



March 22, 2017

EDAP's Ablatherm® Robotic HIFU: Clinical Results Support High-Intensity Focused Ultrasound (HIFU) for Prostate Tissue Ablation after Unsuccessful Radiotherapy

Multicenter Retrospective Analysis of 418 Patients

LYON, France, March 22, 2017 -- EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, today announced the publication of a peer-reviewed article that analyzed Ablatherm Robotic HIFU for prostate tissue ablation in patients who had previously undergone radiotherapy treatment. The article concludes that HIFU should be considered as a valuable therapeutic option for carefully selected patients who failed a previous radiotherapy treatment. The article has been published in the January 2017 edition of the prestigious peer-reviewed British Journal of Urology International.

Authored by Pr. Sébastien Crouzet, M.D., Ph.D., from Edouard Herriot Hospital, Lyon, France, and co-authored by lead urologists from nine institutions across France, Germany, UK, Italy and the USA, this retrospective analysis was designed to evaluate the outcomes of Ablatherm Robotic HIFU for the treatment of patients who had been previously treated with radiotherapy and were indicated for additional prostate tissue ablation. The results were compiled from the Ablatherm treatment registry (@-Registry™), a multicenter secure online database for patients who have undergone prostate HIFU with Ablatherm. Inclusion criteria for the analysis were applied to the database, resulting in 418 patients with available data. Statistical models were applied to the data, using the longest available follow-up timepoint for each outcome and patient. Based on the Kaplan Meier survivorship analysis of this data, the rates of overall survival, cancer specific survival, and metastasis free survival at 7 years were 72%, 82%, and 81%, respectively.

Pr. Sébastien Crouzet commented: "This is the largest series of salvage patients treated with HIFU and followed for data collection. The results are encouraging, and support the use of Ablatherm Robotic HIFU for these patients who are particularly fragile after the failure of their radiation treatment and are limited to minimally invasive treatment options. Patients who require additional treatment after a radiation therapy may benefit from prostate tissue ablation with HIFU."

Marc Oczachowski, Chief Executive Officer of EDAP TMS, added: "There is a growing number of patients who failed their radiotherapy treatment and require a secondary option; this large and growing market opportunity is the result of an as-yet unmet medical need. Pr. Sébastien Crouzet's clinical publication reconfirms that EDAP's Ablatherm HIFU technology offers a valuable answer to this need and is well positioned to serve this growing population with minimal competition."

Link to e-publication abstract: <http://onlinelibrary.wiley.com/doi/10.1111/bju.13766/abstract>

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 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 is approved for commercial distribution in Europe and 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.

Investor Contact

CG CAPITAL
Rich Cockrell
877.889.1972
investorrelations@cg.capital

Company Contact

Blandine Confort
Investor Relations / Legal Affairs EDAP TMS SA
+33 4 72 15 31 50
bconfort@edap-tms.com

 [Primary Logo](#)

Source: EDAP TMS SA

News Provided by Acquire Media