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EDAP Introduces Focal.One(R): A New Robotic HIFU Device for Focal Therapy of Prostate Cancer

Focal.One World Premiere at European Association of Urology Annual Congress

LYON, France, March 14, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today the launch of **Focal.One®**, its new and innovative robotic HIFU device fully dedicated to focal therapy of prostate cancer. **Focal.One®** will be showcased for the first time at the European Association of Urology (EAU) 28th Annual Congress to be held in Milan, Italy on March 15-19, 2013 (booth # D41).

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented, "We are very excited to present to the urological community our latest HIFU technology bringing together many of the latest innovations to fulfill the focal strategy for the treatment of prostate cancer. Focal.One is the first and only device specifically designed to fully answer the need from urologists for a non-invasive, robotic device that fully addresses the quality of life preservation concerns of prostate cancer patients who are increasingly better informed about treatment options."

Focal.One is the first device dedicated to the focal approach for prostate cancer therapy. It combines the three essential components to efficiently perform a focal treatment: (i) state-of-the-art imaging to localize tumors with the use of magnetic resonance imaging (MRI) combined with real-time ultrasound, (ii) utmost precision of HIFU treatment focused on identified targeted cancer areas only and (iii) immediate feedback on treatment efficacy utilizing Contrast-Enhanced Ultrasound Imaging.

As the prostate cancer patient profile has evolved over recent years with earlier diagnosis and life expectancy significantly increasing, men with prostate cancer want to preserve their quality of life more than ever. Until today, those patients are mainly offered two options to address their prostate cancer: either a radical treatment approach with the surgical removal or irradiation of the entire prostatic gland, usually associated with high risk of side effects such as incontinence and impotence, or a "watchful waiting" approach with the monitoring of disease evolution through regular PSA testing and biopsies, usually associated with a high degree patient stress and anxiety ultimately resulting in the necessity for a radical treatment. Between "over-aggressive treatment" and "no treatment," there is definitely a need for a non-invasive therapeutic alternative that offers a control over the disease while focally treating the cancer tumors only.

Hugo Embert, Marketing Director of EDAP TMS, added, "We strongly believe that, in the upcoming years, the focal approach will become more and more prominent in the management of prostate cancer as it is already the case for other organs. This is the reason why we combined the latest imaging modalities with cutting-edge proprietary HIFU technology into one unique device, Focal.One. Thanks to the latest improvements of MR-Imaging in the diagnostic of prostate cancer, HIFU precision combined with a highly performing ultrasound tool to validate treatment efficiency, Focal.One is the first device that meets the need for an optimal focal therapy of prostate cancer while preserving patient quality of life."

Mr. Embert concluded, "By adding Focal.One to our well-established Ablatherm® device, we expanded our range of HIFU devices for localized prostate cancer and have now the capacity to answer a wide array of treatment options and to address every population of urologists by bringing them the right solution for their prostate cancer practice. This is unique to EDAP TMS and the result of many years of R&D expertise and HIFU clinical experience."

EDAP expects to file for CE mark for Focal.One in the second quarter of 2013 and to pursue commercial distribution in Europe thereafter. A global regulatory program will be implemented to pursue requisite approvals across key global markets.

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. 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.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements that involve risks and uncertainties. Such statements are based on management's current expectations and are subject to a number of uncertainties, including the uncertainties of the regulatory process, and risks that could cause actual results to differ materially from those described in these forward-looking statements. Factors that may cause such a difference 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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