



Pressrelease
Lund 2017-03-27

CLS diffusor fiber receives FDA clearance and is thereby ready for sale on the US market

Clinical Laserthermia Systems (CLS) (publ), has received a clearance from the U.S. Food and Drug Administration (FDA), based on the 510(k)-application, to market and sell its TRANBERG CLS|Diffusor Laser Fiber on the US market. The diffusor fiber makes it possible to treat larger size tumors and can be used for treatment with image guided laser ablation as well as with CLS' own immunostimulating therapy, imILT®.

– This positive information from FDA allows us to sell the diffusor fiber on the US market and with that further develop the collaborations we have established with two American hospitals. The fact that we have just recently purchased the diffusor fiber technology from the German company LMTB, brings an extra nice flavor to the FDA clearance, said Lars-Erik Eriksson, CEO of CLS.

CLS develops and markets the TRANBERG®|Thermal Therapy System, as well as disposable materials and methods for heat-induced immunotherapy for safe and gentle treatment of cancerous tumors. The Company recently bought the part of the German laser technology company Laser- und Medizin-Technologie GmbH (LMTB), that includes technology and development of CLS diffusor fiber. The production of the fiber is based on unique expertise in microstructuring of laser fiber, which is the formation of the structure that gives the light its unique diffusion.

The FDA clearance is similar to Europe's CE certificate, and means that CLS' product meets the extensive requirements, which are set by the FDA, on this kind of medical device.

Company contact:

Lars-Erik Eriksson, CEO Clinical Laserthermia Systems AB (publ)
Tel: +46 – (0)702 – 90 33 00 E-mail: lee@clinicallaser.se

This information is such that Clinical Laserthermia Systems AB (publ) is required to publish pursuant to the EU Market Abuse Directive. The contact person arranged for the release of this information on 27 March 2017.

Clinical Laserthermia Systems AB (publ) develops and markets a safe, gentle, effective, and clinically documented therapy for treatment of solid cancer tumors. The product is based on immunostimulating interstitial laser thermotherapy (imILT). CLS is listed on Nasdaq First North under the stock symbol CLS B. Certified Adviser is Västra Hamnen Corporate Finance. More information is available on the Company's website www.clinicallaser.se