

## The FDA's initiative can provide faster market access for SpectraCure

During SpectraCure's ongoing clinical trial, the American FDA (Food and Drug Administration) has created an opening for faster product launch by changing the requirements for endpoints in clinical trials in cancer treatment. The changed requirements provide new opportunities that in the long term may entail faster market access.

The FDA's initiative to admit shorter follow-up times and accelerated approval, is supplemented with requirements for reporting follow-up studies after approval. SpectraCure may launch its treatment system as early as 2020/2021 after approval by the FDA, with the requirement to conduct follow-up studies in parallel, given that the results at the given time are good.

- My hope is that SpectraCure's application for accelerated approval will be approved by the FDA. More patients with recurrent prostate cancer can then be offered our treatment, says Masoud Khayyami, CEO of SpectraCure.

### **Great market potential - from 2 to 63 billion USD**

The market for recurrent prostate cancer is worth approximately 2,2 billion USD at a price of 38,800 USD for SpectraCure's treatment. In two years, the world market for treatment and prevention of prostate cancer is estimated to be worth totally approximately 63 billion USD. For example, treating primary prostate cancer as well means that the potential total market for SpectraCure will increase from 60,000 relapse patients to 580,000 patients with prostate cancer per year in the United States and Europe. A market worth about 21 billion USD.

SpectraCure is already considering expanding its target group and including new indications, as a complement to the existing market.

The company may expand the target group for the treatment system to also include patients with other cancer diagnoses such as primary prostate cancer, pancreatic cancer, liver cancer and cancer in the head and neck region. The market potential will then become even greater.

Source: BCC Market Forecasting

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This information is information that SpectraCure AB is required to disclose under the EU Market Abuse Regulation. The information was provided, through the contact of the above contact person, for publication on October 28th, 2019 at 11.10 a.m.

### **SpectraCure in short**

SpectraCure was founded in 2003 as a spin off from Lund University departments for medical laser applications and physics. The company focuses on cancer treatments using medical systems with laser light sources and reactive drugs, which is referred to as "Interstitial Photodynamic Therapy", PDT, a treatment methodology suitable for internal solid tumours of various kind, e.g. prostate and abdominal salivary glands, but also other indications such as cancer tumours in the head and neck region.