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EDAP's Ablatherm-HIFU Demonstrates Long-Term Efficacy and Safety Over Fourteen-Year Period

Longest Retrospective Study of HIFU Patients to Date Published Confirms Benefits of Treatment

LYON, France, Feb. 8, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today new data demonstrating the safety and long-term efficacy of Ablatherm-HIFU, an ultrasound guided HIFU device for the treatment of localized prostate cancer. The data was electronically published in January 2013 by the British Journal of Urology, International.

Roman Ganzer, M.D., Primary Investigator and Associate Professor of Urology at the University of Regensburg in Germany, summarized, "We studied a large consecutive patient series that underwent primary HIFU for localized prostate cancer, gathering data over the longest follow-up period in current literature, with data extending out to 14 years. Our results improve the understanding of the long term cancer control of HIFU as a primary therapy for prostate cancer as well as the morbidity associated with the procedure. The study solidifies the fact that HIFU is a safe and effective therapeutic option for patients with localized prostate cancer of low and intermediate risk profile. The morbidity experienced by patients was reasonable and, specifically, the rate of serious side effects such as recto-urethral fistulae is very low."

The study, titled "Fourteen-year oncological and functional outcomes of high-intensity focused ultrasound in localized prostate cancer," was a fourteen year retrospective single-center study of 538 patients with localized prostate cancer who underwent primary Ablatherm-HIFU for clinically localized prostate cancer between November 1997 and September 2009 at the University Hospital of Regensburg (Germany). The study had a mean follow-up of 8.1 years and a range of up to 14 years. The findings included favorable oncological outcomes with biochemical disease-free survival rates at five and 10 years of 88% and 71% for low risk patients and 83% and 63% for intermediate risk patients, respectively.

John Rewcastle, Ph.D., Medical Director of EDAP TMS, remarked, "This is a landmark publication as it contains a report of 10 year biochemical outcomes with follow-up extending to 14 years. The biochemical disease free survival rates are comparable with those reported following other prostate cancer treatments and this is balanced with an attractive morbidity profile. This represents the longest follow-up of any series to date, and validates the outcomes of Ablatherm-HIFU as first line, whole gland treatment for prostate cancer."

About Ablatherm-HIFU

Ablatherm-HIFU is an ultrasound guided HIFU device for the treatment of organ-confined prostate cancer. The device consists of a treatment module, a control table with a computer and a computer screen, and a diagnostic ultrasound device connected to the treatment module. After insertion of an endorectal probe, the physician visualizes the prostate and defines the area to be treated. The computer automatically calculates the optimum treatment distribution of lesions. During the treatment, the transducer automatically moves and fires at each predefined lesion until the entire area has been treated, while controlling and imaging the treatment in real time due to its integrated imaging system. Cell destruction by HIFU is accomplished by a combination of thermal and cavitation effects caused by focused application of piezoelectric-generated high-intensity ultrasound. The procedure is performed under general or spinal anesthesia.

Ablatherm-HIFU is cleared for distribution in the European Union, South Korea, Canada, Australia, South Africa, New Zealand, the Philippines, Taiwan, Mexico, Argentina, Brazil and Russia. As of December 31, 2012, more than 32,000 prostate cancer treatments successfully performed clinical outside the U.S. with Ablatherm-HIFU and results have been published in 60 peer-reviewed scientific publications.

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm(R), 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 multi-center U.S. Phase II/III clinical trial under an Investigational Device

Exemption (IDE) 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 (the Sonolith(R) range) 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, and http://www.hifu-planet.com.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements that involve risks and uncertainties. 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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