EDAP Announces Two Publications Highlighting Favorable HIFU Focal Therapy Outcomes in Journal of Urology

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- Studies conducted at the University of Southern California and University of Miami represent the first U.S. publications detailing successful partial-gland ablation using high intensity focused ultrasound therapy to treat prostate cancer patients since FDA cleared the technology in 2015.

LYON, France, August 18, 2020 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, announced today that two papers highlighting successful studies of the Company's high intensity focused ultrasound (HIFU) technology for the effective ablation of prostate cancer tissue have been accepted for publication in the prestigious peer-reviewed *Journal of Urology,* the official journal of the American Urology Association (AUA). The two studies, scheduled for publication in the September and October paper editions of the journal, detail clinical outcomes from HIFU procedures conducted at the first two hospitals to purchase the Ablatherm device in the US shortly after the FDA clearance at the end of 2015.

Details of the publications are as follows:

High Intensity Focused Ultrasound Hemigland Ablation for Prostate Cancer: Initial Outcomes of a United States Series. Andre Abreu et al., USC Institute of Urology, Keck School of Medicine, University of Southern California, Los Angeles, California.

This study describes a study of 100 men with a confirmed diagnosis of prostate cancer, 72% of whom were diagnosed with intermediate or high-risk disease. All study subjects underwent hemi-gland ablation with HIFU as primary treatment for prostate cancer between December 2015 and December 2019. Radical treatment was avoided in 91% of men at two years. There were no major complications, and no rectal fistulas occurred. The study found that urinary symptoms returned to near baseline questionnaire scores within 3-6 months and sexual function returned to baseline by 12 months.

"We are pleased to present this first and largest US study on focal therapy with HIFU as primary treatment for prostate cancer," said Andre Abreu, MD, Assistant Professor of Clinical Urology and Radiology, USC Institute of Urology, and first author of the publication. The results observed from these first 100 prostate cancer patients treated with HIFU partial gland ablation in the US are consistent with the very encouraging results from studies conducted in Europe, both in terms of disease control and genitourinary function preservation. After two years of follow-up, 91% of patients avoided radical treatment and its inherently debilitating side effects. Additionally, all patients maintained full continence and there was no significant decline of erectile function and no major adverse events occurred. This reaffirms our commitment to bringing personalized prostate cancer management, incorporating patients' preference and implementing a risk-adaptive approach, with adequate cancer control and without compromising patients' quality of life."

Prospective Evaluation of Focal High Intensity Focused Ultrasound for Localized Prostate Cancer. B. Nahar et al., Department of Urology, University of Miami Miller School of Medicine, Miami, Florida, Sylvester Comprehensive Cancer Center.

This paper describes a single-center prospective study of 52 prostate cancer patients who underwent HIFU treatment between January 2016 and July 2018. Sixty seven percent of study subjects were diagnosed with intermediate or high-risk disease (Grade Group 2 or greater). All patients were treated with EDAP's Ablatherm ® HIFU device and were followed for a minimum of 12 months post-procedure. Biopsies were performed at 6 or 12 months for high or low/intermediate risk cancers, respectively. Two years post procedure, only one patient (2%) had to undergo radical prostatectomy surgery. No change in continence was observed and sexual function returned to baseline at 12 months.

The full abstract is available online at: https://doi.org/10.1097/JU.0000000000001015

Marc Oczachowski, Chairman and Chief Executive Officer of EDAP, commented: "The very positive results of these two studies – the first published in the United States – add to the significant amount of data demonstrating that our HIFU technology, now led by our latest generation Focal One device, provides unmatched potency and accuracy, thereby eliminating the two most devastating side effects of radical surgery – incontinence and impotence. Importantly, these results are consistent with previously completed European studies that included larger patient cohorts and longer follow-up periods. The fact that these two prestigious academic institutions, based on these early positive clinical results, have both decided to invest in Focal One is a clear sign of the potential of EDAP's HIFU technology."

"We are encouraged to see the continuous adoption and use of our US installed base of HIFU machines. Seeing some of our prominent reference centers already publishing in top-ranked Journals their results with our HIFU technology is clearly another milestone in our US market penetration strategy," Mr. Oczachowski concluded.

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market for almost 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive 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 contains 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 and market acceptance of our HIFU devices and the sustained activity of our lithotripsy business, as well as the length and severity of the recent COVID-19 outbreak, including its impacts across our businesses on demand for our devices and services. 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

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