EDAP TMS SA : EDAP Reports First US Cohort Study Results of Focal HIFU Prostate Ablation Shows Promising Outcomes

April 3, 2018

Clinical Results Presented at the Southeastern Section of the American Urological Association

Confirms HIFU's Safety, Efficacy and Benefits for Patients' Quality Of Life

LYON, FRANCE, AUSTIN, TX -- APRIL 3, 2018 - EDAP TMS (Nasdaq: EDAP) today announced that preliminary results of the first U.S. clinical cohort study of focal therapy, using the company's Ablatherm Robotic HIFU system for partial-gland ablation demonstrated promising outcomes for prostate cancer patients. Patients participating in the study, conducted by the University of Miami Miller School of Medicine, experienced fewer side effects of incontinence and impotence commonly associated with prostate cancer treatments such as surgery and radiation therapy.

In a presentation at the Southeastern Section of the American Urological Association (SESAUA) on March 22, 2018, lead investigators Bruno Nahar, MD and Dipen Parekh, MD showed the initial results of 50 patients enrolled in the study. All patients had been diagnosed with localized prostate cancer and were eligible for focal HIFU therapy, which involves ablating only the diseased part of the prostate, thus preserving healthy prostate tissue and minimizing common side effects.

The University of Miami was among the first medical institutions to acquire Ablatherm Robotic HIFU at the end of 2015 following FDA clearance of the device for prostate tissue ablation. Doctors initiated the clinical study to evaluate focal therapy using HIFU after European studies yielded encouraging short-term results.

"These men showed significantly fewer side effects, such as urinary incontinence and erectile dysfunction, compared to traditional whole-gland treatment like surgery and radiation," said Dr. Nahar. "Most importantly, focal HIFU ablation of the prostate showed promising oncological short-term outcomes, even in clinically-significant prostate cancer."

"These results are very encouraging and in line with EDAP's long-term strategy of partnering with top US academic institutions to collect clinical data in support of the safety and efficacy of HIFU as a prostate ablation tool, as well as to help patients maintain a high quality of life," said Marc Oczachowski, chief executive officer of EDAP TMS.

All 50 patients in the study were carefully selected and have completed a thorough post-treatment follow-up, including a prostate-specific antigen (PSA) test every three months, and MRI-fusion biopsy either at six or 12 months, depending on the aggressiveness of the cancer.

For complete assessment of continence and erectile function in the months following focal HIFU ablation, doctors will also evaluate patients every three months using validated questionnaires, such as the International Prostate Symptom Score (IPSS), Sexual Health History for Men (SHHM) Score and Expanded Prostate Cancer Index Composite (EPIC-26).

"We are seeing great momentum in favor of HIFU," added Oczachowski. "These positive clinical findings were presented on the heels of other great news. Over the last month, renowned medical institutions, including the University of Miami, Weil Cornell-Houston Methodist Hospital, Duke University, and the University of Southern California joined forces to launch the first US-based HIFU patient registry to collect high quality clinical data on hundreds of patients. In addition, CIGNA became the first major private health insurer in the US to cover HIFU for prostate procedures."

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® (currently pending FDA clearance) in 2013 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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