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EDAP Fast-Tracks U.S. Clinical Trial for Non-Invasive Prostate Cancer

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LYON, France, May 22 /PRNewswire-FirstCall/ -- EDAP TMS S.A. (Nasdaq: EDAP), the global leader in High Intensity Focused Ultrasound (HIFU) treatment of prostate cancer is fast-tracking its ongoing U.S. Ablatherm[®]- HIFU clinical trial. Long-term European results presented at the European Association of Urologists (EAU) in March paved the way for unprecedented interest from the U.S. medical community about Ablatherm-HIFU at The Annual Scientific Meeting of the American Urological Association (AUA) held last week in Anaheim, CA.

"We have treated more than 1,800 patients in our center over 10 years and we now have mature data that demonstrates the long-term benefits of Ablatherm- HIFU. Given the success we've had in Europe and the clear consensus from urologists that this therapy is a good selection for patients, it is a priority to make this leading-edge, non-invasive treatment available in the U.S.," commented Christian Chaussy, M.D. Department of Urology, Krankenhaus Muenchen-Harlaching, Germany. "We are also seeing more and more patients coming to Munich from the U.S. to receive Ablatherm-HIFU treatment," he added.

The U.S. Ablatherm-HIFU clinical study is currently enrolling men over 50 years of age, diagnosed with localized prostate cancer. Details of the study and background on Ablatherm-HIFU can be found online at <http://www.clinicaltrials.gov> by searching for "Ablatherm."

"The outstanding clinical outcomes demonstrated by the long-term European clinical data affirmed the early success we have seen with our patients who are currently enrolled in the U.S. trial," Cary N. Robertson M.D. F.A.C.S. Associate Professor, Division of Urology, Duke University Medical Center. "HIFU appears to be very well-tolerated with minimal invasiveness and minor discomfort."

How it works

The Ablatherm[®] Integrated Imaging device is designed to target and deliver high-intensity focused ultrasound (HIFU) energy to the prostate, resulting in thermal destruction of prostate tissue. It is intended for the primary treatment of localized prostate cancer in subjects with low risk, localized prostate cancer.

The focused energy is delivered from an endorectal probe containing ultrasound treatment and imaging transducers. Treatment with HIFU for low risk, localized prostate cancer subjects is expected to result in immediate thermal destruction of prostate tissue. The treatment is conducted under spinal or general anesthesia during one, two-hour session and patients are able to resume normal activity within 24 hours.

"The science is based on strong engineering principles. The HIFU device itself is elegant and very intuitive," added Cary N. Robertson M.D. F.A.C.S. Associate Professor, Division of Urology, Duke University Medical Center.

"We are dedicated to making Ablatherm-HIFU technology the next standard of care. The strong partnerships we have built with our U.S. investigators strengthen our commitment to saving countless patients from having to undergo radical treatment," commented Marc Oczachowski, CEO of EDAP. "This trial will enable U.S. physicians to provide their patients with the newest non-invasive option available for treating prostate cancer," he added.

Editors Note: The latest clinical data and bibliography on Ablatherm HIFU can be found on UroToday website at http://www.urotoday.com/379/browse_categories/hifu_resource_center/1712/.

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. 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 EDAP visit <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.

SOURCE EDAP TMS S.A.