EDAP Outlines U.S. ENLIGHT Clinical Strategy

Ablatherm HIFU Trial Update: IDE Submission Expected in 2012

LYON, France, Apr 26, 2010 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced its strategy for the ongoing U.S. ENLIGHT Ablatherm-HIFU clinical trial. Following the FDA Gastroenterology and Urology Devices Panel in December 2009 and the Company's January 2010 meeting with the FDA concerning its recommendations for the trial protocol, the Company has thoroughly evaluated all options aiming at an IDE submission in a feasible timeframe and with acceptable economics. Based on input from its clinical and regulatory advisors and with concurrence of the Board of Directors, EDAP said it will discontinue enrollment in the Ablatherm-HIFU study in the coming weeks and complete the required 2-year follow-up of all patients treated to that date. The resulting data set, which will include outcomes from more than 100 patients, will form the foundation of a submission to the FDA, which the Company expects to occur in 2012. The Company believes that the submission of data from the patients treated in the U.S. ENLIGHT trial, combined with the strong long-term data in Europe where more than 22,000 Ablatherm-HIFU treatments have been performed to date, and compared with the retrospective clinical data on other therapies from existing registries, will provide a strong clinical profile for FDA evaluation.

Marc Oczachowski, EDAP's Chief Executive Officer, said, "As a Company, we believe there is merit in this strategy as the most practical option to move forward with our U.S. ENLIGHT clinical trial, allowing us to complete the HIFU study in the timeliest possible manner. We believe the data collected from the number of patients that will have been treated in the U.S. with Ablatherm-HIFU represents a valuable asset and, combined with our abundant 10-year data on European patients, should form a strong clinical background for our IDE submission."

Mr. Oczachowski continued, "Our U.S. clinical strategy not only positions us to seek FDA approval in a timely and efficient manner, but also optimizes the Company's financial resources. We will continue to focus our efforts on bringing the Company to profitability through strong global operating efficiencies and business development initiatives. To date, more than 22,000 prostate cancer treatments have been performed with Ablatherm-HIFU and we intend to further expand HIFU adoption through our RPP model. Separately, we also continue our growth initiatives in lithotripsy with our high-range Sonolith I-Sys device which was recently approved in the key markets of Japan and the U.S., as well as our new Sonolith i-move device that was launched in Europe last week. "

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, 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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