

## EDAP Features New Ablatherm(R) HIFU Data Supporting Superior Efficacy for Treatment of Local Prostate Cancer at American Urological Association Annual Meeting

LYON, France, May 12, 2011 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced Ablatherm<sup>®</sup> High Intensity Focused Ultrasound (HIFU) will be featured in four presentations supporting the technology's efficacy for the treatment of localized prostate cancer. The data and EDAP's line of extracorporeal shock wave lithotripsy (ESWL) products will be showcased at the American Urological Association (AUA) 2011 Annual Meeting, held May 14-19 in Washington, D.C.

Ablatherm-HIFU is approved in Europe and currently investigational in the U.S. as a minimally invasive treatment for localized prostate cancer. It uses ultrasound waves to heat and ablate the targeted tumor tissue, while reducing the risk of collateral tissue and nerve damage compared to more invasive therapies. Outcomes data for a pivotal multicenter U.S. Phase II/III clinical trial (ENLIGHT) are expected to be submitted to the FDA the latter part of 2012.

"Ablatherm-HIFU's strong clinical presence at this year's AUA meeting continues to support HIFU as an effective, less traumatic, radiation-free treatment option for prostate cancer," said Marc Oczachowski, Chief Executive Officer of EDAP TMS. "The presented findings mirror interim results from our ongoing ENLIGHT study, which to date have shown positive outcomes and reduced morbidity risk. To expand HIFU access to a greater population of patients, we are in the process of launching a comparison study between surveillance and focal HIFU in a cooperative effort between German and American urologists."

EDAP is a pioneer of ESWL for the non-invasive treatment of urinary stones. The Company will be exhibiting Ablatherm-HIFU and all of its ESWL products at its AUA booth #1017.

## **Scientific Session Highlights:**

Date/Time: Monday, May 16, 10:30 AM

Podium: 10 year outcome and morbidity of High Intensity Focused Ultrasound as a primary therapy for localized prostate

cancer: Outcomes from 2552 men followed with the @-registry.

Date/Time: Monday, May 16, 3:30 PM

Poster: Long term oncologic outcomes of patients treated with High Intensity Focused Ultrasound for localized prostate cancer.

Date/Time: Monday, May 16, 3:30 PM

Poster: Can splitting TURP and HIFU in two sessions reduce complication rate?

Date/Time: Tuesday, May 17, 10:30 AM

Poster: High Intensity Focused Ultrasound for localized prostate cancer: Impact of Nadir PSA on cancer control.

## **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 <a href="http://www.edap-tms.com">http://www.edap-tms.com</a>, and <a href="http://www.hifu-planet.com">http://www.hifu-planet.com</a>.

## **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.

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