

Promore Pharma reaches the Clean File milestone in its phase II clinical trial with ensereptide

STOCKHOLM, 27 February, 2023 -- Promore Pharma AB announces today that the Clean File milestone has been achieved in the PHSU05 clinical trial. The publication of the results from the company's phase II study PHSU05 with ensereptide for prevention of skin scarring is expected to be available in the second half of April 2023.

The company's ensereptide program is currently focused on the prevention of skin scarring associated with surgery or trauma. During 2022, a total of 24 subjects completed the study protocol as planned in PHSU05, the company's phase II study with ensereptide. With this clinical trial, Promore Pharma hopes to be able to demonstrate that treatment with ensereptide reduces the likelihood of scarring on the skin. At the last clinic visit, biopsies were collected and these tissue samples have been evaluated with advanced histological methods during the fall and winter. The remaining work involve statistical processing, unblinding and analysis of the study results. A read-out of results from the trial is expected in the second half of April 2023.

"Our clinical study PHSU05 has so far progressed completely according to our plan in all areas that we can influence. I am very pleased that we have reached this important milestone in the clinical trial. This means that we can determine with greater certainty that the unblinded final results from the study should be available by the end of April," says Jonas Ekblom, CEO of Promore Pharma.

The study is a double-blind, randomized phase II pilot study with the goal of being able to evaluate ensereptide regarding (i) local tolerance, (ii) the application process for the experimental drug, and (iii) preliminary efficacy regarding scar prevention in experimentally induced wounds in healthy volunteers. The clinical part of the study, which has been conducted at Clinical Trial Consultants AB's clinic in Uppsala, has been completed. Analysis of monitoring data from the clinical part of the study shows that the number of deviations from the study protocol has been few, and no major deviations have been reported.

Scars appear after virtually all types of injuries to the skin. Although scars can often be considered trivial, a large proportion of them can be disfiguring and aesthetically undesirable, and they can also cause itching, stiffness, sleep problems, anxiety, depression and create a negative impact on activities of daily life.

The world market for products for the treatment of scars, including laser treatment, scar revision and self-care products, is estimated at USD 25 billion annually with a yearly growth of about 10%, according to independent estimates. Today, there are no prescription pharmaceuticals for scar prevention.

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 Pharms Certified Adviser is Erik Penser Bank

Tel: [+46] 8-463 83 00

E-mail: certifiedadviser@penser.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 with high unmet medical needs, where very few efficacious prescription pharmaceuticals are available. Promore Pharma's two projects are undergoing clinical development and have a very strong safety profile since the products are based on endogenous substances that are administered locally. The leading project, ensereptide (PXL01), that will be used for prevention of post-surgical scarring, is undergoing a clinical phase II-trial if the peptide can prevent the formation of unesthetic scars on the skin. Ropocamtide (LL-37) has recently been evaluated in a clinical phase IIb study with positive results in patients with venous leg ulcers (VLUs). The product candidates can also be deployed for other indications, such as preventing unfavorable tissue attachments (adhesions) after different kinds of surgical procedures and treatment of diabetic foot ulcers. The company is listed on Nasdaq First North Growth Market.

Attachments

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