



edap tms
Bringing New Horizons to Therapy

EDAP Announces Sale of Robotic Focal One® HIFU Device to University of Miami

January 29, 2020

University of Miami Sylvester Comprehensive Cancer Center, a Long-Time EDAP Ablatherm® User, to Upgrade to the Most Advanced HIFU Technology for the Treatment of Prostate Disease

Focal One Successfully Launched with Several Patients Treated to Date

LYON, France, January 29, 2020 – EDAP TMS SA (Nasdaq: EDAP) (“the Company”), the global leader in robotic energy-based therapies, today announced that the University of Miami Sylvester Comprehensive Cancer Center is the latest highly-regarded health care institution to acquire Focal One®, the most advanced technology available for delivering high intensity focused ultrasound (HIFU) to target and ablate diseased prostate tissue.

The Sylvester Cancer Center was one of the first hospitals in the U.S. to offer HIFU using EDAP’s Ablatherm® system, with more than 100 patients successfully treated to date, and the medical center has already performed multiple treatments using Focal One. The evolution from Ablatherm to Focal One allows Sylvester Cancer Center to continue to offer the latest generation HIFU to men with localized prostate cancer.

“Our commitment is to always be at the forefront of healthcare technology for our patients,” said Dipen Parekh, MD, Chairman of the Urology Department at the University of Miami Miller School of Medicine and Chief Clinical Officer of University of Miami Health System. “We believe focal therapy – and HIFU -- represents a promising alternative for some of our prostate cancer patients, targeting the disease with minimal-to-no impact on their quality of life. When the next generation HIFU system, Focal One, was cleared by the FDA, we were excited to move to this new device which gives us even greater precision and customization for each patient.”

Marc Oczachowski, Chief Executive Officer of EDAP, added: “We are very pleased to continue and strengthen our partnership with such a prestigious academic center by providing them the latest state of the art HIFU technology available on the market. This represents a strong vote of confidence for our company and our team, and it also confirms the advantages of Focal One versus the previous generation of HIFU devices, including Ablatherm. We are very excited to see increasing traction and interest in Focal One from both existing users and new prospects.”

The University of Miami also led the charge, along with other esteemed medical institutions, to launch the **Focal Robotic Ultrasound Ablation Registry (FoR-UsA Registry)**. The Registry is being used to track baseline and follow-up information on patients undergoing HIFU, initially using Ablatherm and now Focal One.

Focal One fuses MRI and biopsy data with real-time ultrasound imaging that allows urologists to view integrated, detailed 3D images of the prostate and direct high intensity ultrasound waves to ablate the targeted area. Focal One enables urologists to establish more precise contours around diseased tissue and ablate a smaller portion of the prostate, which lessens the damage to healthy tissue and minimizes the risk of serious side effects, most notably incontinence and impotence.

About Sylvester Comprehensive Cancer Center

Sylvester Comprehensive Cancer Center, part of UHealth – the University of Miami Health System, is the only academic-based cancer center in South Florida and serves as the hub for cancer-related research, diagnosis, and treatment at UHealth. Sylvester now has more than 300 cancer-focused physicians and researchers, including more than 100 cancer experts recruited from the nation’s top cancer institutions over the past three years. Physicians and researchers at Sylvester discover, develop, and deliver more-targeted therapies leading to better outcomes. At Sylvester, patients have access to more treatment options and more cancer clinical trials than most hospitals in the southeastern United States.

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market for 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive robotic medical devices for urology using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® in 2013 in Europe and in 2018 in the US as the answer to all requirements for ideal prostate tissue ablation as a complement to the existing FDA-cleared Ablatherm® Robotic HIFU and Ablatherm® Fusion. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS exclusively utilizes the latest generation of shock wave source in its Sonolith® range of ESWL systems. For more information on the Company, please visit <http://www.edap-tms.com>, and us.hifu-prostate.com.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements. Such statements are based on management’s current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others, the clinical status, regulatory approvals, market acceptance and the continued market potential for our HIFU and lithotripsy devices. Factors that may cause such a difference also may include, but are not limited to, those described in the Company’s filings with the Securities and Exchange Commission and in particular, in the sections “Cautionary Statement on Forward-Looking Information” and “Risk Factors” in the Company’s Annual Report on Form 20-F.

Company Contact

Blandine Confort
Investor Relations / Legal Affairs

EDAP TMS SA
+33 4 72 15 31 50
bconfort@edap-tms.com

Investor Contact

Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com



Source: EDAP TMS S.A.