Promore Pharma reports outcome from clinical Phase II study with ensereptide

STOCKHOLM, April 20, 2023 -- Promore Pharma AB today announces that the results from the company's Phase II study PHSU05 with ensereptide in prevention of skin scarring have been concluded. Results from the study show that the investigational drug ensereptide is safe and tolerable, which was the clinical trial's primary study objective. However, no clear differences in the efficacy on reducing the scarring were observed between ensereptide and placebo.

The company's most recent clinical study of ensereptide has focused on the prevention of scars on the skin associated with surgery or trauma. A total of 24 subjects have completed the study protocol in PHSU05, which is the company's Phase II study with ensereptide. At the subjects' last visit to the clinic, skin biopsies were collected. These biopsies have been evaluated with advanced histological methods during the autumn and winter of 2022/2023. When data from the study has now been analyzed, the following main findings are concluded:

i) The application of the investigational drug ensereptide could be administered without complications and there were no differences between the application of ensereptide and the application of placebo.
ii) No serious adverse events were reported. There was no difference in the frequency of local adverse reactions between ensereptide and placebo. The majority of adverse events were classified as mild and unlikely to be caused by the investigational drug.
iii) There were no statistically verifiable differences between ensereptide and placebo in the secondary endpoints comprising two clinical rating scales for dermal scarring.
iv) In the histopathological analysis of skin biopsies from the subjects, there was no clear evidence of treatment effect of ensereptide compared to placebo.

> "Given previous positive results for ensereptide in our hand surgery study, we had expected to see a treatment effect of ensereptide compared to placebo also in this clinical study. The quality of the study has been high, and we consider its findings to be reliable. It is regrettable that the results indicate that there is no tangible treatment value of ensereptide in this medical indication," says Jonas Ekblom, CEO of Promore Pharma.

Promore Pharma´s Board of Directors and management will now evaluate the situation that has arisen in order to decide on the future of the ensereptide project.

"Promore Pharma´s other project, ropocamptide, which is being developed for the healing of chronic wounds, is not affected by the medical results from the PHSU05 study since ropocamptide is a different substance with a completely different mechanism of action than ensereptide. This means that the Company still sees significant value in the ropocamptide project", he finishes.

The PHSU05 study was a double-blind, randomized Phase II pilot study with the goal of evaluating ensereptide regarding (i) local tolerance, (ii) the application process of the investigational drug, and (iii) preliminary efficacy regarding scar prevention after experimentally induced wounds in healthy volunteers. The clinical part of the study, which was carried out at Clinical Trial Consultants AB's clinic in Uppsala, has been completed and a total of 24 subjects have been included. No major deviations were reported following analysis of monitoring data from the clinical part of the study.

Pre-clinical studies have shown that ensereptide has an anti-inflammatory and pro-fibrinolytic effect. Ensereptide has previously undergone a randomized double-blind phase IIb study with 138 patients with flexor tendon injuries in the hand with a positive outcome, that reflected a lower degree of scar formation in patients treated with ensereptide.

About Promore Pharma

Promore Pharma is a biopharmaceutical company that develops pharmaceutical product candidates for bioactive wound care. Today, the company has two drug candidates in late clinical development stages, that are based on endogenous peptides, and thus have a strong safety profile. These two products are intended for treatment of chronic wounds, and prevention of scarring on the skin and other tissues. The company is listed on the Nasdaq First North Growth Market.

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Attachments

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