EDAP Adds World Renowned Cancer Center for Phase II/III Ablatherm-HIFU Clinical Trial

LYON, France, April 10, 2008 (PRIME NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that it has received Institutional Review Board (IRB) approval for Memorial Sloan-Kettering Cancer Center in New York City to participate in EDAP's ongoing Phase II/III clinical trial of Ablatherm®-High Intensity Focused Ultrasound (HIFU). The trial compares the outcomes of Ablatherm and Cryotherapy for the treatment of low-risk prostate cancer. This IRB approval brings the total number of active sites in the trial to 10 HIFU sites and 6 Cryotherapy sites.

"This clinical trial will evaluate the safety and efficacy of HIFU for the treatment of prostate cancer," said Dr. James Eastham, Attending Surgeon in the Urology Service at Memorial Sloan-Kettering. "Results from Europe have been encouraging, and it is hoped that they will be substantiated by this study and help further define the role of the procedure both within the United States and around the world."

John Rewcastle, Ph.D., Medical Director of EDAP TMS, commented, "Memorial Sloan-Kettering is one of the most respected and active prostate cancer treatment sites in the world. Their participation in the ENLIGHT study represents a significant milestone for EDAP as accrual is expected to rapidly progress due to the large prostate cancer patient population in Manhattan and the surrounding boroughs."

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We are extremely pleased to add a world premier center like Memorial Sloan-Kettering to participate in the prospective non-inferiority trial evaluating Ablatherm-HIFU versus Cryotherapy. As a major U.S. leader in the treatment of prostate cancer, Memorial Sloan-Kettering further validates the potential of our non-invasive approach to treating localized prostate cancers and adds credibility to our technology overall. We believe that the quality of participating sites in this trial enhances EDAP's profile among urologists, which is supported by the continued momentum for our patient awareness trial program to accelerate our screening and recruitment of patients."

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. 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 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 or http://www.urotoday.com

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