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EDAP Completes Follow-Up Phase and Data Collection for FDA ENLIGHT Trial

LYON, France, Aug. 17, 2012 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today provided an update regarding its Ablatherm-HIFU (High Intensity Focused Ultrasound) ENLIGHT U.S. clinical trial for the indication of low risk, localized prostate cancer. The trial is a multi-center U.S. Phase II/III clinical trial conducted under an Investigational Device Exemption (IDE) granted by the FDA. As previously announced, the last Ablatherm-HIFU patient was treated in June 2010. The two year anniversary of the last patient treated occurred on June 30, 2012, which marked the conclusion of the two year follow-up phase, and the Company confirms the completion of all two year follow-up visits.

John Rewcastle, Medical Director of EDAP-TMS, remarked, "After the second anniversary of the last patient treated, and according to the approved protocol, patients have two months to present at the trial sites for their last follow-up visit. Now that every patient has completed their follow-up visit, we will be in a position to commence the clinical analysis of the collected data. In parallel with this analysis, EDAP's team in the U.S. and France has already started to compile the comprehensive Premarket Approval (PMA) submission that includes a detailed review of the Company's technical and manufacturing capabilities, along with the clinical analysis of the collected U.S. patient data."

Marc Oczachowski, Chief Executive Officer of EDAP-TMS, stated, "Our integrated team in the U.S. and France is committed to assembling the technical, non-clinical laboratory studies and clinical investigations sections of the submission, which is hundreds of pages long. We are on track to submit the filing to the U.S. FDA in the fourth quarter of 2012."

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm®, the most advanced and clinically proven choice 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. Approved in Europe as a treatment for prostate cancer, Ablatherm-HIFU (High Intensity Focused Ultrasound) is currently undergoing evaluation in a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA, the ENLIGHT U.S. clinical study. The Company also is developing this 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*

About ISTU

The International Society for Therapeutic Ultrasound (ISTU) is a non-profit organization founded in 2001 to increase and diffuse knowledge of therapeutic ultrasound to the scientific and medical community, and to facilitate the translation of therapeutic ultrasound techniques into the clinical arena for the benefit of patients worldwide.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements that involve risks and uncertainties. These include statements regarding the Company's growth and expansion plans, the conclusiveness of the results of and success of its Ablatherm-HIFU clinical trials and expectations regarding the IDE submission to and approval by the FDA of the Ablatherm-HIFU device. 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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