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EDAP Reports Superior Outcomes of Focal Ablatherm-HIFU Compared to Robotic Radical Prostatectomy

Similar Cancer Control at 5 Years, Significantly Less Incidence of Incontinence and Erectile Dysfunction

LYON, France, Dec. 19, 2016 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced the publication of results comparing Ablatherm Focal HIFU with Robotic Radical Prostatectomy. The results of the study have been electronically published in the prestigious peer-reviewed medical Journal of Endourology; the study will subsequently appear in a print edition.

This matched pair analysis of HIFU hemiablation vs robotic assisted laparoscopic prostatectomy was conducted by Professor Roland van Velthoven, Head of the Urology Department at the Institut Bordet Oncology Center in Brussels, Belgium. In this study, 55 patients with unilateral localized prostate cancer were treated using Ablatherm-HIFU and their outcomes were compared 1:1 with patients, having similar clinical criteria but underwent robotic assisted laparoscopic prostatectomy. The matched pair analysis concluded that HIFU was comparable to robotic-assisted radical prostatectomy in the management of prostate cancer and showed HIFU to have significantly better functional outcomes.

Prof. van Velthoven commented: "Clinical outcomes from this comparative study are extremely encouraging as they confirm the efficacy of HIFU focal in the treatment of localized prostate cancer, reporting similar results to radical prostatectomy in terms of cancer control at 5 years. More importantly, the study proves focal HIFU superiority in terms of side effects with significantly higher continence and potency preservation rates at both 1 month and 2 years after the procedure. Focal HIFU is the ideal minimally invasive approach for patients with low risk prostate cancer seeking treatment of their disease while preserving their quality of life".

Marc Oczachowski, EDAP TMS Chief Executive Officer, added: "We are very enthusiastic about the published results from this study. Once again, the data confirms HIFU as a viable option in the focal ablation of prostatic tissue. It offers patients a non-invasive alternative to current radical treatments. The need for our HIFU treatment is now more evident following the recent publications of the ProtecT study in the New England Journal of Medicine and the Ablatherm-HIFU hemiablation study in the European Urology journal."

Link to abstract: https://www.ncbi.nlm.nih.gov/pubmed/27799004 (epub ahead of print in Journal of Endourology).

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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