Promore Pharma modifies its Phase III trial of PXL01 and expands the number of clinics in the study

STOCKHOLM, February 1, 2019 - Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that the company is making adjustments to the manufacturing chain of the investigational medicinal product for the company's clinical phase III study, PSHU03, with PXL01 for prevention of adhesions following tendon repair surgery. The adjustments mean that the provision of investigational medicinal product is delayed. To minimize the overall delay, the company intends to increase the number of clinics in order to enable faster recruitment of patients to the study.

Promore Pharma has previously announced that the company in 2018 has worked on solving a number of manufacturing issues for the investigational medicinal product for the PSHU03 study. The product consists of a kit with several components and is supplied through contract manufacturing where service providers in both the USA and Europe are engaged. One of these service providers has not succeeded in renewing all of the manufacturing permits required, which affects the coordination of the manufacturing chain, and it consequently cannot be implemented according to the original plan.

The objective of the changes in the manufacturing network is to improve production capacity as well as process quality in the long term, as well as reduce the risk and dependence on individual service providers in the manufacturing process. In order to reduce the likelihood of time losses on the way to market approval, the company plans to increase the number of clinics in the PHSU03 study by also including a number of hospitals in Italy, thereby minimizing the overall delay by accelerating the recruitment of patients.

"PXL01 is provided as a sterile-packaged product for use in surgery," said Jonas Ekblom, President and CEO of Promore Pharma. "We are convinced that these planned changes help us build a manufacturing supply chain with optimal quality and commercial scalability of our future product for the prevention of undesirable adhesions following tendon repair surgery. We are working towards the goal of being able to start our clinical study no later than the first half of 2020", 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. Serious tendon injuries affect more than one million persons per year in the traditional pharmaceutical markets, of which around 30% in the hand. It is estimated that up to 50% of these patients never recover full mobility in the hand.

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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 09.45 CET on 1 February 2019.

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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 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 approximately 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.