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EDAP Presents Results of Its Ablatherm-HIFU FDA Study at 4th International Symposium of the Focused Ultrasound Foundation, Washington D.C.

LYON, France, Oct. 13, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that data on clinical outcomes of its Ablatherm-HIFU FDA study (the "Enlight Trial") will be presented at the 4th International Symposium of the Focused Ultrasound Foundation ("FUSF"), being held October 12-14, 2014 in Washington D.C. This symposium is the world's largest gathering of clinical and scientific experts in the area of focused ultrasound, and a forum for the latest clinical advances in image-guided focused ultrasound applications across a variety of therapeutic areas.

A clinical abstract from Dr. Cary Robertson, MD, Associate Professor of Urology at Duke University and Coordinating Principal Investigator of the IDE Enlight Study showing patient outcomes from the Enlight trial will be presented during the conference. The outcomes presented were a fundamental element of the PMA application submitted by EDAP to the FDA. The study, which evaluated patients that received HIFU as a monotherapy procedure, showed a biochemical success rate greater than 90% at two years, with minimal lasting side effects. This is in contrast to other treatments such as radiation and surgery, which are often combined with another treatment. The study concluded: "HIFU appears to be a safe and efficacious primary therapy for localized prostate cancer."

Dr. Robertson commented, "This is a unique, multicenter study that used a monotherapy to treat localized prostate cancer and achieved excellent biochemical control. The adverse event profile demonstrates promising erectile function preservation and low rates of long term morbidity. These results complement published long-term outcomes from Europe and elsewhere in the world, where HIFU is utilized in a variety of situations including in repeat treatments, as salvage treatment and as part of a combination therapy."

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are pleased that the FUSF has accepted our abstract, and grateful for the opportunity to present our positive Enlight Trial outcomes. We believe that the acceptance of this abstract by a panel of renowned international experts is a significant validation of HIFU in the treatment of low-risk prostate cancer. Moreover, it speaks to the importance of ongoing dialog within the medical and regulatory communities around the efficacy of innovative approaches such as HIFU compared with existing treatment options for those who suffer from prostate cancer."

Oczachowski concluded: "With more than 40,000 Ablatherm HIFU treatments safely performed worldwide over more than 15 years, we believe that HIFU represents a viable therapeutic approach and are steadfastly committed to maximizing patient and physician access to our technology through the advancement of our strategic regulatory and reimbursement initiatives."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® 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. Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in February 2013 after the completion of a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. In March 2013, the Company introduced a new innovative HIFU device, the Focal One®, dedicated to focal therapy of prostate cancer. Focal One® is CE marked but is not FDA approved. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith® range) 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.

About Focused Ultrasound Foundation

The Focused Ultrasound Foundation was created to improve the lives of millions of people with serious medical disorders by accelerating the development and adoption of focused ultrasound.

Focused ultrasound is an early-stage, non-invasive therapeutic technology that could transform the treatment of many medical disorders by serving as an alternative to surgery and radiation. The Focused Ultrasound Foundation is working to provide patients with this non-invasive, life-changing treatment option in the shortest time possible. For more information on the Foundation, please visit http://www.fusfoundation.org.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others the uncertainties of the U.S. FDA approval process, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device. Factors that may cause such a difference also may include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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