Status update on clinical trial for the treatment of relapsed prostate cancer patients

The pandemic has led to a significant slowdown in SpectraCure's clinical activities. Several hospitals suspended the conduct of studies for an extended period of time and SpectraCure staff have been prevented from travelling due to travel bans in the countries where the study is being conducted. The clinical study protocol involves a number of follow-up examinations, which before the pandemic was perceived positively by patients, but during the pandemic has been perceived negatively, with the result that potential patients chose not to participate in the study to minimize hospital visits due to the risk of infection. SpectraCure therefore intends to simplify the protocol regarding follow-up visits.

> We are in continous contact with the hospitals involved in the study and are hopeful that we will soon be up and running again. Travel restrictions to the US and Canada are now being eased and it is hoped that local bans on visits to the hospital by non residents will be lifted soon. This will then allow the clinical trial to get underway in North America again. To further accelerate the study, the possibility of hiring local staff is also being explored. In September, part of SpectraCure's management team visited University College London Hospitals (UCLH) to discuss the continuation of the study directly on site and it is gratifying to note that UCLH is very keen to recruit patients for the study, comments SpectraCure's CEO Johan Folkunger.

As previously announced, the new generation P18 system has been approved by the FDA for use in the study and the company is awaiting approval in the UK and Canada as well. The production of new devices is on schedule and provides entirely new opportunities to add additional hospitals to the study. This work has already begun and in parallel, work is underway to accelerate patient recruitment.

SpectraCure's ambition has been to obtain accelerated approval for its product and associated treatment for the US market. After extensive dialogue with several regulatory experts during the late summer and autumn, SpectraCure's management and board now believe that the likelihood of obtaining accelerated approval has decreased. The main reason for this is that the Food and Drug Administration (FDA) is now considered to be more restrictive in its decisions on accelerated approval. This in turn means that product approval for market launch in the US is more likely only after a successfully completed Phase 3 study.

> Following our discussions with the hospitals, we hope that the recruitment and treatment of patients for phase 2 will be completed in 2022. A more detailed timeline will be developed once the phase 2 results are complete and we have anchored the design of the phase 3 study with the FDA, says Johan Folkunger.

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, by the contact person named in this press release, at 4:00 p.m. on October 13, 2021.

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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 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, ca@gwkapital.se, tel +468-503 00 050, and trades under the short name SPEC.