



**edap tms**  
Bringing New Horizons to Therapy

September 11, 2017

## **EDAP Announces Filing of New 510(k) Application for Focal One® Device**

*510(k) Includes New Clinical Data to Support EDAP's File*

LYON, France, September 11, 2017 -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that the Company submitted a new 510(k) application for its Focal One device, including an updated clinical section for FDA review.

As reported on July 17, 2017, the Company decided to withdraw its existing Focal One 510(k) application to allow the inclusion of a new set of clinical data.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented: "The new 510k review may be more efficient as the updates only pertain to the clinical section which includes new studies from active and academic Focal One centers in Europe. Our regulatory and clinical teams have been working diligently to gather the new set of data."

Marc Oczachowski added: "As the new 510(k) application differs mainly within the clinical section, we will work closely with the agency to facilitate a straightforward review."

### **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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