Promore Pharma has had a successful meeting with the FDA regarding PXL01

STOCKHOLM, 23 October, 2018 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that that it has had a successful meeting with the US Food and Drug Administration (FDA) regarding the continued development of PXL01.

Promore Pharma has had a Pre-Investigational New Drug Meeting with the FDA to discuss manufacturing, quality, nonclinical and clinical documentation for PXL01, the design of a potential Clinical Phase III study in North America, as well as the road to a market approval in North America. The FDA confirmed that completed manufacturing documentation and plans, as well as nonclinical safety and local tolerability studies, provide a good basis for a proposed next clinical trial. The FDA concluded that the next clinical trial in the United States, where design is still being discussed, in combination with the results of the Clinical Phase III trial in Europe (PHSU03) could be feasible as a basis for a U.S. Market Application. The FDA had no concerns regarding Promore Pharma's product concept, with a pre-filled sterile syringe for local administration in connection to the surgery.

"We are very pleased with the outcome of the meeting with the FDA. We have now confirmed that we have satisfactory material for the continued development of PXL01 and we have received valuable recommendations for our regulatory roadmap in the US," said Jonas Ekblom, President and CEO of Promore Pharma. "This is a very important step for discussions with potential partners for a clinical study in North America", he continued.

The development of PXL01 is initially aiming at preventing postsurgical adhesions after tendon repair surgery in the hand. Postsurgical adhesions constitute a substantial clinical problem after most surgical procedures, and particularly in conjunction with hand surgery. Flexor tendon injury and repair result in adhesion formation around the tendon, which restricts the gliding function of the tendon, leading to decreased digit mobility and impaired recovery of normal hand function. Promore Pharma is preparing for a clinical Phase III study in EU and India which will form the basis for a market approval in the EU. The trial is planned as a randomized, double-blinded study including 500-600 patients with flexor tendon injuries in the hand, where a single administration event of PXL01 at two different doses will be compared with placebo.

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This information is information that Promore Pharma AB 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 17.30 CET on 23 October 2018.

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 where very few efficacious prescription pharmaceuticals are available, thus, addressing high unmet medical needs. Promore Pharma's two projects are in late stage clinical development phase and have a very strong safety profile since they are based on innate substances that are administered locally. The leading project, PXL01, that will be used for prevention of post-surgical adhesions and scars, is being prepared for clinical phase III-studies in patients undergoing tendon repair surgery in the hand. LL-37 has initiated a clinical phase IIb study in patients with venous leg ulcers (VLU). The product candidates can also be deployed for other indications, such as preventing dermal scarring, adhesions after other surgical procedures and treatment of diabetic foot ulcers. The company is listed on Nasdaq First North.

About PXL01

PXL01 is derived from a human anti-bacterial protein (lactoferrin), which is part of the innate immune system. This protein and its fragments have several modes of action, including immunomodulation and enhancement of fibrinolytic activity. It is well established that inflammation and fibrin formation after surgery are two pivotal mechanisms that strongly contribute to scar formation. The development of PXL01 is initially aiming at preventing postsurgical adhesions after tendon repair surgery. In a Phase II clinical study that has been completed by the company in several EU countries, it has been demonstrated that PXL01 is efficacious and safe.

Promore Pharma is preparing for a clinical Phase III study in EU and India. The trial is planned as a randomized, double-blinded study including 500-600 patients with flexor tendon injuries in the hand where a single administration event of PXL01 at two different doses will be compared with placebo. The company's ambition is to carry out a similar Phase III clinical trial of PXL01 in North America in order to achieve market authorization in the US and Canada.

Postsurgical adhesions constitute a substantial clinical problem after most surgical procedures, and particularly in conjunction with hand surgery. Flexor tendon injuries and repair result in adhesion formation around the tendon, which restricts the gliding function of the tendon, leading to decreased digit mobility and impaired recovery of normal hand function. Small decreases in mobility greatly impact the quality of life due to difficulties in performing easy tasks, such as closing buttons or using a key board. Tendon injuries affects more than 300,000 persons per year in the US, of which around 30% in the hand. It is estimated that up to 50% of these patients never recover full mobility in the hand.