Promore Pharma receives approval for Phase III study with PXL01 in India

STOCKHOLM, 19 November, 2018 -- Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that the Drug Controller General in India (DCGI) has approved the company's application to start a clinical Phase III study with PXL01 to prevent post-surgical adhesions after tendon repair surgery.

The Indian medical authority, Drug Controller General in India has approved the company's application for a clinical Phase III study with PXL01. The approval is for a double-blind clinical study on patients undergoing tendon repair surgery in the hand. The filing is part of a multi-national clinical trial (PHSU03) that aims at enrolling approximately 600 patients where a single administration event of PXL01 at two different doses will be compared with placebo. The company is aiming to submit filings in several in the EU under the same protocol.

" This is an important confirmation of our global regulatory plan for PXL01 and India is an essential region in our forthcoming clinical trial", said Jonas Ekblom, President and CEO of Promore Pharma. "Our work is now focused on eliminating remaining challenges with the manufacturing of investigational medicinal product, so that clinical trial applications can also be filed in the EU countries where this study will be conducted", 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 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 significantly impact the quality of life due to difficulties in performing easy tasks, such as closing buttons or using a key board.

"It is pleasing that this multinational venture is progressing with an approval and the filing of national clinical trial applications in the key EU countries where this trial will also be conducted as a next step," said Varada Bidargaddi, CEO of Kentron Biotechnology Ltd, Promore Pharma's contract research organization and partner.

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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 16.00 CET on 19 November 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 and will enrol 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. 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 significantly 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.