PRESS RELEASE
27 July 2022 16:00:00 CEST

ProstaLund has filed its 510(k) application to the FDA for the Schelin Catheter™

ProstaLund AB (publ) announces today that the company has submitted its application for 510 (k) approval to the U.S. Food and Drug Administration (FDA) for the Schelin Catheter™

- The submission of our application to the FDA today is a very important milestone for ProstaLund and a positive result of the intensive work carried out by our regulatory department. Our objective has been to provide the FDA with an application that meets their requirements for information and data in the best possible way. This application takes us one step closer to introduce the Schelin Catheter in the important U.S market, says Johan Wennerholm, CEO of ProstaLund.

The Schelin Catheter™ is a unique injection tool that allows the urologists to administer drugs into the prostate in a sterile way through the urethra.

Recently, ProstaLund started to offer the Schelin Catheter as a stand-alone product. In the beginning of 2022, the device was for the first time used to administer local anesthetics before water vapor therapy (Rezūm™, Boston Scientific) for benign prostate enlargement (BPE). The Schelin Catheter then allowed the urologist to, in a sterile way, provide excellent pain relief. Just like when it is used before ProstaLund´s CoreTherm® treatments, these water vapor procedures were essentially painless for the patients. It took less than 4 minutes per patient to provide anesthetics with the Schelin Catheter.

Until today, pain relief before most minimal invasive prostate procedures, is usually either local anesthesia injected through the rectum or that patients are general anesthetized during the procedure. The former entails a significant risk of severe infections, and the latter is also associated with risks and takes up considerable resources. With the Schelin Catheter, the prostate can effectively be anaesthetized in a sterile way, thus avoiding the risk of pathogens from the rectum enter the body at the time of injection. At the same time, the patient does not need to be general anesthetized and can go home immediately after treatment.

It is estimated that 35 million men are affected by BPE in the US alone. Yearly it is estimated that around 400,000 out of these have a need for a for an active treatment. The yearly number of minimal invasive BPE procedures performed in the US alone are estimated to be about 80,000 – 120,000 and growing. In this market segment Boston Scientific (Rezūm™) and Teleflex (UroLift®) are the major players, right now.

- “We estimate the approval process to take 8-10 months and we hope and are planning for a launch of the Schelin Catheter in the US at American Urological Association´s (AUA) Annual Meeting in Chicago next year, 28th April - 1st May”, says Johan Wennerholm.

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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.

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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 2022-07-27 16:00 CEST.

Attachments

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