

EDAP Announces First Focal One(R) HIFU Treatments Performed in Germany

LYON, France, May 6, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, reported the first Focal One HIFU treatments performed in Germany.

The Department of Urology at the Fuerth Hospital, Germany, headed by Dr. Andreas Blana, has recently initiated the use of the Focal One HIFU device for treatment of prostate cancer, on a mobile revenue per procedure (RPP) basis. Among the first patients treated with Focal One were three US patients who traveled to Germany to benefit from this non-invasive HIFU focal therapeutic approach.

Dr. Blana is a global expert in HIFU and has been performing HIFU with the Ablatherm for more than fourteen years, first as Resident and Consultant Urologist at the University Hospital of Regensburg, then as the Chief of Urology at Fuerth Hospital. He has treated several hundred patients using EDAP's HIFU technology and has published many peer reviewed papers on the topic.

Dr. Blana commented, "I am very excited to be the first one in Germany to perform prostate cancer treatments with Focal One. I was really impressed by the capabilities of the device that offers efficacy and safety for the patient. Combining the precision of the MRI and its ability to visualize tumors with Focal One ablation technology makes it the perfect tool for focal therapy. The ability to verify treatment effect during the procedure with contrast ultrasound is unique and beneficial."

Marc Oczachowski, EDAP's Chief Executive Officer, said, "The initiation of treatments with Focal One in a key market such as Germany is an important milestone for the commercial development of our device. It is particularly encouraging to have a physician such as Dr. Blana perform these treatments. Dr. Blana is a long term user of HIFU and is well positioned to assess the clinical and technical differentiations from both devices in our HIFU range."

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 February 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 <u>http://www.edap-tms.com</u>, and <u>http://www.hifu-planet.com</u>.

About Fuerth Urology Clinic: Fuerth Urology Clinic (Urologische Klinik Fuerth) is specialized in treating prostate cancer at its certified prostate cancer center located in Fuerth, Germany. In addition, the clinic offers a wide spectrum on urological treatments and treated close to 5000 urological patients last year on an in- and out-patient basis.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements.. Such statements00 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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