

Promore Pharma receives permits to start a phase II clinical trial regarding scar prevention

Stockholm, November 9, 2021 - Promore Pharma AB, a Swedish biopharmaceutical company that develops peptide-based drug candidates, announced today that the company has received approval from the Medical Products Agency and the Swedish Ethics Review Authority to begin a clinical phase II trial of ensereptide for skin scarring prevention.

The company announces today that a clinical trial permit has been obtained from the Medical Products Agency in Sweden and that the company's application for approval from the Ethical Review Authority has also been granted. PHSU05 is a Phase II pilot study with the aim of being able to evaluate ensereptide regarding (i) local tolerance, (ii) the application process of the experimental drug, and (iii) preliminary effect on scar prevention after experimentally induced wounds in healthy volunteers. Planned study start is Q1 2022 and results from the study are expected in the winter of 2022/2023.

"This is an important step in our long-term goal of developing a new product concept to prevent the occurrence of post-surgical and post-traumatic scars on the skin. These approvals are fully aligned with our operational plan in the ensereptide project", says Jonas Ekblom, CEO of Promore Pharma.

Bolagets ensereptide-program fokuseras för närvarande på prevention av ärr i huden i samband med kirurgi eller trauma, men det finns även potential att utveckla produkten för andra medicinska applikationer som prevention av sammanväxning efter hand- och ryggradskirurgi.

The company's ensereptide program is currently focused on the prevention of scarring of the skin in connection with surgery or trauma, but there is also potential to develop the product for other medical applications such as prevention of adhesions after surgeries in the hand or spine.

Scars develop 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 pleasing, and they can also create itching, stiffness, sleep problems, anxiety, depression and negatively affect activities of daily life.

The world market for products for the treatment of scars, including laser treatment, scar revision and self-care products, amounts to USD 25 billion with an annual growth of about 10%, according to independent estimates. Today, there are no prescription drugs for wound 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 being prepared for 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.

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 2021-11-09 11:38 CET.

Attachments

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