

EDAP Adds High Volume Cryotherapy Center for Phase II/III Ablatherm-HIFU Clinical Trial

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LYON, France, April 22, 2008 (PRIME NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that Atlantic Urology in Daytona Beach, Florida has received Institutional Review Board (IRB) approval to participate in EDAP's ongoing ENLIGHT Phase II/III clinical trial of Ablatherm[®]-High Intensity Focused Ultrasound (HIFU) in patients with localized prostate cancer.

Dr. Martin Dineen, one of fourteen urologists in the single specialty group Atlantic Urology, said, "High Intensity Focused Ultrasound is an interesting new technology for the treatment of prostate cancer as several centers in Europe have reported intriguing clinical outcomes. Atlantic Urology is proud to participate in the FDA approved Investigational Device Exemption evaluation of HIFU. Our center draws upon a large population of elderly patients residing in central Florida which should be very beneficial to our accrual efforts. We hope that our participation helps to drive a timely completion of this study, which is critical in the U.S. FDA approval process of Ablatherm-HIFU."

Atlantic Urological Associates is one of the largest and most reputable private urologic research practices in the United States. For over 15 years, the center has collaborated with the world's leading pharmaceutical manufacturers and healthcare companies to pursue a wide array of clinical research studies. The center has the distinct advantage of providing its patients with access to novel treatments several years before they are available to the general public.

John Rewcastle, Ph.D., Medical Director of EDAP, commented, "Dr. Dineen is a very well respected private practice urologist who has some of the most extensive cryoablation experience within the U.S. His participation in numerous clinical research trials has built him a proven track record for accruing a large patient volume. We are confident that his role in the ENLIGHT trial will potentially increase the current pace of enrollment in the cryoablation arm of the study."

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We are pleased with the continued progress in attracting high-quality and well respected academic centers and private practices to participate in the ENLIGHT trial. The advancement of HIFU technology could have a significant impact on the approach to prostate cancer treatment within modern urology practices. We believe the enthusiasm at clinical sites participating in the Ablatherm-HIFU trial underscores the need for a safe and effective non-invasive treatment option."

About the ENLIGHT 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 and http://www.hifu-planet.com or http://www.urotoday.com

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