



EDAP and Duke Medical Restart Ablatherm-HIFU Localized Prostate Cancer Clinical Study

Duke Performs First Treatments under EDAP Study Sponsorship

LYON, France, May 3 /PRNewswire-FirstCall/ -- EDAP TMS S.A. (Nasdaq: EDAP), the global leader in High Intensity Focused Ultrasound (HIFU) treatment of prostate cancer, announced the continuation of its US Phase II/III clinical trial with treatment of an additional two patients at Duke University Medical Center, Durham, North Carolina.

"We are excited to resume our US program," said Marc Oczachowski, CEO of EDAP. "EDAP's more than 10 years of experience in HIFU therapy plus extensive peer reviewed and published clinical references demonstrate the potential of HIFU in the US. We continue to show solid growth outside the US where Ablatherm-HIFU use is already approved and growing as Ablatherm achieves standard of care status in the treatment of localized prostate cancer in Europe, the only HIFU device able to demonstrate such progress and market adoption. Ablatherm is the true HIFU leader in Europe and clearly the preferred HIFU system. This success outside the US is due to our clear commitment to clinical excellence, and we have absolute confidence our US sites will adhere to the same high standards of excellence in the US study programs."

"HIFU appears to very well tolerated with minimal invasiveness and minor discomfort," states Cary N. Robertson M.D. F.A.C.S. Associate Professor, Division of Urology, Duke University Medical Center. "This technology offers an alternative to other approved therapies for prostate cancer and may be effective in selected individuals as a primary therapy. This is an important trial that will define the role of HIFU as a treatment for localized prostate cancer."

Further treatments are scheduled to follow immediately at multiple centers, with enrollment again open to patients meeting the study criteria.

The study is currently enrolling men over age 50 diagnosed with clinical stage T1a, b or c or T2a localized prostate cancer. HIFU is a noninvasive therapy using highly focused ultrasound energy to ablate the prostate tissue. Details of the study and background on Ablatherm-HIFU can be found online at <http://www.clinicaltrials.gov> by searching for "Ablatherm."

"We observed a good initial start to the clinical study and a strong commitment to resume the clinical sessions at our centers due to their support for Ablatherm-HIFU," said Hugues de Bantel, in charge of the US FDA programs for EDAP. "We intend to complete multiple opportunities already presenting themselves to add centers and achieve full patient enrollment as rapidly as possible. We will achieve the clinical goals necessary to demonstrate the efficacy of Ablatherm-HIFU in the prostate cancer therapy spectrum for the US while advancing to standard of care status in Europe where the treatment is already approved."

About EDAP TMS S.A.

EDAP TMS S.A. 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. The company is also developing this technology for the potential treatment of certain other types of tumors. EDAP TMS S.A. also produces and commercializes medical equipment for treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy (ESWL).

For more information on the Company, contact Magnolia Investor Relations at (972) 801-4900, the Corporate Investor Relations Dept at +33 (0)4 78 26 40 46 or see the Company's Web sites at <http://www.edap-tms.com> and <http://www.hifu-planet.com>.

To sign up for alerts please visit <http://www.b2i.us/irpass.asp?BzID=1053&to=ea&s=0>

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 yet FDA approved or marketed in the United States.

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