



## EDAP Reports on FDA Meeting

LYON, France, Feb 2, 2010 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced that the FDA at its meeting on January 28, 2010 confirmed the recommendations of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting of the U.S. Food and Drug Administration (FDA), which met on December 11, 2009.

The Company met with the FDA to discuss alternatives to the cryoablation comparative arm and guidelines for a submission of an amended protocol for the U.S. ENLIGHT trial.

The FDA favoured the concept of broadening HIFU enrollment inclusion criteria by including higher-risk patients as well as increasing flexibility in the procedures to treat larger prostates. As previously communicated, this inclusion criteria change could significantly increase the available eligible patient population and further improve the pace of enrollment in the Ablatherm-HIFU arm of EDAP's ongoing trial.

In discussing alternatives to the cryo comparative arm, the FDA was open to a change for a brachytherapy control arm, as recommended by the Panel in December 2009. The FDA also reiterated the Panel's concerns regarding the concept of patient randomization and the follow-up period. Given the FDA's feedback, EDAP still continues to evaluate the best options to keep the ENLIGHT study within an acceptable cost and timeframe for the Company and its shareholders.

### 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 multicenter 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>, <http://www.hifu-planet.com> and <http://www.pcaresearch.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. 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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

This news release was distributed by GlobeNewswire, [www.globenewswire.com](http://www.globenewswire.com)

### SOURCE: EDAP TMS SA

CONTACT: EDAP TMS SA  
Investor Relations / Legal Affairs  
Blandine Confort  
+33 4 72 15 31 72  
[bconfort@edap-tms.com](mailto:bconfort@edap-tms.com)  
The Ruth Group  
Investors:  
R.J. Pellegrino  
646-536-7009

[rpellegrino@theruthgroup.com](mailto:rpellegrino@theruthgroup.com)

Nick Laudico

646-536-7030

[nlaudico@theruthgroup.com](mailto:nlaudico@theruthgroup.com)

(C) Copyright 2010 GlobeNewswire, Inc. All rights reserved.

News Provided by COMTEX