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EDAP Completes FDA Q&A Session for Its Ablatherm-HIFU Pre-Market Approval Application

LYON, France, March 20, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that it has completed its response to questions from the FDA regarding the Company's Ablatherm-HIFU Pre-Market Approval ("PMA") application, closing this step within the U.S. Food and Drug Administration ("FDA") review process.

Marc Oczachowski, Chief Executive Officer of EDAP TMS SA, commented, "This is another significant milestone within the FDA approval process for our Ablatherm-HIFU device. As per the standard FDA review timeframe, the next step is an advisory committee meeting that we expect to be held within the next four to six months. We do not believe there will be any further questions related to the filing or additional requests from the FDA prior to the panel meeting. With this step behind us, we are focusing our efforts to be fully prepared for the upcoming panel meeting."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm[®] 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[®] 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 commercializes medical equipment (the Sonolith[®] 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 statements00 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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