



FOR IMMEDIATE RELEASE:

CLS Americas and Focalyx Co-Marketing Agreement for Image-Guided Focal Laser Ablation of Prostate Tumors Using TRANBERG and Focalyx Fusion Systems

Minimally Invasive, Outpatient Treatment Designed for Quick Recovery and Low Risk of Unwanted ED and UI Side Effects

Irvine, CA and Miami, FL – August 25, 2023 – [CLS Americas](#), a leading provider of office-based, focal laser ablation systems in the US urology market, and [Focalyx®](#) today announced a co-marketing agreement to sell and market their integrated, minimally invasive, fusion-guided focal laser ablation treatment for low-to-intermediate risk prostate cancer patients. CLS's [TRANBERG™ Thermal Therapy System](#) and the [Focalyx® Fusion](#) image-guidance system will initially be offered under a Mobile Services Provider (MSP) Agreement that includes consumable accessories, training, and on-site clinical and technical support to physicians and staff during procedures.

Focalyx® currently serves centers for diagnosis and treatment of Prostate Cancer in Boston, Connecticut, Miami, New York, Ohio and Pennsylvania with plans to expand to also serve centers in Atlanta, Chicago, Houston and Los Angeles.

In the US, over one million prostate biopsies are performed every year leading to a diagnosis of prostate cancer for almost 250,000 men. Focal laser ablation of prostate tumors has demonstrated high levels of precision and accuracy with low risk of side effects, such as erectile dysfunction and urinary incontinence.

“CLS Americas is excited to enter into this co-marketing agreement with Focalyx®. The Focalyx® system will enable both companies to offer and support our complementary solutions for image-guided focal laser ablation,” stated Michael Magnani, President of CLS Americas. “Dr. Bianco’s earlier results from our twenty patient feasibility study using our TRANBERG Thermal Therapy System with Focalyx® for image guidance were positive. We look forward to expanding the commercial availability and clinical support of our two systems, which can effectively and efficiently perform minimally invasive MR/US Fusion, image-guided, focal laser ablation of prostate tumors in an office setting.”

“Fusion-guided focal laser ablation is a safe and effective minimally invasive treatment for low-to-intermediate risk prostate cancer that offers patients a lower risk of unwanted side effects such as ED or urinary incontinence,” stated Dr. Fernando J. Bianco, CEO of Focalyx®, LLC. “This is made possible

because the TRANBERG laser system used under Focalyx image guidance provides a higher degree of precision and control over the ablation shape, size, and margin than cryotherapy or other focal therapies I've worked with and seen. Additionally, the TRANBERG system is very easy and intuitive to operate and the procedure workflow for FLA is very similar to other office-based procedures routinely being performed by urologists, such as fusion-guided prostate biopsies and cryoablation of the prostate.”

In his role as principal investigator at [Urological Research Network, LLC](#), Dr. Bianco has safely treated twenty patients over the past year in the previously announced Phase I clinical study titled, “*Targeted MRI/US Fusion Transperineal Laser Ablation of Low-to-Intermediate Risk Prostate Cancer.*”

Recent Company Video Highlights

CLS Americas is currently expanding its commercial market development for the TRANBERG focal laser ablation system and has two informational videos available to view and download.

- 1.) [TRANBERG DEMO – Fusion-Guided Focal Laser Ablation.](#)
- 2.) [FOCAL 2022 Conference - TRANBERG & FOCALYX Presentation.](#)

About Focalyx®

Focalyx via it's exclusive client, is the provider of the Focalyx® Fusion Device, the only platform tailored for Diagnosis with Focalyx Bx and Treatment with FocalyxTx to precisely diagnose and destroy cancer within the prostate while sparing healthy tissue. The Focalyx® Fusion Device is 510(k) cleared for the fusion/registration of MRI and transrectal ultrasound (TRUS) images of the prostate during a transperineal biopsy or therapy procedure. For more information, visit www.focalyx.com.

TRANBERG™ Thermal Therapy System

The TRANBERG Thermal Therapy System can be configured for MR/US fusion-guided procedures using real-time tissue temperature measurements for precise therapy and ablation control. It includes a desktop mobile laser unit, innovative non-cooled laser applicators, tissue temperature probes, and procedure-specific accessories. The TRANBERG system can be deployed in either a transperineal or transrectal approach. The TRANBERG system is 510(k) cleared for soft tissue ablation, such as prostate.

About CLS Americas

Clinical Laserthermia Systems Americas Inc, based in Irvine, CA, is responsible for the sales, commercial development, operations and clinical support for the TRANBERG™ Thermal Therapy System and accessories for the US urology market. The powerful system provides minimally invasive, high precision, focal laser ablation using MR or MR US Fusion for image guidance and has received FDA clearance in the US for soft tissue ablation, such as prostate tumors.

CLS Americas is a subsidiary of Clinical Laserthermia Systems AB (publ) headquartered in Lund, Sweden. which has subsidiaries in Germany, the US and Singapore. *For more information about CLS, please visit the Company's website: www.clinicallaser.com. **CLS Americas Contact:** Phone: +1 (949) 504-5440, E-mail: contact-us@clinicallaser.com.*

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