Promore Pharma updates its strategy and focuses on scar prevention

STOCKHOLM, 31 March, 2021 – The Nasdaq First North-listed life science company Promore Pharma's board has decided to adjust the company's strategy. The development of the drug candidate ensereptide (PXL01) will focus on scar prevention in connection with surgery. The decision is based on a strong and improved patent situation in the USA and that a robust production process has been ensured. The changed strategic priorities mean that the capital requirement for the company is considerably reduced at the same time as ensereptide can address a significantly larger market than before.

During the first quarter of 2021, Promore Pharma analyzed and reconsidered the conditions for the company's two projects ensereptide (PXL01) and ropocamptide (LL-37). An improved patent situation in the US for ensereptide and a more robust production process have contributed to the decision to focus on scar prevention. Financially, the refocusing means that the capital requirement for the clinical development of ensereptide will be significantly lower in the coming years compared with previous assessments. The company now intends to carry out a smaller phase II trial in scar prevention instead of a large phase III trial in flexion surgery. At the same time, the company believes that the new plan creates better opportunities for strategic collaborations and, not least, opportunities to reach the several-fold larger and more lucrative market for prevention of skin scarring after trauma or aesthetic and general surgery, areas where there is currently no prescription pharmaceutical. The total annual market for scar treatment, including laser treatment, scar plastic surgery and over-the-counter drugs, is estimated at almost USD 25 billion with an annual growth of about 10%*.

“The Board's and management's recent strategic analysis means that Promore Pharma focuses on how ensereptide can reduce scarring on the skin, which creates better conditions for value growth for shareholders than our prior, broader strategy. With this focus, Promore Pharma's drug candidate, ensereptide, addresses a very interesting and large market while significantly reducing the need for capital. This considerably improves the relationship between risk and return, says Göran Pettersson, Chairman of Promore Pharma's Board of Directors, and continues: “We believe that this adjustment in Promore Pharma's strategy is optimal where the company stands today. At the same time, it is important to note that this adjustment can be made without eroding the value of previous investments in the company. ”

Updated strategy for ensereptide (PXL01)

Recent developments for the drug candidate ensereptide have led Promore Pharma to analyze and reconsider the conditions of the project and decide on a new strategy. The patent situation in the USA regarding the use of ensereptide for the treatment of scars on the skin, and a solid production process that has been developed for the product, comprise two important components that led to the decision. Changes in the rest of the world, with changing priorities in healthcare, which in turn increase the risks in, and thus also the costs of, conducting major clinical trials in the next few years have affected the decision.

The company now intends to carry out a smaller phase II study with ensereptide for concept validation in scarring instead of carrying out the previously communicated phase III study for late ruptures. The planned clinical trial of ensereptide for the prevention of skin scarring is expected to begin during the first quarter of 2022 and is expected to take six months to complete.

"This changed focus for our work with ensereptide means that we can continue our value creation within the project at a significantly lower cost, while we can use all the information and knowledge that we have built up around ensereptide in recent years," says Jonas Ekblom , CEO Promore Pharma, and continues: “While we will conduct this work in a somewhat earlier development phase and thus with a higher development risk, we are increasing the project's market potential in several-fold. In parallel, we will also seek opportunities in strategic collaborations to bring the indication of injuries in the hand forward. ”

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The development of ropocamptide (LL-37)

Within the ropocamptide project, for the treatment of venous leg ulcers, which is the most common type of chronic leg ulcer, a phase II trial, the HEAL LL-37 study, was completed in the fall of 2020. The most important finding from the clinical trial was that ropocamptide shows a clear treatment effect in the subgroup of patients who had large wounds (≥10 cm2).

Promore Pharma now plans to conduct technical development of the ropocamptide dosage form to improve the product. The purpose is to develop a product that is easier to use. Regardless of whether the company conducts future clinical studies on its own or together with strategic partners, the development of a more user-friendly product is important both in a clinical trial environment and when the product reaches the market. In parallel, the company will opportunistically seek strategic partnerships and alliances within this program.

Capital requirements

The activities described in the ensereptide and ropocamptide projects are expected to be completed by the fall 2022 at the latest, and the outcome will then form the basis for further development of the product portfolio. An important consequence of the company's updated strategy is that the need for capital decreases significantly compared with the previous objective of financing the phase III trial for PXL01 on our own. The company is now analyzing the capital requirement for future clinical studies in detail and reviewing various financing alternatives for the revised investment. Given the new updated strategy, Promore Pharma has sufficient liquidity to finance its operations throughout 2021 and aims to secure capital for future clinical studies during the current year.

** Source: grandviewresearch.com*

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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 with high unmet medical needs, where very few efficacious prescription pharmaceuticals are available. Promore Pharma's two projects are undergoing clinical development and have a very strong safety profile since the products are based on endogeneous substances that are administered locally. The leading project, ensereptide (PXL01), that will be used for prevention of post-surgical scarring, is being prepared for a clinical phase II-trial if the peptide can prevent the formation of unesthetical scars on the skin. Ropocamptide (LL-37) has recently been evaluated in a clinical phase IIb study with positive results in patients with venous leg ulcers (VLUs). The product candidates can also be deployed for other indications, such as preventing unfavorable tissue attachments (adhesions) after different kinds of surgical procedures and treatment of diabetic foot ulcers. The company is listed on Nasdaq First North Growth Market.

This information is information that Promore Pharma 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 2021-03-31 07:10 CEST.

Attachments

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