A well-accomplished annual audit in accordance with ISO 13485:2016

SpectraCure AB (publ) announces today that the company has successfully undergone the annual audit according to ISO 13485:2016. The audit, conducted by a notified body, confirms that SpectraCures's quality management system meets the stringent requirements of the international standard.

SpectraCure's quality management system has undergone the annual ISO 13485:2016 audit. The authorised auditor confirmed that the company's quality management system complies with the requirements of ISO 13485:2016.

> "Our goal is to streamline healthcare through focal and minimally invasive treatment, improving the quality of life for the thousands of men affected by prostate cancer. Meeting the stringent requirements is a step towards achieving our goal," comments Acting CEO Masoud Khyyami.

SpectraCure has been certified according to ISO 13485:2016 since March 2022, meaning that the company strictly adheres to the regulations governing medical devices. The certification covers all aspects of the business, including the development, manufacturing, service, and installation of equipment for photodynamic therapy. Certification significantly facilitates the process of obtaining market approval for medical devices globally. The annual audit by a notified body is an essential part of SpectraCures's commitment to continuous improvement and compliance with international standards in medical technology.

For further information:
Masoud Khayyami, Acting CEO
E-mail: ir@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.

Attachments

A well-accomplished annual audit in accordance with ISO 13485:2016