EDAP Continues FDA Discussion on U.S. ENLIGHT Trial Protocol

LYON, France, Jan 25, 2010 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced that a meeting with the U.S. Food and Drug Administration (FDA) has been scheduled for later this month. The discussion follows the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, held on December 11, 2009

EDAP and the agency plan to discuss alternatives to the cryo comparative arm and guidelines for a submission of an amended protocol for the U.S. ENLIGHT trial. The study is currently evaluating high intensity focused ultrasound (HIFU) treatment using cryo as the comparative treatment arm.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are pleased to continue our discussions with the FDA. While the company does not expect any formal decision from this meeting, it is the initial step towards a formal submission of an amended protocol that will aim to complete enrollment in the timeliest manner possible. We look forward to our continuing dialogue with the agency and will continue to move aggressively towards treating additional patients in the HIFU arm."

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 multicenter U.S. Phase II/III clinical trial under an Investigational Device Exemption 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 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, http://www.hifu-planet.com and http://www.pcaresearch.com.

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. 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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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