EDAP Reports on FDA Panel Meeting

LYON, France, Dec 16, 2009 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced that the Company attended the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting of the U.S. Food and Drug Administration (FDA) on December 11, 2009.

The Panel of experts met at the request of the FDA to discuss and provide general recommendations regarding the study designs and endpoints of trials intended to support approval or clearance of devices indicated for the treatment of localized prostate cancer. The Panel provides recommendations to the FDA, and while the FDA is not bound by those recommendations, the Agency often follows them.

During the meeting, the Panel discussed the advantages and disadvantages of utilizing retrospective versus prospective controls in evaluating endpoints. At this time, the Panel indicated a preference for prospective control data for endpoint evaluation of treatments for localized prostate cancer.

The Panel reacted favorably to the concept of broadening enrollment inclusion criteria by including higher risk categories provided that an active control treatment is used. This inclusion criteria change potentially increases the available eligible patient population from which EDAP could enroll patients.

Consistent with the Company's prior communications, EDAP met with the FDA in March 2009 to propose alternatives to the prospective cryoablation comparative arm of the U.S. ENLIGHT HIFU trial. The Panel discussed this issue during the December 11th meeting. As a result of the Panel's recommendations, EDAP will engage in continuing discussions with the FDA to further address options and alternatives to move forward with its HIFU trial in the U.S. Given the time necessary to engage in further discussions with the FDA, the Company's previously anticipated approval date of 2012 will likely be delayed.

Marc Oczachowski, EDAP's Chief Executive Officer, concluded, "While we undertake these initiatives in the comparative arm, we continue to move forward with our efforts and actions regarding treatments in the HIFU arm of the trial. We believe there is growing momentum with an increasing number of HIFU patients being screened and scheduled for treatment."

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.

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