyses described in the statistical analysis plan for the total population. It is generally recognized that wound area size of 10 cm2 or larger represents an important negative prognostic factor for venous leg ulcers (VLUs). Hence, that is why the company has chosen this particular cut-off point. It is notable that the randomization schedule in the clinical study protocol was also stratified based on wound size (<10 cm2 eller ≥10 cm2).

- **Treatment doses:** It is expected that ropocamptide has a bell-shaped dose response curve, as is the case for several other immunomodulating and paracrine substances. The outcome in this study confirms the findings in the company's first clinical trial, as 0.5 mg/ml seems to be the most effective dose in both studies.

- **Results in the subgroup "Large wounds ≥10 cm2":** TThe findings regarding efficacy in the patient group with large VLUs are clear and convincing (complete healing 28.8% with ropocamptide 0.5 mg/ml vs. 8.1% with placebo). A substantial part (46%) of the randomized patients in HEAL LL-37 had wounds equal or larger than 10 cm2. Moreover, the fact that statistical significance ($p<0.05$) is reached for several interrelated parameters, minimizes the risk of serendipitous findings.

- **Market potential:** The company estimates that there is a very appealing opportunity to introduce a differentiated product to the market that represents a treatment value for the patients with larger VLUs. Data from other studies suggests that approximately 20-40% of all VLUs are 10 cm2 or larger [ref. 1 - 3], i.e. the subgroup where ropocamptide 0.5 mg/ml has shown significant efficacy. Today, large VLUs costs are approximately 6-15 times [ref. 3] more expensive than wounds smaller than 10 cm2 (not least due to the longer treatment time and no current effective treatment), which implies a potential premium prizing for the segment. That would in turn imply that ropocamptide could address 60-90% of the value of the VLU market.

- **Study quality:** The company emphasizes that the technical quality of HEAL LL-37 is very high. For a study of this size, there has been few significant deviations, and no deviations are judged to compromise the trial quality.

References

1) Ebbeskog B, et al. Leg and foot ulcer patients. Epidemiology and nursing care in an urban population in South Stockholm, Sweden. Scand J Prim Health Care 1996;14:23&243

2) Margolis DJ, et al. The accuracy of venous leg ulcer prognostic models in a wound care system. Wound Repair Regen. 2004 Mar-Apr; 12(2):163-8

3) Ragnarsson Tennvall G et al. The cost of treating hard-to-heal venous leg ulcers: results from a Swedish survey. World Wide Wounds 2005, http://www.worldwidewounds.com/2006/november/Tennvall/Cost-of-treating-hard-to-heal-venous-leg-ulcers.html

For additional information, please contact

Jonas Ekblom, CEO
Phone: [+46] 736 777 540
E-mail: jonas.ekblom@promorepharma.com

Erik Magnusson, CFO
Phone: [+46] 708 565 245
E-mail: erik.magnusson@promorepharma.com

Promore Pharma's Certified Adviser is Redeye AB.
Phone: [+46] 8 121 576 90
E-mail: certifiedadviser@redeye.se

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.

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 2020-11-20 16:25 CET.

Attachments

Clarification of outcome in the clinical trial HEAL LL-37