July 17, 2017

EDAP Announces Withdrawal of 510(k) Application for Focal One® to be Followed by New Submission to Conform to FDA Review Rules

- New 510(k) With New Clinical Data to be Submitted for Focal One®
- Initial 510(k) to be submitted for Ablatherm Fusion®

LYON, France, July 17, 2017 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that the Company has withdrawn the 510(k) application for its Focal One device currently under review by the FDA. Following advanced discussions with the agency, EDAP plans to submit a new 510(k) file including new clinical data.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented: "As mentioned during our last quarterly call, a shift in biopsy protocol has created difficulties in comparing biopsy data under the current 510k application. We actively worked with some of our key users in Europe to gather new and additional clinical data on Focal One in order to provide them to the agency for review. It is not possible to include this new clinical data in our current file under review, and thus need to withdraw our current application and submit a new 510(k) with the new set of clinical data, which will be filed very soon."

Marc Oczachowski added: "We remain committed to having our HIFU Focal One device FDA cleared as rapidly as possible. With the exception of the new clinical data, the new application remains unchanged."

Oczachowski concluded: "In our effort to continue to continue making our HIFU technology and devices available in the U.S., we will also submit a 510(k) filing to the FDA for the clearance of our Ablatherm Fusion device in the near future, enabling American patients to benefit from the latest innovations in prostate tissue ablation with HIFU."

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. Ablatherm Fusion is not FDA cleared yet. 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 cleared. 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-prostate.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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