March 28, 2013

EDAP Receives U.S. FDA Filing Acceptance of Pre-Market Approval Application

Ablatherm(R)-HIFU PMA Application Proceeds to Substantive Review

LYON, France, March 28, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that the U.S. Food and Drug Administration has provided a positive Filing Review Notification on the Company's Pre-Market Approval (PMA) application for its Ablatherm Integrated Imaging HIFU (High Intensity Focused Ultrasound) device for the treatment of low-risk, localized prostate cancer. The FDA conducted a filing review of EDAP's PMA, and found it to contain all of the information needed to proceed with the substantive review, in which the FDA will evaluate the safety and effectiveness of Ablatherm Integrated Imaging HIFU device, as well as EDAP's engineering, manufacturing and quality systems.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented, "Receiving FDA filing acceptance for our PMA in less than two months is both very timely and a major milestone. We are moving forward in the PMA Review Process as the agency commences its substantive review. We will continue to work closely with the FDA review team."

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 conducted under an Investigational Device Exemption (IDE) granted by the FDA. 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 that involve risks and uncertainties. Such statements are based on management's current expectations and are subject to a number of uncertainties, including the uncertainties of the regulatory process, and risks that could cause actual results to differ materially from those described in these forward-looking statements. Factors that may cause such a difference 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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Source: EDAP TMS SA