Press Release
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SpectraCure takes the next step in the work with the new clinical study

SpectraCure AB (publ) continues in the process of initiating a clinical study, for primary localised prostate cancer. The study's protocol has been submitted to the U. S. Food and Drug Administration (FDA), which has not expressed any specific comments, and the work to initiate the clinical study can proceed.

In November 2023, the board decided to seek approval for a clinical study, for primary localised prostate cancer, which will be run in parallel with the ongoing study regarding recurrent prostate cancer. After the board's decision, the study's protocol was sent to the FDA, which did not express any specific comments, and thus the work can continue as planned. The study is planned, as previously communicated, to begin in the first half of 2024. The next step in the work with the clinical study, for primary localised prostate cancer, is to write additional agreements with already existing hospitals that will be included in the new study.

The company's already good and established relationships with hospitals in Europe and North America facilitate the process of initiating the study for primary localised prostate cancer. The aim of the study is to investigate the treatment effect on the body, to determine the effective treatment dose, and to investigate the safety of the Q-PRO® treatment system in combination with the light-sensitive drug verteporfin. SpectraCure intends to introduce a new method for treating prostate cancer, through a minimally invasive, individualised and focal treatment strategy with the Q-PRO® treatment system.

"By initiating a clinical study for primary localised prostate cancer, we broaden the recruitment base and open up a significantly larger market, which has been our strategy from the beginning. The progress made in our ongoing clinical study, including the establishment of a network of prominent urologists and hospitals, creates good conditions as we now can proceed with the process of initiating the clinical study for primary localised prostate cancer" says Masoud Khayyami, acting CEO SpectraCure.

In 2022, 730,000 new cases of prostate cancer were reported in Europe and North America, of which around 70% were localised prostate cancer, i.e. prostate cancer without spread. SpectraCure sees the potential of being able to offer a favorable alternative for a large proportion of patients with intermediate-risk localised prostate cancer.

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SpectraCure is developing a treatment system for the elimination of internal solid cancer tumors. We are initially focusing on recurrent prostate cancer, with the hope of being able to treat other cancers such as primary prostate cancer, breast cancer, pancreatic cancer, and head and neck cancer in the future. The approach is based on a proprietary and patented treatment system, Q-PRO®, consisting of a hardware device, a laser unit, which performs PDT treatment and treats the prostate itself, combined with a software device, the patented IDOSE® dose planning platform. The method allows the laser light dose to be controlled so that the tumour is exposed to an optimal dose to achieve sufficient treatment effect. The treatment system has the potential to make interstitial PDT treatment accurate, precise, safe for every patient. The goal is that in addition to being tumor free, the patient will be able to maintain their quality of life, with limited side effects. We are conducting clinical trials as an important part of the continued development of the company's treatment system.

The company is listed in the Premier segment of the Nasdaq First North Growth Market with G&W Fondkommission as Certified Adviser, and trades under the short name SPEC.

Attachments
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