

Promore Pharma Regains Rights for PXL01 Manufacturing

STOCKHOLM, SWEDEN, February 15, 2018 – Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that it will assume responsibility for the manufacturing of the investigational medicinal product for the clinical Phase III trial for PXL01 and at the same time, the company regains the global manufacturing rights for the commercial product.

In March 2016, Promore Pharma entered into an agreement with PharmaResearch Products Ltd ("PRP") regarding development collaboration on PXL01, complemented by a manufacturing agreement in January 2017. In accordance with the agreements, PRP has contributed to the financing of the Phase III clinical trial on PXL01 through milestone payments as well as manufacturing of investigational medicinal product for the trial. In cooperation with Promore Pharma, PRP has been working intensively to prepare the manufacturing. Since the clinical trial will be conducted primarily in Europe, the parties have now agreed that Promore Pharma will assume responsibility for the manufacturing of investigational medicinal product to facilitate control of manufacturing and product supply for the trial. At the same time, Promore Pharma regains the global manufacturing rights for the commercial product.

"This restructuring of manufacturing responsibility for PXL01 is a logical consequence of having reached a detailed plan for the implementation of the company's first Phase III study. Significant parts of the manufacturing will be done in Sweden. Scandinavia is also an appropriate base for coordinating product supply for the approximately ten clinical centers that will recruit patients in Northern Europe," said Jonas Ekblom, CEO of Promore Pharma. "The fact that we regain global manufacturing rights also opens up for new business arrangements that can generate value for the company," 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 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. 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 aims to start recruitment to the trial in 2018.

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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 08.30 CET on 15 February 2018.

Promore Pharma in brief:

Promore Pharma is a biopharmaceutical company specialized in the development of therapeutic peptides for the bioactive wound care market. The company's aim is to develop two first-in-category products for indications where very few efficacious prescription pharmaceuticals are available, thus, addressing high unmet medical needs. Promore Pharma's two projects, PXL01 and LL-37, are in late stage clinical phase. 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 is being prepared for a clinical Phase IIb study in patients with venous leg ulcers. The product candidates can also be deployed for other indications, such as preventing dermal scarring and treatment of diabetic foot ulcers. The company is listed on Nasdaq First North with Redeye AB as Certified Adviser.

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. Promore Pharma, aims to conduct as much preparatory efforts in the project as feasible and plans for a dialogue with the US Food and Drug Administration (USFDA) in the first half of 2018.

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.