



## **EDAP Reports Publication of Head-to-Head Study of Ablatherm-HIFU Versus Other HIFU Technology for Prostate Cancer**

**Journal of Endourology Highlights Ablatherm's Unique Sustainable Long-Term Clinical Data**

### **Ablatherm's Superior Safety and Efficacy Confirmed**

LYON, France, Feb. 14, 2008 (PRIME NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that the Journal of Endourology published results in its February 2008 issue from a head-to-head study entitled "Transrectal High-Intensity Focused Ultrasound Devices: A Critical Appraisal of Available Evidence." Based on a thorough review of the existing medical literature, the objective of the study was to evaluate clinical outcomes and unique characteristics comparing EDAP's Ablatherm®-HIFU versus Sonablate500® for the treatment of prostate cancer.

The article highlights the clinical superiority of Ablatherm in terms of present and longer-term data available. For the purposes of the study, clinicians referenced six publications on Ablatherm-HIFU featuring 2,032 patients treated, compared to three publications relating to Sonablate500 with 287 patients treated. Reviewed published articles have included Ablatherm patients with up to 10 years of follow up, whereas disease-free rate cannot be reported beyond five years for the competitive technology. Clinicians note that Ablatherm has been used in a greater number of centers for a longer period of time, providing more clinical information regarding its effects. The article also demonstrates the need for additional clinical studies for the use of other HIFU devices in order to draw the same short-term treatment success results as Ablatherm.

The article concludes that the availability of more short- and long-term oncologic outcomes with the Ablatherm device creates less uncertainty about the actual efficacy of the device-specific treatment.

Although both HIFU devices are built on the same scientific foundation, critical differences exist. Ablatherm-HIFU is unique in offering three specific treatment protocols addressing each of the targeted types of prostate cancer patients: (i) patients diagnosed with prostate cancer who have yet to undergo any previous treatment (primary treatment), (ii) patients who failed radiotherapy and HIFU being their only available therapeutic option, and (iii) patients with recurrence of their cancer. In addition, Ablatherm's probe integrates two ultrasound transducers, one for localizing and imaging the tumor and one for HIFU treatment, thus offering the best imaging quality, while ensuring a safe and efficient treatment.

John Rewcastle, medical director of EDAP, commented, "We are pleased this review, in addition to several other positive publications, provides further validation of Ablatherm-HIFU's unique technological merits in comparison to other HIFU devices. Substantial and longer-term data following Ablatherm-HIFU is increasingly available, which allows physicians to accurately discuss outcomes as they guide patients through the treatment selection process. With over 15,000 treatments performed worldwide, we believe Ablatherm is the standard-of-care in HIFU treatment of localized prostate cancer."

Marc Oczachowski, EDAP's chief executive officer, said, "We are delighted this review confirms both the unique expertise and experience of our Ablatherm device in treating localized prostate cancer. We are pleased this review has been published at a time when we are actively recruiting patients for our U.S. Phase II/III clinical trial of Ablatherm-HIFU. We are confident that the results of this published study could have a positive effect on the enrollment pace in our ongoing trial. We look forward to confirming Ablatherm's efficacy and safety in the U.S. market and are pleased with the progress to-date."

EDAP's Ablatherm-HIFU is not approved for the treatment of prostate cancer in the United States and currently is undergoing evaluation in a multicenter Phase II/III clinical trial under an Investigational Device Exemption granted by the FDA.

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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States. 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> or <http://www.urotoday.com/HIFU>.

## 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. 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

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