Promore Pharma Adjusts Plans for PXL01 in North America

STOCKHOLM, SWEDEN, January 2, 2018 – Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that it will continue and widen its efforts to seek funding for a Phase III clinical trial on PXL01 in North America.

Promore Pharma signed a co-development agreement with Cellastra Inc. ("Cellastra") on 17 March 2017 regarding development and commercialization of PXL01 in North America. According to the agreement, Cellastra had an option to participate in the funding of the phase III clinical trial in patients undergoing tendon repair surgery.

If Cellastra solely funded the trial, it would have received a license to commercialize PXL01 in North America. The option expired by 31 December 2017, since Cellastra has not reached its fundraising objectives by the shift of the year. As announced in the Q3 2017 report, the phase III clinical trial for PXL01 in the US will be postponed until necessary funding can be secured. However, Promore Pharma still prepares for a dialogue with the US Food and Drug Administration in the first half of 2018 in the path towards IND approval.

Promore Pharma completed a share issue in connection with the listing on Nasdaq First North in July 2017. The intention was to use proceeds from this share issue to also finance the Phase III clinical trial in North America for PXL01, should not Cellastra do so. However, Promore Pharma received less capital than anticipated at the time of the IPO, and will primarily focus its resources into the EU region, which represents the main market opportunity for PXL01. In parallel, the company continues its discussions with Cellastra to explore new approaches to accomplish the co-funding and co-development aims but will also consider new and complementary avenues for financing a US-based initiative.

"We would have liked to see the funds for the US PXL01 phase III trial secured by Cellastra, but at this juncture, we feel it is important for us to widen our efforts to secure financing, alongside with Cellastra's continued search for funds" said Jonas Ekblom, President and CEO of Promore Pharma. "We will as planned continue preparing for the US trial by having discussions with the FDA to be ready to start when necessary funding is secured", he continued.

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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 2 January 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.

Postoperative adhesions constitute a substantial clinical problem after most surgical procedures, but in particular 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 hand recovery. 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.