EDAP TMS SA : Houston Methodist Medical Center Research Study Sheds Positive Light on Use of HIFU for Localized Prostate Cancer

September 26, 2018

AUSTIN, TX - LYON, France, September 26, 2018 - EDAP TMS (Nasdaq: EDAP) today announced the results of a study conducted at Houston Methodist Medical Center in Houston, TX that showed High Intensity Focused Ultrasound (HIFU) to be safe and effective, with oncologic control for prostate cancer patients. The study will be formally presented at a sectional meeting of the American Urological Association in Nashville, TN on September 26, 2018.

Researchers evaluated the clinical outcomes from July 2016 to July 2018 on 24 patients who had a whole-gland HIFU procedure using the EDAP Ablatherm Robotic HIFU machine. Significantly, during initial follow-up with participants in the Houston study, 80 percent of the patients had PSA scores below 0.5 ng/mL.

HIFU is a technology that was cleared by the Food & Drug Administration for prostate tissue ablation in 2015. It has since provided a middle ground for localized prostate treatment, serving as an option between active surveillance and radical prostatectomy or radiation, which has a high occurrence of impotence and incontinence. HIFU can be repeated-unlike surgery and radiation-and lowers the chances of long-term side effects.

Brian Miles, MD was the lead researcher for the study. He is a board-certified urologist, professor of Urology at Weill Cornell Medical College of Cornell University and Baylor College of Medicine, and practicing urologic oncologist at Houston Methodist Hospital.

"We were pleased to see that the majority of patients had undetectable PSA levels at three months," said Dr. Miles. "In addition to the PSA results, the main outcomes reported in our HIFU study included feasibility, learning curve, PSA and Quality of Life, i.e., side effects such as erectile dysfunction, stress urinary incontinence and urinary symptom scores.

"As one of the leading academic medical institutions in the country we believe our study data is a good indicator for urologists who want to offer a greater range of safe options to their patients when making decisions about their prostate health."

While longer-term follow-up on patients undergoing HIFU is still in process, the study lends weight to a growing body of research conducted at major medical institutions in the U.S., including the University of Miami and Duke University, as well as multiple studies reported in Europe. All studies so far have pointed to the effectiveness of the procedure, which is increasingly being offered as an alternative to radical prostatectomy or radiation for patients with localized prostate cancer.

Houston Methodist patients' prostate health will be followed on a regular basis, with PSA tests given every six months for the first five years and yearly tests after that period. The results from these study participants will also be incorporated in the American HIFU Patient Registry designed to collect outcome data on those who went through the procedure.

HIFU is a non-invasive therapeutic technique that uses ultrasound waves to destroy prostate tissue without damaging the structure of the prostate wall and attached nerve-endings. Since the early 1990s, researchers in France, Germany and the United Kingdom have been reporting positive outcomes among the 75,000 patients worldwide who have had the HIFU procedure for treating prostate cancer.

The Houston Medical Center study will be presented by at the 97th Annual Meeting of the South Central Section of the American Urological Association meeting in Nashville, TN, taking place September 26 to 29, 2018. Spencer Craven, M.D. and Vivian MacDonnell, CCRP, also contributed to the study.

About EDAP TMS
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 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 and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device. 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.

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