

Largest Long-Term Study Confirms EDAP's Ablatherm® HIFU is Effective, Highly Reproducible Primary Treatment for Localized Prostate Cancer.

2,552 Patient, International, Multi-Center, 10-year Study Shows 83% of Patients Cancer Free

EDAP, the global leader in therapeutic ultrasound, announced today that new 10 year data from an international registry-based multi-center study shows 83 percent of patients had no biopsy evidence of disease after treatment with Ablatherm® HIFU, supporting the technology as a standard primary treatment for localized prostate cancer. Study results were presented at the American Urological Association (AUA) 2011 Annual Meeting, Washington, D.C. The largest, long-term study ever presented on high-intensity focused ultrasound (HIFU) reported outcomes from 2,552 patients treated throughout Europe, where Ablatherm-HIFU is currently available. Patients diagnosed with stage T1-T3 prostate cancer with low, moderate or high risk for disease progression were treated with Ablatherm-HIFU. Outcomes were followed using a secure online registry database, which tracked progression as measured by prostate-specific antigen (PSA) levels and prostate biopsy data. Andreas Blana, MD, Senior Investigator and Chairman of @-Registry Board, Associated Professor at the University of Regensburg Germany, explained, "Results from this robust, multi-center study were remarkably consistent across progression risk groups, demonstrating that HIFU is effective at controlling prostate cancer for all patients. These favorable clinical outcomes were also highly reproducible, which has a critical real-world impact on how effectively HIFU can be used to treat the disease worldwide." The study revealed cancer cells could no longer be detected by a prostate biopsy in 83 percent of patients across all risk levels (low 89%, moderate 81%, high 78%). Consistent with previous HIFU studies, patients also experienced a mild side-effect profile. Ablatherm- HIFU is a fully automated, incision- and radiation-free procedure that uses focused ultrasound waves to precisely destroy cancerous tissue within the prostate, while protecting surrounding healthy tissue. Unlike more invasive therapies, Ablatherm-HIFU helps preserve normal bowel, urinary and sexual functions. "Ablatherm- HIFU is recognized as a standard primary treatment for prostate cancer throughout Europe, and is highly anticipated in the U.S. based on positive long-term outcomes data such as this," stated investigator and HIFU pioneer, Professor Christian Chaussy, MD, Department of Urology, University of Regensburg, Germany. "Today, patients with prostate cancer are being diagnosed younger and living longer. It is more important than ever to have an effective, less invasive treatment option for prostate cancer at any stage that will have minimal impact on quality of life and remain effective for a longer period of time." HIFU has been performed more than 30,000 times throughout the world since 2000. The therapy is currently undergoing evaluation in a multi-center U.S. Phase II/III clinical trial; however, is not yet approved for non-investigational use. Marc Oczachowski, Chief Executive Officer of EDAP TMS, stated, "All of the Ablatherm-HIFU data presented at the AUA meeting, including the 10-year registry study, continue to

substantiate the clinical value of the technology. We are committed to working with the FDA to offer this proven, less traumatic alternative to American patients as soon as possible.”