SpectraCure has decided to seek approval for a clinical study of primary prostate cancer

SpectraCure AB (publ) has decided to seek approval to start a clinical study for primary localised prostate cancer. During autumn, the board and management have evaluated the conditions for approval to start a clinical study from authorities in the USA, Great Britain, Canada and Sweden and assessed these as good. The goal is to start the clinical study in the first half of 2024.

SpectraCure is currently running a clinical study for patients who have recurred prostate cancer after previous radiotherapy. The study is investigating a new method for the treatment of prostate cancer and is conducted using the company's medical technology system, Q-PRO®. The board of SpectraCure has now decided to also seek approval to start a clinical study for primary localised prostate cancer. Based on the result obtained in the ongoing study, the board assesses the chances as good that the authorities will approve the initiation of a study for primary cancer.

The fact that the company already has good and established relationships with hospitals and doctors in North America and Europe, is facilitating the process of getting started with the clinical study for primary localised prostate cancer. The study will be run in parallel with the ongoing study for recurrent prostate cancer. SpectraCure broadens the recruitment base and addresses a significantly larger market by initiating a clinical study for primary localised prostate cancer. In addition, by running two parallel studies, the risks are reduced since the company obtains independent data sets to confirm the results while achieving redundancy.

In 2020, 675,000 new cases of prostate cancer were reported in Europe and the USA, of which around 70% with localised prostate cancer. Of all localised prostate cancers there is a spectrum of risks within that group and we are intending to address intermediate risk prostate cancer. The company assesses that SpectraCure's treatment method is applicable to a large part of these patients. The global market for prostate cancer treatment in general was valued to approximately USD 12 billion in 2022, with an expected annual growth of close to 10%.

SpectraCure is currently conducting a clinical study for patients who have recurrent prostate cancer after previous radiotherapy. The strategy to focus on this indication was based on recruiting subjects with strong incentives and limited options.

SpectraCure's treatment system Q-PRO® has the potential to offer a highly precise and focal treatment method, providing a more individualised and minimally invasive solution for the treatment of prostate cancer. The treatment also has the potential to allow patients to maintain a higher quality of life during and after their treatment journey compared to conventional treatment.

"The way that SpectraCure is doing prostate cancer treatment, using PDT, really allows to both tailor the procedure to the particular individual and also offer a very compelling focal treatment technique that allows it to treat prostate cancer regardless of where the tumour is within the prostate gland in a focal localised fashion and being able to do that with a minimal amount of side effects", says Homer Pien, PhD and board member of SpectraCure with a background from Harvard Medical School and Chief Scientific Officer and CTO for Imaging Systems at Philips.

"By seeking approval for a clinical study for primary prostate cancer, we broaden the recruitment base and address a significantly larger market. This strengthens the company's position and increases the possibilities for our treatment to become an alternative for prostate cancer treatment. As we already have good and developed relationships with hospitals and doctors in North America and Europe, it facilitates the process of getting started with the clinical study for primary localised prostate cancer," says Masoud Khayyami, interim CEO SpectraCure.

For further information:
Masoud Khayyami, Acting CEO
E-mail: mk@spectracure.com
Website: www.spectracure.com

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.

This information is information that SpectraCure 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 2023-11-16 15:30 CET.

Attachments
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