July 30, 2014

EDAP Updates on FDA Advisory Committee Meeting on Ablatherm-HIFU for the Treatment of Prostate Cancer

LYON, France, July 30, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that the U.S. Food and Drug Administration's (FDA) Gastroenterology and Urology Devices Panel (GUDP) voted 3 yes, 5 no with 1 abstention on the question of safety, 9 no on the question of efficacy, and 8 no with 1 abstention for the risk/benefit ratio for the use of its Ablatherm-HIFU device for the treatment of low-risk, localized prostate cancer.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are disappointed by the Committee's recommendation regarding Ablatherm-HIFU for the treatment of low-risk, localized prostate cancer and we appreciate the dialogue during today's meeting. We look forward to subsequent discussion with the FDA. We will continue to work diligently with the FDA as it carefully completes its final review for Ablatherm-HIFU's PMA."

Prostate cancer is the most prevalent form of cancer in men with approximately 233,000 new cases diagnosed in the United States and approximately 380,000 in Europe each year.

The FDA is not bound by the GUDP's recommendation but will consider the committee's guidance in reviewing the Pre-Market Approval (PMA) application for Ablatherm-HIFU.

Documents presented at the advisory committee meeting, which includes EDAP's executive summary and presentation, will be available online and can be accessed from the investor relations page of the Company's corporate website at www.edap-tms.com.

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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