Clinical Laserthermia Systems receives FDA 510(k) clearance for its MR guided laser ablation system in neurosurgery and initiates commercialization

Lund, Sverige – Clinical Laserthermia Systems AB (publ) (CLS) today announced that its second generation TRANBERG® Thermal Therapy System with Thermoguide™ Workstation has received 510(k) clearance from the US Food and Drug Administration (FDA). The clearance marks a breakthrough in the field of neurosurgery and for minimally invasive treatments of brain lesions that will now be performed more efficiently and safely. The system will be commercialized by CLS's global distributor ClearPoint Neuro, Inc (Nasdaq:CLPT).

CLS's 510(k) clearance was achieved thanks to a close collaboration with CLS's global distributor ClearPoint Neuro who has supported CLS during the entire 510(k) application process. ClearPoint Neuro provides a global, therapy-enabling platform for navigation and delivery to the brain which together with CLS's system provides a fully integrable system for MR-guided, stereotactic laser ablation of brain lesions.

Having secured the FDA 510(k) clearance, commercialization of the integrated system can be initiated. The integrated system will be commercialized under the brand name ClearPoint Prism™ Neuro Laser Therapy System by ClearPoint Neuro that is the exclusive global distributor of CLS's system for the neurosurgery market segment.

One of the neurosurgeons who has high expectations for the new system is one of ClearPoint Neuro's Key Opinion Leaders, John Rolston, MD, PhD, Director of the Mapping & Engineering Neural Dynamics (MEND) Laboratory at Brigham and Women's Hospital and Harvard Medical School. He stated:

"It's wonderful to see new innovation in the space of laser interstitial thermal therapy. Laser ablation is an important and growing part of our surgical armamentarium and offers minimally invasive and powerful treatments for a variety of neurological diseases. The new laser system offered by ClearPoint has several exciting technical innovations that are expected to make this therapy simpler and more accessible to surgeons and their patients."

"The 510(k) clearance is a significant milestone for CLS as it opens a whole new market for our technology that now will be used in neurosurgery. Moreover, it is a breakthrough for minimally invasive treatment of brain tumors and drug-resistant epilepsy. We look forward to continuing our collaboration with ClearPoint Neuro in their commercialization of ClearPoint Prism™ Neuro Laser Therapy System for the benefit of both patients and healthcare providers," said Dan J. Mogren, CEO of CLS.

"We are excited that CLS has achieved 510(k) clearance and are ready to initiate the commercialization of our one-piece, MR-guided stereotactic laser ablation system in the United States and beyond in coming years. Since the ClearPoint neuro navigation platform is already established in over 60 active sites in the United States, Canada, and Europe, we expect to see

a swift start to sales," said Joe Burnett, President and CEO of ClearPoint Neuro.

The ClearPoint Prism Neuro Laser Therapy System is currently in limited market release at selected academic medical centers across the United States. Full indications for use can be found here: https://www.clearpointneuro.com/terms-of-service/label-indications/

This information is such information that Clinical Laserthermia Systems AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person set out below on 23 September 2022, at 08:45 CEST.

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About CLS
Clinical Laserthermia Systems AB (publ) develops and sells the TRANBERG® Thermal Therapy Systems, including Thermoguide™ Workstation and sterile disposables, for minimally invasive treatment of cancer tumors and drug-resistant epilepsy, according to regulatory approvals in the EU and the US. The products are marketed for image-guided laser ablation and used in studies for treatment with imILT®, the Company's interstitial laser thermotherapy for immunostimulant ablation with potential abscopal effects. CLS is headquartered in Lund and has subsidiaries in Germany, the US and Singapore. CLS is listed on the Nasdaq First North Growth Market under the symbol CLS B. The Certified Advisor (CA) is FNCA Sweden AB, Tel: +46 8 528 00 399. E-mail: info@fnca.se

For more information about CLS, please visit the Company's website: www.clinicallaser.se

About ClearPoint Neuro
ClearPoint Neuro's mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders with pinpoint accuracy. Applications of the Company's current product portfolio include deep brain stimulation, laser ablation, biopsy, neuro-aspiration, and delivery of drugs, biologics, and gene therapy to the brain. The ClearPoint® Neuro Navigation System has FDA clearance, is CE-marked, and is installed in over 60 active sites in the United States, Canada, and Europe. ClearPoint Neuro is partnered with more than 45 pharmaceutical and biotech companies, academic institutions, and contract research organizations providing solutions for direct CNS delivery of therapeutics in pre-clinical studies and clinical trials worldwide. To date, more than 5,000 cases have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners worldwide. For more information, please visit www.clearpointneuro.com.