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EDAP's Ablatherm-HIFU Demonstrates Long Term Efficacy, Durability and Reproducibility With Prospective Fourteen -Year Study

Third Long Term Study Published in 2013 Validates Ablatherm-HIFU as First Line Treatment of Prostate Cancer

LYON, France, May 20, 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 and overall survival of patients treated with high-intensity focused ultrasound (HIFU). The study led by Drs. Sebastien Crouzet and Albert Gelet of Edouard Herriot Hospital, located in Lyon, France evaluated the morbidity and long term oncologic outcomes of primary HIFU therapy for localized prostate cancer. The prospective, single-arm, single-institution cohort study was electronically published by European Urology, the official journal of the European Association of Urology.

The study, titled "Whole-gland Ablation of Localized Prostate Cancer with High-intensity Focused Ultrasound: Oncologic Outcomes and Morbidity in 1002 Patients," examined 1002 patients treated from 1997 to 2009 and followed through 2012. Overall, the ten year cancer-specific survival rate was 97%. Stratified by risk group, the cancer-specific survival was 99%, 98% and 92% for men with low, intermediate, and high-risk disease, respectively. The overall metastasis-free rate was 94% and was 99%, 95%, and 86% for low, intermediate, and high-risk groups, respectively.

Sebastien Crouzet, M.D., Urologist at Edouard Herriot Hospital, Lyon, France, said, "We are proud to have published the largest long-term study of HIFU. It is a minimally invasive therapeutic option with encouraging cancer-specific survival rates in patients with localized prostate cancer. The 10-year prostate cancer survival rates and metastases free survival rates were low, and the morbidity acceptable. We continue to routinely prescribe HIFU to our patients as standard of care. These results should encourage other centers worldwide to do so as well."

John Rewcastle, Ph.D., Medical Director of EDAP-TMS, commented, "The Lyon study is the third peer reviewed publication this year reporting 10 year cancer specific survival and metastates free survival rates following Ablatherm HIFU. Significantly, this is a prospective study and is the largest of the three. Following patients long enough to generate 10 year cancer specific survival rates is a formidable task and no other ablative therapy for prostate cancer has ever produced such a study, let alone three. These studies not only clearly demonstrate durable cancer control but taken together they also make evident the reproducibility of the procedure.

Marc Oczachowski, Chief Executive Officer, concluded, "These are great long term results and it is extremely positive to see these publications in top tier journals. Corroboration of high 10 year rates for both cancer specific survival and freedom from metastases furthers Ablatherm-HIFU as a standard of care treatment for prostate cancer. It is positive to have this published as we move forward in the final stages of our FDA clinical trial."

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 markets today Ablatherm® 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. Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in January 2013 after the completion of a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith® 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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