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EDAP Announces Results of World's First Focal HIFU Trial

100% Cancer Specific Survival, 94% Continence Preservation and 80% Potency Preservation

LYON, France, Jan. 19, 2016 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced the publication of long term results of Ablatherm Focal HIFU in the peer reviewed journal "Prostate Cancer and Prostatic Diseases," part of the Nature Publishing Group.

This pioneering prospective study of HIFU hemiablation of prostate cancer was conducted by Professor Roland van Velthoven, Head of the Urology Department at renowned Institut Bordet Oncology Center, Brussels, Belgium. With the initial patient treated in early 2007, it is the first prospective study of focal HIFU to enroll patients a follow-up extending to 8 years. The publication reports a 100% cancer specific survival at 5 years, a 94% rate of continence preservation and 80% rate of potency preservation.

Pr. van Velthoven commented: "We are extremely encouraged by the results of this prospective study initiated in 2007, at a time when multi-parametric MRI and ultrasound guided biopsies were simultaneously available. The availability of these technologies allowed us to identify the sub-group of patients presenting localized, unilateral and significant index lesion eligible for a treatment with curative intent. Low morbidity associated with favorable oncological outcome enables us to keep these patients under close monitoring of PSA and MRI imaging when necessary. This approach enabled us to spare patients from unnecessary iterative biopsy policies, as well as from the costs and side effects of hormonotherapy or radiotherapy aimed at local control of a limited disease."

Marc Oczachowski, EDAP TMS Chief Executive Officer, added: "We are very pleased with the published results from this study, the first and the longest follow up Focal HIFU trial in the technology's history. It confirms the leadership of our HIFU technology for the ablation of prostatic tissue."

Oczachowski, concluded: "These high level clinical outcomes are very encouraging, as they were obtained using the exact Ablatherm Robotic HIFU device that was recently cleared by the FDA in the United States. They are consistent with other single and multicenter studies of focal Ablatherm HIFU. This demonstration of reproducibility of outcomes is important and clearly indicates that similar high quality results can be duplicated commercially in the U.S."

Link to abstract:Â www.ncbi.nlm.nih.gov/pubmed/26597660

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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