Promore Pharma is granted a patent for PXL01 in the US

STOCKHOLM, SWEDEN, February 1, 2018 – Promore Pharma AB, a Swedish biopharmaceutical developer of therapeutic peptides, today announced that its subsidiary Pergamum AB was granted a patent for the formulation of the product candidate PXL01 in the US.

Promore Pharma's subsidiary Pergamum owns the intellectual property rights of PXL01, which initially is being developed to prevent post-surgical adhesions after tendon repair surgery. The U.S. Patent Office (USPTO) issued a Notice of Allowance in November 2017 and has now announced that they formally granted a patent, US 9,878,019, regarding PXL01 in combination with high molecular weight hyaluronic acid. The patent is valid until January 12, 2030. Patents within the same patent family have previously been granted in several countries in Europe, South Africa and Australia.

"This is an important step in our long-term path to develop the first prescription pharmaceutical for prevention of post-surgical adhesions associated with tendon repair surgery." said Jonas Ekblom, President and CEO of Promore Pharma. "We are developing a unique drug product, and It is of course essential for our business concept to be able to create strong and far-reaching intellectual property protection. This patent grant proves that our formulation of PXL01 is an indisputable invention, which gives us broad protection in many therapeutic treatment areas for PXL01", he continued.

Promore Pharma is preparing for a clinical Phase III study in EU and India, which will form the basis for a market authorization in EU. The trial, which is planned as a randomized, double-blinded study, will include 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, which together with the European study will form the basis for market authorization in the US and Canada. Promore Pharma, aims to conduct as much preparatory efforts in North America as feasible until financing of the study can be secured and plans for a dialogue with the US Food and Drug Administration (USFDA) in the first half of 2018.

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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.

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.