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Bringing New Horizons to Therapy

October 11, 2016

EDAP's Ablatherm® Robotic HIFU Positioned as Efficient Option for Unilateral Prostate Ablation in Breakthrough Multicenter Study Published in Major Medical Journal

LYON, France, Oct. 11, 2016 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced the results of a multicentric study using Ablatherm Robotic HIFU which demonstrates promising oncologic outcomes with low side effects. The results of the study have been electronically published in the prestigious peer-reviewed medical journal *European Urology*; the study will subsequently appear in a print edition.

The prospective, independent, multi-institutional study conducted by the French Urological Association (AFU) was designed to evaluate HIFU hemiablation (treatment of the half of the prostate where the tumor is located, sparing the rest of the gland) as a primary treatment for localized, unilateral prostate cancer. In the study, 111 patients received focal hemiablation using EDAP's Ablatherm® Robotic HIFU at 10 different clinical institutions. Control biopsies were performed 1 year following treatment, with 95% of subjects showing absence of clinically significant cancer on the treated side. The study also showed very low side effects with continence preserved in 97% of patients at 1 year and erectile function preserved in 78% of patients. There was no significant decrease in Quality of Life score observed at 12 months, and the rate of radical treatment free survival at 2 years was 89%, meaning that only 11% of patients underwent surgery or radiotherapy.

Pascal Rischmann, Chairman of the Department of Urology, kidney transplantation and Andrology, University Hospital of Rangueil in Toulouse, France at the time of the study, and lead author on the study said, "This study supported by the French Association of Urology builds upon the interest in focal therapy and demonstrates its role in the management of prostate cancer based on quality of life preservation and efficacy. I have long thought HIFU was an ideal ablation modality for focal therapy and this is substantiated by the study results."

Marc Oczachowski, Chief Executive Officer of EDAP TMS, added: "This focal HIFU study and its promising clinical outcomes confirms HIFU as a true alternative for select patients diagnosed with prostate malignancy. When these patients wish to avoid radical surgery or radiotherapy but feel uncomfortable just "watching and waiting" for the development of their disease, HIFU with a partial-ablation approach seems to be a good compromise between these two extreme options. This is a real opportunity for EDAP's superior HIFU technology."

Link to e-publication: [http://www.europeanurology.com/article/S0302-2838\(16\)30679-0/abstract/focal-high-intensity-focused-ultrasound-of-unilateral-localized-prostate-cancer-a-prospective-multicentric-hemiblation-study-of-111-patients](http://www.europeanurology.com/article/S0302-2838(16)30679-0/abstract/focal-high-intensity-focused-ultrasound-of-unilateral-localized-prostate-cancer-a-prospective-multicentric-hemiblation-study-of-111-patients)

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) for prostate tissue ablation in the U.S. and for treatment of localized prostate cancer in the rest of the world. HIFU treatment is shown to be a minimally invasive and effective option for prostatic tissue ablation with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. Ablatherm-HIFU is approved for commercial distribution in Europe and some other countries including Mexico and Canada, and has received 510(k) clearance by the U.S. FDA. The Company also markets an innovative robot-assisted HIFU device, the Focal One®, dedicated to focal therapy of prostate cancer. Focal One® is CE marked but is not FDA approved. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and distributes medical equipment (the Sonolith® lithotripters' range) for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL) in most countries including Canada and the U.S. For more information on the Company, please visit <http://www.edap-tms.com>, and <http://www.hifu-planet.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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