



July 31, 2017

## **EDAP Announces filing of 510(k) Application for Ablatherm-Fusion® device**

LYON, France, July 31, 2017 -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that the Company submitted a 510(k) application for its Ablatherm Fusion device, enabling a more precise method for targeting of diagnosed areas within the prostate.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented: "As recently mentioned, the next generation of Ablatherm devices merge MRI, 3D biopsy maps, and ultrasound images by integrating EDAP's proprietary software and fusion algorithm. This innovative, state of the art option tremendously improves the imaging and targeting capabilities of the Ablatherm while maintaining its unique, proven tissue ablation efficacy."

Marc Oczachowski added: "Ablatherm Fusion is well positioned to perfectly complement our already commercialized range of HIFU devices and offerings. The submitted 510k file is straightforward as it maintains same treatment parameters from the previously approved current generation of Ablatherm devices."

### **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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Source: EDAP TMS SA

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