Publication in *Journal of Neurosurgery* Demonstrates Distinct Advantages of CLS´s Core Technology in Neurosurgical MR-guided Laser Ablation

Lund, Sweden – Clinical Laserthermia Systems AB (publ) (CLS) today announces that a publication with the title "Preclinical assessment of a non-cooled MR thermometry-based neurosurgical laser therapy system" has been published in the well renowned Journal of Neurosurgery[1]

The research presented was conducted by CLS and our partner ClearPoint Neuro, Inc., with neurosurgeon Dr. John Rolston, MD, PhD leading the study as Principal Investigator. An animal model was used to demonstrate the safety, accuracy, and efficacy of the neuro laser therapy system including MR thermometry software developed and manufactured by CLS. Commercialization and design input are ongoing by ClearPoint, using the brand name ClearPoint Prism™.

The results were achieved by demonstrating safe and highly efficient use of CLS TRANBERG® non-cooled laser applicators in porcine brain. The laser light caused thermal damage in the target tissue leading to coagulative necrosis and finally to cell death. Thermoguide™ thermometry software estimated the thermal damage and provided color-coded Thermal Damage Thresholds that predicted irreversible tissue damage, and clearly delineated safety margins to eloquent brain structures. Additional results were achieved by evaluating the accuracy of temperature prediction by Thermoguide compared to calibrated temperature probes in vivo, and by histology of the brain tissue after 3 days survival.

The authors conclude that Thermoguide provided an accurate near-real-time temperature map of the brain tissue, demonstrated by high correlation between Thermoguide thermometry and physical temperature probes. Dimensions and location of the irreversible tissue damage estimate, as visualized by the software, agreed well with histopathology.

"The safety and efficacy of the Thermoguide software demonstrated in this in vivo porcine model was essential for our full FDA 510(k) clearance in neurosurgery", says Verena Knappe, Chief Product Officer at CLS, and co-author of the publication. "Moreover, our experiences from the pre-clinical procedures, together with the favorable safety profile and excellent predictability of cell death, enabled us to take the next main step proceeding with clinical use for patients with brain tumors or epilepsy."

Currently, a CLS-sponsored clinical study is ongoing at Skåne University Hospital, Lund, Sweden. The Prism system is in limited market release at selected academic medical centers across the United States.

[1]Singh et al. Preclinical assessment of a noncooled MR thermometry-based neurosurgical laser therapy system. J Neurosurg. Published online March 8, 2024.

For more information, please contact:

Dan J Mogren, CEO, Clinical Laserthermia Systems AB (publ)
Phone: +46 (0) 70-590 11 40
E-mail: dan.mogren@clinicallaser.com
Website: www.clinicallaser.se

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 immunostimulatory 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.

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