

EDAP Successfully Completes Preliminary Trial of HIFU in Liver Cancer

Plan for Second, Larger Trial

LYON, France, Oct 26, 2010 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, reported today successful completion of the first phase of the clinical protocol aimed at evaluating High Intensity Focused Ultrasound (HIFU) technology in patients with metastatic liver cancer. HIFU has the potential to destroy liver tumors through ablation and to reduce bleeding during surgery.

In an initial preliminary protocol phase, six patients were successfully treated using a newly-developed HIFU tool delivering focused ultrasound to cancerous liver tumors. Clinical results observed fully conformed with those obtained in pre-clinical studies and validated HIFU as being an additional potential option to address liver cancer. More studies need to be implemented and EDAP, together with the clinical team from Lyon-based Centre Leon Berard and INSERM U556, will enter into a second clinical phase that will include a larger number of patients. This study is designed to further validate the performance of this new HIFU instrument in the treatment of liver cancer.

Pr. Michel Rivoire, Head of Digestive Cancer Surgery Department at Centre Leon Berard, Lyon, commented, "The initial phase of this clinical trial allowed us to confirm safety and efficacy of this new powerful device. All our clinical hypotheses have been confirmed and we were pleased to make these preliminary assessments in less than six months. After validation of these results by an external independent committee, we will begin the second phase of this trial that will be designed to demonstrate the ability and precision of this new tool to fully destroy liver tumors without inducing damage to normal surrounding liver parenchyma."

Marc Oczachowski, EDAP Chief Executive Officer, added, "We are very pleased with the performance of our HIFU technology in this early stage study addressing liver cancer. Our expertise in focused ultrasound, together with the close and long term relationship we have with INSERM in developing HIFU technology, should help in advancing future therapies. In the meantime, we remain fully focused on expanding the Ablatherm-HIFU activity for patients with localized prostate cancer."

The HIFU device was jointly developed by EDAP, Centre Leon Berard and INSERM Unit 556 with the financial support from the French organizations CLARA and OSEO that are dedicated to supporting innovative cancer treatment initiatives and technological innovation.

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.

About Leon-Berard Cancer Center

Leon-Berard Cancer Center is a private, non-profit, comprehensive hospital dedicated to cancer treatment and research. It is affiliated with the French Federation of Cancer Centers (20 hospitals, created by government ordinance in 1945). Its missions include: (i) cancer treatment: patient care and aftercare, screening and prevention, (ii) research and innovation: basic, applied and clinical research, (iii) education and training in the field of oncology. The cancer center has become a leader in its field, and a pole of reference for the treatment of cancer in the Rhone-Alpes region. It has received full, unreserved agreement of the HAS (Haute Autorite de Sante), a French governmental organization for Healthcare Quality. For more information, please visit http://www.lyon.fnclcc.fr.

INSERM is the only French public organization entirely dedicated to biological, medical and public health research. The participating Unit 556 in Lyon is entirely focused on therapeutic applications of ultrasound. For more information, please visit http://www.inserm.fr.

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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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