Clinical Laserthermia Systems Submits CE-Marking Application for its ClearPoint Prism® branded Neuro Laser Therapy System seeking European Regulatory Approval for use in Neurosurgery

Lund, Sweden – Clinical Laserthermia Systems AB (publ) (CLS) today announces that it has formally applied for CE marking of its ClearPoint Prism branded Neuro Laser Therapy System, seeking regulatory approval in Europe for use with 1.5T and 3.0T magnetic resonance imaging (MRI) guidance in neurosurgical procedures.

Seeking regulatory approval in EU follows on CLS's 2024 ISO-certification in accordance with the European Medical Device Regulation (MDR), and the successful completion of the sponsored clinical study at Skåne University Hospital, which assessed safety and feasibility of MRI-guided laser interstitial thermal therapy (LITT) in patients with glioblastoma, the most aggressive and lethal form of brain cancer.

The ClearPoint Prism System — commercialized globally in partnership with ClearPoint Neuro, Inc. — combines CLS's laser ablation technology with MRI guidance and neuro-navigation to enable minimally invasive treatment of brain lesions, also those that may otherwise be hard to reach through open surgery.

Key factors behind applying for CE-marking:

- The patients with recurrent malignant brain tumor that were treated with Laser Interstitial Thermal Therapy (LITT) in the clinical study at Skåne University Hospital had increased median survival compared to a matched control group treated with open surgery. The study's primary objective – to investigate whether the CLS proprietary LITT platform was safe and feasible in the treatment of brain tumors – was also successfully achieved.
- With the CE marking, CLS aims to enable commercial launch of the ClearPoint Prism branded neuro laser therapy system, offering European hospitals and neurosurgical centers a minimally invasive treatment option for lesions in the brain.

"This application is a major strategic step for CLS," commented Dan J. Mogren, CEO of CLS. "Upon approval, the CE mark will allow for an expansion of our market presence outside of U.S by unlocking access also to European neurosurgery markets and bring our MRI guided neuro laser ablation technology to more patients in need of less invasive neurosurgical options."

Regulatory approval through CE-marking is expected in second half of 2026

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About CLS

Clinical Laserthermia Systems AB (publ), develops and sells TRANBERG® Thermal Therapy System and ClearPoint Prism® Neuro Laser Therapy System with sterile disposables, for minimally invasive treatment of cancer tumors and drug-resistant epilepsy. The products are marketed and sold through partners for image-guided laser ablation. CLS is headquartered in Lund, Sweden, with subsidiaries in Germany, the United States and a marketing company in Singapore. CLS is listed on Nasdaq First North Growth Market under the symbol CLS B. Certified adviser (CA) is FNCA Sweden AB.

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