

Promore Pharma signs agreement on production of hyaluronic acid with Italian manufacturer Fidia

Stockholm 28 April 2021 – Promore Pharma AB and Fidia Farmaceutici S.p.A. ("Fidia") have today signed an agreement 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, and the agreement will make it possible for Promore Pharma to procure raw material of optimal quality at the required future scale. Ensereptide is being developed as a treatment to prevent the skin scarring and post-surgical adhesions.

Promore Pharma has previously announced that the company has worked to solve a number of manufacturing-related technical problems, and to optimize the production process for the experimental drug ensereptide, which is a new treatment to prevent undesirable scarring after surgery. The product consists of a kit with several components and is provided through contract manufacturing where service providers in both the USA and Europe are involved.

Fidia holds an international key position in the production of both natural and functionalized hyaluronic acid. The company, that is privately owned, manufactures its own products that are available on a large number of international markets. Given its expertise on manufacturing processes for a range of hyaluronic acid products, Fidia also serves as a CMO partner for other companies.

"I am very happy to enter into this agreement with Fidia, that is an industry-leading manufacturer of hyaluronic acid. This means that we will now be able to keep a high pace in the continued development of the ensereptide project. At the same time, Fidia has a reliable production process and manufacturing capacity that is highly suitable for our requirements, not least in regard to upscaling and future commercial production of key components of our ensereptide product kit", says Jonas Ekblom, CEO of Promore Pharma.

"We are very excited to support an innovation company such as Promore Pharma, and to expand the range of applications of our hyaluronic acid products," says Carlo Pizzocaro, President and CEO of Fidia Farmaceutici. He continues: "Our high-viscosity hyaluronic acid materials represent an important competitive advantage of Fidia."

Promore Pharma's ensereptide program is currently focused on the prevention of skin scarring after surgery or trauma but the company 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. The company is currently planning to conduct a Phase II clinical trial with the aim of investigating the utility of ensereptide for prevention of skin scarring after surgical incisions in Europe.

Scars arise after almost every dermal injury. While scars are often considered trivial, a notable proportion of scars can be disfiguring, 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 drugs, is estimated at 25 billion USD 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 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.

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&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.

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

 $\textbf{E-mail:} \ \underline{erik.magnusson@promorepharma.com}$

Promore Pharmas Certified Adviser is Erik Penser Bank

Tel: [+46] 8-463 83 00

E-mail: certifiedadviser@penser.se

Attachments

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