Status update regarding clinical studies for the treatment of patients with recurrent prostate cancer

Following the discussions at Investigator Meetings during November 2020 - February 2021, in which doctors and representatives of the clinics included in the company's clinical study participated, a status update follows in light of the current pandemic. Participating hospitals are University College London Hospital, Princess Margaret Cancer Centre in Toronto, University of Pennsylvania Hospital in Philadelphia and Memorial Sloan Kettering Cancer Center in New York.

In the first part of the clinical studies, SpectraCure has achieved its goal of optimizing the drug dose and compiling the initial safety profile for the treatment of patients with recurrent prostate cancer. In the second part of the studies, work is underway to evaluate the effectiveness of the treatment, as well as continued monitoring of safety.

A total of 17 patients have undergone treatment (10 at the Princess Margaret Cancer Centre in Toronto and 7 at University College London Hospitals NHS Foundation Trust (UCLH), London. The most recent patient treatment was conducted in January 2020 in London.

The pandemic outbreak paused all clinical trials except those related to covid-19 at most hospitals around the world.

In March 2020, a formal start-up meeting of the study was conducted at the Memorial Sloan Kettering Cancer Center in New York, but shortly thereafter, entry bans were introduced to the United States from Europe and New York was put under lock-down. The restrictions still apply, which prevents us from making the necessary preparations at the Memorial Sloan Kettering Cancer Center. The team at Memorial Sloan Kettering is ready to begin patient treatments as soon as circumstances allow.

At the Princess Margaret Cancer Centre in Toronto, cancer studies have been suspended for the time being. In addition, a two-week quarantine applies upon entry, which makes it impractical to work in Canada. The team at Princess Margaret Cancer Center is also ready to start patient treatment as soon as circumstances allow.

At UCLH in London, the study resumed on October 8, 2020 and recruitment is now underway. Carrying out treatments is hampered by the general Covid situation in the UK, but the assessment of our partners at UCLH is that treatments should be able to be carried out shortly, as all prostate cancer treatments are offered.

Evaluation of data

In the safety evaluation, a side effect has been reported in one patient, classified as severe, at the Princess Margaret Cancer Centre, in the form of post-treatment pain. The symptoms were transient. SpectraCure, together with the doctors, assesses that the pain was caused by a procedural error during the procedure, which has since been corrected. No serious side effects have been reported at UCLH, nor any further at the Princess Margaret Cancer Centre.

Effectiveness endpoints are based on evaluation of the effectiveness of the treatment using magnetic resonance imaging (MRI) images. In a series of meetings with the doctors November 2020 - February 2021, the results have been compiled and evaluated so far. The MRI images of tissue death show a good correlation with the dose plans from SpectraCure's IDOSE system, which is the primary endpoint. This assessment is based on that tissue death seen on MRI images in the region where the tumour is situated is expected to mean that the tumour tissue also has been destroyed. SpectraCure’s and the doctors' assessment is thus that the results regarding the effect of the treatment so far follow expectations. The purpose of this kind of endpoint is to avoid assessments that take a long time, such as overall survival. This could decrease the time to market.

Continued plan

SpectraCure intends, as previously communicated, to apply for so-called accelerated approval for the method. This requires robust clinical data from phase 2. The advantage of this procedure is to be able to launch the product on the market in parallel with the implementation of a phase 3 study, instead of having to wait for results from phase 3 before market launch. In consultation with our regulatory advisors in the United States, SpectraCure estimates that the prospects of having an accelerated approval approved will increase if we conduct an extended phase 2b study to strengthen clinical outcomes. SpectraCure plans to implement this change by modifying the existing study with an extension of the number of patients and modification of the clinical protocol. Planning work on this has begun. The purpose is, among other things, to modify the study's endpoints so that they more clearly comply with what the FDA expects in an accelerated approval. This is planned to be done in dialogue with the FDA with the help of our regulatory consultants.

While the work on the change of the clinical protocol is carried out, the work with the clinical study will continue under the current protocol, in order to collect more clinical data and further refine the treatment.

Timeline for the continued clinical program

As a result of the situation with Covid-19, SpectraCure considers that there are uncertainties associated with communicating a timeline at present. We intend to return with a timeline as soon as the situation with the pandemic becomes more predictable.

Work during the pandemic

During the ongoing pandemic, work has been ongoing in several parallel projects with the new generation P18 system with IDOSE and the team has been strengthened with software and hardware engineers. The system has a design and features that are close to what it will have at a future launch. The technology has been fine-tuned and further developed so that we can offer a competitive product in the future when the treatment options can be expanded with more indications. We have prepared asubmission to start using the new system

in the clinical study.

Work on initiating new possible clinical programs has begun.

This information is information that SpectraCure AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out below, on March 5, 2021, at 08:30 a.m.

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SpectraCure was founded in 2003 as a spin off from Lund University and LTH Faculty of Engineering. The company focuses on cancer treatments with medical systems based on laser light sources, connected to the tumour by way of optical fibers, in combination with a photoreactive drug. The method is referred to as Interstitial Photodynamic Therapy, PDT. The treatment is suitable for internal solid tumours of various kind, such as prostate and pancreatic tumours, but also for example for cancers of the head and neck.www.spectracure.com.

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