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EDAP Granted European Market Clearance for Focal.One(R)

Positions Focal.One Robotic HIFU Device for Commercialization

LYON, France, June 18, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that it received CE Mark (European regulatory approval) for **Focal.One®**, its new and innovative robotic HIFU device fully dedicated to focal therapy of prostate cancer. Focal.One was showcased as world premiere at the European Urology Association Congress in Milan, Italy on March 15-19, 2013.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented, "This is a significant regulatory achievement and a key milestone as we received EU market clearance for the first robotic HIFU device dedicated to a focal targeted treatment approach. This CE mark positions Focal.One for full commercialization in Europe and in many other countries. It confirms EDAP's expertise in managing R&D and regulatory programs successfully. I wish to deeply congratulate the EDAP team for their extraordinary efforts in bringing Focal.One to market in a timely manner."

Mr. Oczachowski continued, "Utilizing a focal therapy approach to target the cancer cells within the prostate gland for the treatment of prostate cancer is gaining wider acceptance across the international urological community. Combining into one unique HIFU device the latest imaging modalities, such as MRI localization and contrast-enhanced ultrasound control, with the ultimate dynamic focusing HIFU technology, Focal.One will offer an optimal focal therapy of prostate cancer while preserving patient quality of life."

Focal.One is the first device fully 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.

EDAP's unique and exclusive range of HIFU products, including Ablatherm Integrated Imaging and Focal.One, has now the capacity to offer a wide array of treatment options to patients with prostate cancer.

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 contains 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 FDA PMA review process, our ability to expand our U.S. operations and execute our growth strategy and the market potential for our medical technologies, as well as 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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