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AUA Booth # 364

CLS Americas Debuts Office-Based, Fusion-Guided TRANBERG Focal Laser Ablation System at AUA 2022 Conference

Irvine, CA – May 12, 2022 – CLS Americas, a subsidiary of Clinical Laserthermia Systems AB, today announced it will debut its Office-Based, MR/US Fusion-Guided, [TRANBERG® Thermal Therapy System](#) for high precision, focal laser ablation of soft tissue, such as prostate cancer tumors, at the upcoming **AUA 2022 Conference** being held May 13-16, 2022 in New Orleans. The system is designed to work with multiple MR/US fusion image guidance systems for precise and accurate ablation in a minimally invasive setting, while preserving healthy prostate tissue. Focal therapies generally produce few side effects, such as erectile dysfunction and urinary incontinence. CLS Americas will be located in Booth #364.

In the US, over one million prostate biopsies are performed every year leading to a diagnosis of prostate cancer for almost 250,000 men. These patients are demanding emergent therapies as alternatives to the standard treatments that have shown to carry long term harmful side effects.

“The AUA 2022 Annual Conference is the world’s premier event for physicians, clinicians, and researchers to explore the latest advancements in urologic medicine,” stated Michael Magnani, president of CLS Americas. “CLS is pleased to introduce its Office-Based, Fusion-Guided TRANBERG Thermal Therapy System at this year’s conference. We believe there is significant patient need and market interest for an Office-Based, high precision focal laser ablation treatment of prostate tumors which also maximizes the preservation of healthy prostate tissue. We are commercializing this innovative technology so that patients can benefit from being treated with focal laser ablation in a urology office or clinic instead of a hospital.”

“While treating prostate cancer tumors successfully is the primary goal, some current treatment options expose patients to unacceptably high risks of complications such as erectile dysfunction or urinary incontinence,” said Dr. Fernando J. Bianco, Investigator-In-Chief for the Urological Research Network, and Principle Investigator of the Phase I clinical study running at Urological Research Network, Miami Lakes. “Based on my initial clinical trial experience with the TRANBERG laser, I believe that partial gland fusion ablation provides the precision to successfully treat the cancerous lesions while offering patients a superior side effect profile. The ongoing study will provide us with more information on this.”

CLS History & Experience – Image-Guided, Focal Laser Ablation of Prostate Tumors

CLS’s TRANBERG® Thermal Therapy System has been used in hundreds of tumor laser ablation procedures in patients with localized prostate cancer in the US and EU using an in-bore, MRI-guided procedure. With the safety and diagnostic accuracy of MR/US fusion-guided transperineal prostate biopsy being well documented, this doctor’s office procedure and technology are seeing a strong global adoption. Based on CLS’s in-bore MR experience and by applying MR/US, fusion-guided transperineal procedures and technology to focal laser ablation performed with the TRANBERG® Thermal Therapy System, CLS is aiming at reducing the ‘focal therapy learning curve’ and provide more patients the added benefit of a safe, fast and precise tumor ablation procedure.

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CLS & URN Conducting US-Based, 20-Patient Clinical Study

CLS Americas and the [Urological Research Network, LLC](#), a Florida-based, not-for-profit clinical research organization are currently conducting a 20-patient, Phase I clinical study titled, **“Targeted MRI/US Fusion Transperineal Laser Ablation of Low-to-Intermediate Risk Prostate Cancer.”** The study utilizes CLS’s TRANBERG System in combination with the [Focalyx® Fusion](#) medical device for treatment planning, image fusion, and real-time image guidance during the high-precision, focal laser ablation treatment. The first five patients have been enrolled in the study and successfully treated without any major safety issues.

The study is being performed by Dr. Fernando Bianco, a widely recognized pioneer of fusion target therapies in the office setting under local anesthesia and respected throughout the US and international medical community as an innovative urologic oncologist. He began his comprehensive MRI/US, Transperineal Fusion program in 2013 and has since performed over 2,500 biopsies and 1,000 fusion target cryoablations in the office setting.

High Precision Thermal Therapy System

The TRANBERG® Thermal Therapy System has been developed for image-guided, high-precision soft tissue thermal therapy and ablation procedures. The system can be configured for MR, or MR/US fusion-guided procedures using tissue temperature feedback for precise therapy and ablation control. It includes a desk-top mobile laser unit, innovative non-cooled laser applicators, external tissue temperature probe sensors, and procedure-specific accessories. The TRANBERG system can be deployed in either a transperineal or transrectal approach. Its non-cooled, laser fiber technology optimizes heat distribution, eliminates the need for external cooling and helps reduce procedure times.

About CLS and the TRANBERG® Product Portfolio

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. All components of the TRANBERG® Thermal Therapy Systems have received EU-wide regulatory approval as medical devices (CE-marked class II) for the treatment of soft tissue lesions. CLS is developing its systems to get CE-mark class III for disposable TRANBERG laser applicators to be used in brain as well as expanding the current CE-mark for treatment with imILT®, the Company's interstitial laser thermotherapy for immunostimulatory ablation with potential abscopal treatment effect. 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.com.

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The use of TRANBERG® Thermal Therapy System for immune stimulating interstitial laser thermotherapy (imILT®) and the Thermoguide™ thermometry software has not yet received market clearance by the Food and Drug Administration (FDA) in the United States of America (USA).

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