

## **Published 15-Year Clinical Review Supports EDAP's Ablatherm(R) HIFU as Viable Primary Treatment for Local Prostate Cancer at Any Stage**

### **Study to Appear in June 2011 Current Urology Report**

LYON, France, May 9, 2011 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced a published 15-year clinical review of Ablatherm® HIFU data supports the potential for this minimally invasive treatment to be used as a primary local therapy for men with any stage of prostate cancer. The paper was co-authored by renowned urology experts and HIFU pioneers Professor Christian Chaussy and Dr. Stefan Thuroff of Germany.

Ablatherm-HIFU is a fully automated, localized treatment for prostate cancer that has been performed more than 30,000 times throughout Europe over the past 10 years. The therapy is currently undergoing evaluation in a multi-center U.S. Phase II/III clinical trial; however, HIFU is not yet approved for non-investigational use in the United States.

The paper titled, "Robotic High-intensity Focused Ultrasound for Prostate Cancer: What Have We Learned in 15 Years of Clinical Use?" has been published online in *Current Urology Reports* (March 23, 2011) and will appear in the June 2011 print edition. The authors have drawn conclusions from their own clinical experience using Ablatherm-HIFU, as well as data from landmark publications from around the world describing clinical outcomes following HIFU treatment.

The review concluded that HIFU, specifically Ablatherm-HIFU, has high potential as a primary localized treatment option and is effective in controlling prostate cancer at any stage, while preserving quality of life. The less invasive treatment also allows physicians to delay more radical interventions such as surgery, radiation or hormonal ablation while preserving the option for these more aggressive therapies at a later time, if needed.

"The increased availability of long-term clinical outcomes data has further elevated the potential of HIFU in treating local stage T1 and T2 prostate cancers, where it is currently used most often," stated Prof. Chaussy. "More recent studies are also very encouraging because they demonstrate HIFU's potential for treating patients with advanced disease and very poor prognoses. These study results support the notion that this local, single-session tumor debulking therapy should be considered as a primary treatment option for the full spectrum of prostate cancer."

High-intensity focused ultrasound (HIFU) is an incision- and radiation-free procedure that uses focused ultrasound waves to precisely destroy cancerous tissue within the prostate while protecting surrounding healthy tissue. Unlike other more invasive therapies, this helps preserve normal bowel, urinary and sexual functions. Patients usually return to their normal lives within a very short amount of time due to minimal side effects.

Prof. Chaussy explained, "Over the last 25 years, there has been a shift in the patient profile. Men are being diagnosed 10 years earlier and living an average of four years longer. This new

dynamic is causing doctors to reevaluate current treatment methods and develop new ways to care for patients over this extended timeframe when the risk for recurrence is higher, while effectively maintaining their quality of life. I would say HIFU is an ideal solution to this challenge, as clinical experience continues to show the procedure is safe and effective for patients at any age and health status."

Marc Oczachowski, Chief Executive Officer, EDAP TMS, stated, "We are pleased with the findings of this 15-year clinical review, which elegantly describes the functional and quality of life benefit HIFU offers, as well as its ability to effectively treat prostate cancer at any stage. We are in agreement that HIFU has tremendous value as a primary treatment for prostate cancer, and the less invasive nature of the procedure is especially advantageous to address the increasing therapeutic timeframe of today's prostate cancer patient."

Prostate cancer is the second most common cancer in men worldwide. Around 910,000 cases of prostate cancer were recorded in 2008, accounting for around 14% of all new cancer cases in men. It is predicted that the number of cases will almost double (1.7 million) by 2030.<sup>1</sup>

### **About EDAP TMS SA**

EDAP TMS SA 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. 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 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 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 contains forward-looking statements that involve risks and uncertainties. These include statements regarding the Company's growth and expansion plans, the conclusiveness of the results of and success of its Ablatherm-HIFU clinical trials and expectations regarding the IDE submission to and approval by the FDA of the Ablatherm-HIFU device. 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.

<sup>1</sup>GLOBOSCAN, 2008: <http://globocan.iarc.fr/>