November 6, 2014

EDAP Receives FDA Guidance on PMA for Ablatherm-HIFU

Guidance Provides Specific Recommendations for Amendments to Make PMA Approvable

LYON, France, Nov. 6, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today received a letter from the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) on its current PMA application for Ablatherm Integrated Imaging Device. The FDA letter stated that while EDAP's Ablatherm-HIFU PMA is not approvable in its current form, it provides specific guidance and recommendations as to a path forward. This guidance was provided in accordance with the requirements of 21 CFR 814.44(f), which states that the FDA, where practical, must identify measures necessary to make the PMA approvable.

Consistent with feedback received during the Gastroenterology and Urology Devices Panel meeting, the FDA has recommended considering a modified indication for use in a population of localized prostate cancer patients that have greater risk of morbidity and/or mortality from their disease. The FDA made further recommendations regarding the potential use of the company's European registry, along with the already existing safety data from the previous U.S. IDE, to support approval for the modified indication. Although additional data and analyses will be necessary to address FDA's requests, the letter did not require a new U.S. IDE study.

In order to continue the process, the Company must submit a major amendment, to include the additional information requested by the FDA, by April 29, 2015. This major amendment, which will have the same PMA number as the Company's initial filing, may extend the FDA review period up to 180 days after submission.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "This response from the FDA reflects the extensive and ongoing discussions between our team and agency staff since the Advisory Panel meeting in July. We appreciate the FDA providing us with constructive and comprehensive recommendations, and believe this may be a potential opportunity to advance through the approval path for our PMA."

Oczachowski continued: "We will host a conference call to discuss our third quarter 2014 financial results on November 20, 2014, and look forward to further discussing this significant development on the call."

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 March 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 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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