PRESS RELEASE
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ProstaLund decides to withdraw its 510(k) application and intend instead to submit a De Novo application for Schelin Catheter® in the US

ProstaLund AB (publ) today announces that the Company has decided to withdraw its 510(k) application and intend instead to submit a "De Novo" application for market approval for the Schelin Catheter® in the US.

The background is that ProstaLund applied for a 510(k) application in July 2022. A 510(k) application is based on the fact that there are already similar approved products launched in US. The FDA has now announced that they do not believe there are similar products (predicate device) to Schelin Catheter® - it is unique. This means that a "De Novo" application, i.e. an extended application is required to verify the safety and efficacy for the intended use.

A De Novo application means an application process that is adapted to low- or medium-risk medical devices where similar products are not available on the US market. The next phase will include a pre-submission meeting with the FDA to get the agency's preliminary view on how the final application should be designed. This phase is expected to start after the summer. It is estimated that the registration process takes 12 months.

Schelin Catheter® is a unique injection tool that allows urologists to administer drugs into the prostate in a sterile manner through the urethra. Until today, pain relief for most minimally invasive treatments of benign prostatic hyperplasia (BPH/BPE) is usually in local anesthesia injected through the rectum, spinal anesthesia or patients being under full anesthesia during the procedure. It can entail significant risks of severe infections and even full anesthesia is associated with risks and requires large resources in the form of monitoring and beds. This is avoided when using Schelin Catheter® It takes about 4 minutes per patient to administer anesthetic with Schelin Catheter® before the intended treatment and the patient can go home almost immediately after treatment.

- We have during this process had a very good dialogue with the FDA, and we will continue our work to meet their requirements for extended tests. The FDA's view that there is no comparable product on the market is very interesting from one point of view, where the conclusion is that our product is so unique that we will be the only company with a product for injection directly into the prostate if it is approved.", comments CEO Johan Wennerholm.

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For further information, please contact:

Johan Wennerholm, CEO
Tel. +46 (0) 730 429997
Email: johan.wennerholm@prostalund.com

About ProstaLund

ProstaLund AB is a Swedish medical technology company and a leading developer and manufacturer of innovative urological devices and treatments. The company's lead product, CoreTherm, is a patented Thermotherapy treatment method for Benign Prostatic Hyperplasia (BPH) which can be tailored to suit the needs of each individual patient. CoreTherm is used today in hospitals and clinics in Sweden and worldwide. ProstaLund is listed on the Nasdaq First North Growth Market.

Certified Adviser:
Västra Hamnen Corporate Finance AB
Phone: +46 40 200 250
E-mail: ca@vhcorp.se

This information is information that ProstaLund AB (publ) 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 2023-07-10 21:57 CEST.

Attachments

ProstaLund decides to withdraw its 510(k) application and intend instead to submit a De Novo application for Schelin Catheter® in the US