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Positive Outcomes From Prostate Cancer Hemiablation Study With EDAP Ablatherm Robotic HIFU Presented at 109th French Urology Congress

LYON, France, Nov. 24, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced data from a multicenter trial demonstrating encouraging outcomes of focal HIFU as a new treatment strategy for patients with unilateral localized prostate cancer.

The dataset was presented in a poster session during the [109th French Urology Congress](#), held November 18-21, 2015 in Paris, France.

Data from the abstract, entitled "*Focal HIFU (High Intensity Focused Ultrasound) treatment of unilateral localized prostate cancer - Hemiablation strategy: a prospective French multicentric study with 111 patients*," demonstrated the potential of hemiablation (removal of half the prostate) using focal HIFU to achieve a local control of the tumor in patients with unilateral prostate cancer.

The study, which was conducted at 10 centers throughout France, was sponsored and designed by the French Urological Association (AFU). The aim of the study was to assess the effectiveness and side effect profile of prostatic hemiablation using Ablatherm HIFU to treat the pathologically affected lobe.

Pascal Rischmann, Professor and Chairman, Department of Urology, Ranguel University, Principal Investigator of the trial and President of 109th French Urology Congress commented, "The data from the trial are highly encouraging in comparison to other existing treatments: 88% of the study patients showed no significant findings on biopsy after Focal HIFU, while 97% of patients maintained continence and 78% retained sexual function. We believe that hemiablation HIFU will be an attractive treatment option for many patients."

Pierre Reboul, France Business Unit Director, added: "We had a strong presence throughout this year's AFU Congress, which was well attended by members of the French urology community. There was clearly a growing interest in HIFU technology for the management of localized prostate cancer, which we believe was supported by the French authorities' decision to reimburse HIFU at the same rate as surgery. At this annual event, we further established EDAP as the leading company in therapeutic ultrasound with a complete urology offering in stone and prostate disease management."

Marc Oczachowski, EDAP TMS Chief Executive Officer, concluded: "This study is another excellent clinical paper from Ablatherm users and experts; these data complement the already comprehensive clinical background of Ablatherm-HIFU, confirming its best-in-class capabilities in prostate tissue ablation."

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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