



May 22, 2014

## **EDAP's Ablatherm-HIFU FDA Panel Meeting Confirmed for July 30, 2014**

LYON, France, May 22, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that the U.S. Food and Drug Administration (FDA) Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee will review the Pre-Market Approval ("PMA") application for EDAP's Ablatherm-HIFU device for the treatment of localized prostate cancer on July 30, 2014.

Marc Oczachowski, EDAP's Chief Executive Officer, said, "Confirmation of this important milestone is great news for the Company and its PMA application. The FDA provided us with a worksheet that details the deadlines and documents to be prepared and sent to the panel members for review ahead of the advisory committee meeting on July 30, 2014. We are very excited to now have a much clearer path toward FDA approval and the entire team at EDAP is diligently preparing for this major event in the PMA application process."

### **About EDAP TMS SA**

EDAP TMS SA markets today Ablatherm<sup>®</sup> for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option 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 and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in February 2013 after the completion of a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. In February 2013, the Company introduced a new innovative HIFU device, the Focal One<sup>®</sup> dedicated to focal therapy of prostate cancer. Focal One<sup>®</sup> 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 commercializes medical equipment (the Sonolith<sup>®</sup> range) for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). 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 uncertainties of the U.S. FDA approval process, 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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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