# EDAP Adds Sites in Phase II/III Ablatherm-HIFU Clinical Trial for Localized Prostate Cancer

**IRBs Approve Five Additional Sites**

**12 Active Sites Now Screening and Enrolling Patients**

LYON, France, Jan. 29, 2008 (PRIME NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in high-intensity focused ultrasound (HIFU) for the treatment of prostate cancer, announced today that it has received Institutional Review Board (IRB) approvals for five additional sites in the United States and Canada. These sites will participate in EDAP's ongoing Phase II/III clinical trial of Ablatherm®-HIFU ("Ablatherm"). The trial compares the outcomes of Ablatherm and cryotherapy for the treatment of low-risk prostate cancer. These IRB approvals bring the total number of active sites in the trial to 12.

Ablatherm is a non-invasive therapy that uses highly focused ultrasound energy to ablate the prostate tissue. The device is approved in the European Union and several countries outside the United States, where it is widely accepted as a viable treatment alternative to surgery and radiation. By treating the entire height of the prostate with a single pass, the procedure is faster and requires less anesthesia time than other HIFU procedures. In the United States, Ablatherm is considered investigational and is being studied under an Investigational Device Exemption granted by the FDA.

The five additional sites are the Urology Associates of North Texas in Dallas, Texas, Hackensack University Medical Center in Hackensack, N.J., Maple Leaf HIFU in Toronto, Canada, and the University of Colorado at Boulder, all of which will recruit for the Ablatherm-HIFU arm of the study. Scott and White in Temple, Texas will participate in the cryotherapy arm.

Pat Hezmall, MD, of the Urology Associates of North Texas in Dallas, one of the nation's largest fully integrated urology practices, commented: "HIFU represents a significant departure from a traditional incision procedure without radiation. Results from Europe have been encouraging, and it is hoped that they will be substantiated by this trial."

John Rewcastle, Ph.D., Medical Director of EDAP TMS, commented: "I am pleased with the progress we have made in recruiting high-quality and well respected academic centers and private practices to participate in this trial. The IRB approval of these five additional sites should significantly increase the current pace of enrollment. I believe that Ablatherm is a novel non-invasive treatment approach for prostate cancer and if data from the trial support its effectiveness, will fill a void in the treatment spectrum by allowing non-invasive yet definitive treatment of prostate cancer."

Marc Oczachowski, EDAP TMS Chief Executive Officer, stated, "We are delighted to add these five new sites as participants in the trial. We believe the enthusiasm at these sites to participate in our Ablatherm study underscores the desire among prostate cancer specialists and patients alike for non-invasive treatment alternatives. Our public relations promotion program, for which we have partnered with Fleishman Hillard, is gaining momentum and should further accelerate screening and recruitment of patients."

"Within the United States, we hope to mimic our success in international markets, particularly in the European Union, where our device is approved and recognized as the leader in HIFU for the treatment of prostate cancer. Given Ablatherm's extensive track record of safety and efficacy, we are confident that our U.S. clinical trial will deliver promising results and enable us to successfully file for market approval with the FDA. Over 15,000 patients worldwide have been treated with Ablatherm, and extensive clinical data from several studies have been covered in peer-review publications. We look forward to confirming our device's efficacy and safety in the United States and are pleased with the progress to date."

About the Study

The prospective non-inferiority study is designed to evaluate the safety and efficacy of EDAP's Ablatherm-HIFU system versus cryotherapy for the treatment of low-risk, localized prostate cancer. The clinical trial is currently enrolling men over age 60 diagnosed with clinical stage T1a, b, or c or T2a localized prostate cancer. The primary outcome measure of the trial will be a statistically significant reduction and stability of the prostate-specific antigen (PSA) throughout a 24-month follow-up period. Details of the study and background on Ablatherm-HIFU can be found online at www.ClinicalTrials.gov by searching for "Ablatherm."

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. 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).

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. Such statements are based on management's current expectations and are subject to a number of uncertainties 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. Ablatherm-HIFU treatment is in clinical trials but not FDA-approved or marketed in the United States.

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