Promore Pharma provides an update on the Phase II clinical trial with ensereptide

STOCKHOLM, 1 November 2022 – Today, Promore Pharma AB announces that the results from the company's phase II study PHSU05 with ensereptide for prevention of skin scarring is expected to be available in April 2023. The clinical part of the trial was completed according to plan earlier this year, but the limited availability of qualified personnel and specialized image analysis equipment results in a slightly longer duration of the subsequent histopathological analysis than originally expected.

The company's ensereptide program is currently focused on the prevention of skin scarring associated with surgery or trauma. In the spring, a total of 24 subjects completed the clinical study protocol according to plan in the phase II study with ensereptide, PHSU05. In this study, Promore Pharma hopes to demonstrate that treatment with ensereptide reduces the likelihood of scarring on the skin. At the last clinic visit, biopsies were collected that are being analyzed with advanced histological methods during the autumn and fall of 2022 /2023. However, the limited availability of qualified personnel and specialized image analysis equipment has caused a few weeks' shift in the original timeline. A final study report with results from the trial is expected in April 2023.

“Our clinical study PHSU05 has so far progressed entirely according to our plan in all parts that we can influence. Access to advanced equipment for digital image analysis at our service providers means that we are forced to carry out certain analysis steps serially rather than in parallel. This means a minor time shift until we can unblind the data and compile final results. However, we would like to emphasize that this does not have any negative impact on the quality of the study execution,” says Jonas Ekblom, CEO of Promore Pharma.

The study is a double-blind, randomized phase II pilot study with the aim of evaluating ensereptide regarding (i) local tolerance, (ii) the application process for the experimental drug, as well as (iii) preliminary effect on scar prevention in healthy volunteers with experimental wounds. The clinical part of the study that was conducted at the Clinical Trial Consultants AB's clinic in Uppsala was completed and a total of 24 subjects were included. 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 were reported. The company expects to reach the milestone of Clean File in the project during the first quarter of 2023, which will be announced by the company. At that time, the timeline for subsequent work with the aim of achieving an outcome report can be determined with higher precision.

Scars appear after virtually all types of damage 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.

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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 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 endogeneous 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 unesthetical scars on the skin. Ropocamptide (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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