



EDAP Receives FDA Permission to Amend Ongoing Ablatherm-HIFU U.S. Clinical Study Protocol

Broader HIFU Patient Inclusion Criteria Aims to Accelerate Enrollment

LYON, France, Mar 10, 2009 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that the U.S. Food and Drug Administration (FDA) approved the following protocol amendments for the Company's ongoing U.S. clinical study of Ablatherm-HIFU (high intensity focused ultrasound) for the treatment of patients with localized prostate cancer:

- * Minimum patient age of 50 years old (formerly 60 years of age)
- * Potential to add three clinical trial sites to the Ablatherm-HIFU study arm, for a total of 27 participating U.S. sites
- * Replacement of the required five day follow-up visit with a telephone call consultation
- * Inclusion of patients currently treated with alpha blockers and saw palmetto

The U.S. ENLIGHT clinical study of Ablatherm-HIFU, a minimally invasive, robotized treatment approach of localized prostate cancer, is currently recruiting patients at 24 U.S. clinical trial sites. In January 2008, EDAP submitted an investigational device exemption (IDE) supplement requesting that the FDA allow broader patient selection parameters and additional investigational sites to expand the HIFU patient pool and potentially accelerate enrollment.

Dr. John Rewcastle, Medical Director of EDAP, commented, "While these amendments seemingly represent minor changes to the overall study protocol, they significantly increase the number of potential candidates that meet inclusion criteria for the trial. The lower minimum age requirement allows us to screen younger patients who typically have smaller prostates. Prostate size has been a limitation for our accrual efforts to date. In addition, we are able to screen patients currently treated with alpha blockers and saw palmetto, which are commonly used by many men with benign prostatic hyperplasia. These patients which were previously rendered as non candidates can now potentially participate in our U.S. clinical trial. This potential widening of the patient pool along with the possible addition of three new Ablatherm-HIFU sites is a very positive step forward."

Marc Oczachowski, EDAP's Chief Executive Officer, added, "We are extremely encouraged by the FDA's approval of these protocol amendments and the potential to add three new participating sites could further support patient recruitment. Pending the successful completion and positive outcome of the study, EDAP's priority remains bringing this minimally invasive therapy to U.S. patients with localized prostate cancer."

Mr. Oczachowski, concluded, "More than 18,000 treatments have been successfully performed worldwide using Ablatherm-HIFU. In the past few quarters we have seen an uptick in U.S. patient screening rates as we continue to enroll patients at our world-renowned participating clinical sites. With the FDA's permission for our protocol amendments, we have the potential to recruit from an even wider pool of patients. We look forward to completing the U.S. clinical study using the amended protocol."

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 U.S. ENLIGHT 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> or <http://www.urotoday.com/HIFU>.

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 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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