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EDAP's Ablatherm-HIFU Offers Reliable Therapy for Localized Prostate Cancer

Munich Study Concludes 15 Year Outcome Data May Warrant Closing of Investigational Phase for HIFU

LYON, France, Feb. 22, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today new long term data demonstrating high rates of both cancer-specific survival, and freedom from salvage therapy for patients treated with high-intensity focused ultrasound (HIFU) therapy. The study was performed by Drs. Stefan Thürroff and Christian Chaussy and evaluated the cancer control and morbidity of HIFU, in combination with transurethral resection of the prostate prior to treatment, over a 15 year period. The study was electronically published in February 2013 by the Journal of Urology, the Official Journal of the American Urological Association.

The study, titled "Evolution and outcomes of 3 MHz High intensity focused ultrasound therapy for localized prostate cancer over 15 years," examined 704 patients treated from 1995 to the end of 2009 at the Munich-Harlaching Clinic located in Munich, Germany. Within the study population, 78.5% of men had intermediate- or high-risk disease. Data showed a cancer-specific survival rate after treatment of 99% and a metastasis-free survival rate of 95%. The salvage treatment-free rates were 98% for low-risk, 72% for intermediate-risk, and 68% for high-risk disease. The overall survival of the patients in the study did not differ across risk groups and was identical to current local (Bavarian) population survival statistics.

Stefan Thüroff, M.D., Primary Investigator and Vice Chairman of the Department of Urology at the Harlaching Clinic, said, "These study results show that HIFU offers men with localized prostate cancer a standardized, reliable therapy with a low rate of perioperative co-morbidity and an absence of serious morbidity. Importantly, we found that salvage therapy was not required by 98% of low-risk patients. This outcome is extremely important from the perspective of the patient, and clearly demonstrates the extent of cancer control afforded by HIFU therapy."

Dr. Thüroff concluded, "HIFU has remained investigational because the published research on the therapy has not yet reached sufficient maturity to be considered definitive. The authors of this study concur that the collected data of 15 year outcomes may warrant the possible closing of the investigational phase of whole gland HIFU. The confidence this study provides in the ability to ablate prostate cancer may also encourage the use of focal therapy."

John Rewcastle, Ph.D., Medical Director of EDAP-TMS, commented, "This is an extremely important publication as it not only further establishes the safety, efficacy, and long term durability of HIFU as a prostate cancer treatment, it also demonstrates reproducibility. Cancer control outcomes are similar to those recently published by a separate German research group that reported outcomes over a 14 year period. Importantly, within this larger and longer independent study, prostate cancer did not appear to reduce the life expectancy of those men diagnosed with the disease who underwent HIFU. Impressively, this was achieved with less than 2% of low-risk patients seeking salvage treatment and in absence of serious morbidity. This is an impressive further validation of Ablatherm-HIFU as 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 have been successfully performed in clinics 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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