# Positive discussions at SpectraCure's Investigator Meeting

**SpectraCure has held an Investigator Meeting where the topic of discussion was statistics and results from the treatments conducted in the Company's clinical study. The discussions at the meeting will also form the basis of the forthcoming application for Accelerated Approval. Physicians and representatives of the hospitals included in the study participated in the meeting: 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.**

- On the basis of the positive results obtained thus far in our clinical study and the recommendations we have received from our American advisors regarding the application for Accelerated Approval with the Food and Drug Administration (FDA), the Phase 2 study will continue with additional treatments of patients, beginning in London. A broad basis of data will improve our possibilities to be approved for the Accelerated Approval Program, and at the same time responds to the requirement of a larger patient group for a future Phase 3 study, says SpectraCure's CEO, Masoud Khayyami.

The jointly updated treatment system that integrates SpectraCure's IDOSE® platform with MedCom's image processing technology is scheduled for introduction in January, in conjunction with treatments of patients during the Phase 2 study at University College London Hospital. It is anticipated that MedCom by then will have obtained CE marking of its part of the system's software.

Another Investigator Meeting will be held in February. Among other things, a review of simulations and continued analyses of conducted treatments will be on the agenda.

- My and the Company's reflections on the Investigator Meeting are that our physicians remain very positively disposed towards the study. We plan to conduct the meeting with the FDA in preparation for the application for Accelerated Approval as soon as we consider the supporting data strong enough to result in a favourable decision. SpectraCure still considers two possible scenarios, both of them somewhat delayed due to the situation surrounding COVID-19, says Masoud Khayyami.

Under the first scenario, SpectraCure is approved for Accelerated Approval by the FDA during 2021, on the basis of the Phase 2 study results. Under this scenario, the product is expected to be put on the market between 2021 and 2022, provided that the Phase 2 study is successful.

Under the second scenario, the Company completes the Phase 2 study in parallel with the FDA process, and subsequently carries out a Phase 3 study regardless of the FDA's decision. In the scenario 2 timeline, the Phase 3 study would be initiated during the period 2021-2022, with patient recruitment estimated to go on for about 12 months.

In parallel and independently of the aforementioned FDA decision, SpectraCure has started to build additional values by initiating clinical programs for novel indications. In addition to primary prostate cancer, the possible indications under consideration include pancreatic cancer and cancers of the head and neck. The Company expects to be able to start clinical programs for extended indications during the period 2021-2022.

- The time estimates are assessments that may be revised if additional COVID-19-related restrictions impact the recruitment of patients or the carrying out of treatments, thus affecting the timeline, says Masoud Khayyami.

**For more information, please contact:**

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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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