

Promore Pharma receives delivery of hyaluronic acid from Italian manufacturer Fidia

Stockholm 00 September 2021 – Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, have today announced that a product component of ensereptide has been manufactured, released according to Good Manufacturing Practice, and delivered to Promore Pharma.

Promore Pharma has partnered with Fidia Farmaceutici S.p.A. ("Fidia") for the production of hyaluronic acid, which is one of the components of Promore Pharma's investigational drug ensereptide. Fidia is a world-leading manufacturer of pharma grade hyaluronic acid. Fidia has delivered high quality services resulting in the successful milestone being met. Ensereptide is being developed as a treatment to prevent skin scarring and post-surgical adhesions.

The manufacturing, technical release and delivery of this product component means that the PHSU05 project is on schedule. PHSU05 is a Phase II pilot study aimed at evaluating local tolerance, the application process for ensereptide and the preliminary effect of the study drug to prevent scarring after experimentally induced full-thickness wounds in healthy volunteers.

"We are well on our way in preparing a clinical trial application with the aim of starting patient enrollment during the first quarter of 2022" says Jonas Ekblom, CEO of Promore Pharma.

The company's ensereptide program is currently focused on the prevention of skin scarring after surgery or trauma but foresees potential to also develop products based on ensereptide for other medical applications such as prevention of adhesions after tendon repair surgery and spinal surgery.

Scars arise after almost every dermal injury. While scars are often considered trivial, a notable proportion of scars can be disfiguring and aesthetically unpleasant and cause severe itching, tenderness, pain, sleep disturbance, anxiety, depression, and disruption of daily activities.

The global scar treatment market, including laser treatment, scar revision surgery and over-the-counter products, is estimated at USD 25 billion with an annual growth of approximately 10%, according to independent estimations. Today, there are no pharmaceutical prescription products available for preventing scar formation.

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 being prepared for a clinical phase II-trial if the peptide can prevent the formation of unesthetic 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.

Fidia Farmaceutici in brief

Fidia is an Italian multinational company, with R&D, manufacturing, marketing and sales capabilities, and an extensive product portfolio mainly based on hyaluronic acid (HA) in joint care, advanced wound care, ophthalmology, aesthetic and autologous biological therapy. Over 55 years of R[PE1] &D have placed Fidia at the forefront in the production of natural and functionalized HA, with different ranges of MW (1,100 patents). The corporation has its manufacturing operations located in Italy, which is inspected and approved by major international health authorities, including the US and Korean FDA, the Brazilian ANVISA and the G-MED Notified Body, and comply with the strictest international regulations and safety standards. Fidia extends its global reach through local partners in 100+ countries worldwide, as well as wholly owned subsidiaries in USA, Germany, Austria, Spain, France, Russia, Czech Republic, Slovakia, Romania, Egypt, and Middle East.

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Attachments

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