Largest Long-Term Study Confirms EDAP's Ablatherm® HIFU is Effective, Highly Reproducible Primary Treatment for Localized Prostate Cancer

-- 2,552 Patient, International, Multi-Center, 10-year Study Shows 83% of Patients Cancer Free --

LYON, France, May 17, 2011 /PRNewswire/ -- EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, announced today that new 10 year data from an international registry-based multi-center study shows 83 percent of patients had no biopsy evidence of disease after treatment with Ablatherm® HIFU, supporting the technology as a standard primary treatment for localized prostate cancer. Study results were presented at the American Urological Association (AUA) 2011 Annual Meeting, Washington, D.C.

To view the multimedia assets associated with this release, please click: http://multivu.prnewswire.com/mnr/edap/49862/

The largest, long-term study ever presented on high-intensity focused ultrasound (HIFU) reported outcomes from 2,552 patients treated throughout Europe, where Ablatherm-HIFU is currently available. Patients diagnosed with stage T1-T3 prostate cancer with low, moderate or high risk for disease progression were treated with Ablatherm-HIFU. Outcomes were followed using a secure online registry database, which tracked progression as measured by prostate-specific antigen (PSA) levels and prostate biopsy data.

Andreas Blana, MD, Senior Investigator and Chairman of @-Registry Board, Associated Professor at the University of Regensburg Germany, explained, "Results from this robust, multi-center study were remarkably consistent across progression risk groups, demonstrating that HIFU is effective at controlling prostate cancer for all patients. These favorable clinical outcomes were also highly reproducible, which has a critical real-world impact on how effectively HIFU can be used to treat the disease worldwide."

The study revealed cancer cells could no longer be detected by a prostate biopsy in 83 percent of patients across all risk levels (low 89%, moderate 81%, high 78%). Consistent with previous HIFU studies, patients also experienced a mild side-effect profile.

Ablatherm- HIFU is a fully automated, incision- and radiation-free procedure that uses focused ultrasound waves to precisely destroy cancerous tissue within the prostate, while protecting surrounding healthy tissue. Unlike more invasive therapies, Ablatherm-HIFU helps preserve normal bowel, urinary and sexual functions.

"Ablatherm- HIFU is recognized as a standard primary treatment for prostate cancer throughout Europe, and is highly anticipated in the U.S. based on positive long-term outcomes data such as this," stated investigator and HIFU pioneer, Professor Christian Chaussy, MD, Department of Urology, University of Regensburg, Germany. "Today, patients with prostate cancer are being diagnosed younger and living longer. It is more important than ever to have an effective, less invasive treatment option for prostate cancer at any stage that will have minimal impact on quality of life and remain effective for a longer period of time."

HIFU has been performed more than 30,000 times throughout the world since 2000. The therapy is currently undergoing evaluation in a multi-center U.S. Phase II/III clinical trial; however, is not yet approved for non-investigational use.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, stated, "All of the Ablatherm-HIFU data presented at the AUA meeting, including the 10-year registry study, continue to substantiate the clinical value of the technology. We are committed to working with the FDA to offer this proven, less traumatic alternative to American patients as soon as possible."

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.

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