EDAP Receives U.S. FDA 510(k) Approval for Sonolith I-Sys

Novel, Innovative and Robotized Next-Generation Lithotripsy Device to Enter U.S. Market

LYON, France, Aug 19, 2009 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that the U.S. Food and Drug Administration has granted 510(k) marketing clearance for its newly designed, high-end Sonolith I-Sys device.

Sonolith I-Sys is a novel, robotized device that has been developed by EDAP to provide a highly effective product configuration to address what is one of the largest lithotripsy markets in the world. The integrated lithotripter utilizes EDAP's unique and patented electroconductive technology, an advanced shockwave approach differentiated by its superior ability to successfully disintegrate urinary stones in association with combined x-ray or ultrasound systems.

The Sonolith I-Sys received CE mark approval in July 2007 and was launched in the E.U. in late 2007. The device's superior x-ray and ultrasound imaging systems and user friendly features have contributed to its impressive adoption, positive treatment outcomes and high standards that benefit both patients and hospitals.

Marc Oczachowski, EDAP's Chief Executive Officer, said, "We are very pleased that the U.S. FDA has granted 510(k) approval for Sonolith I-Sys, which marks a clear milestone for EDAP, further validates our technology and supports our objective to expand the Sonolith I-Sys into additional geographic territories. With the U.S. approval, we will be positioned to enter one of the largest global markets for lithotripsy. This is an excellent opportunity for EDAP. We will now actively market Sonolith I-Sys and its patented electroconductive technology. We strongly believe that this is the most advanced and robotized lithotripsy system and that it will play a role in the high end market in the U.S. as it was designed to respond to the specificities of this established market."

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm, the most advanced and clinically proven choice 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. Approved in Europe as a treatment for prostate cancer, Ablatherm-HIFU (High Intensity Focused Ultrasound) is currently undergoing evaluation in a multicenter U.S. Phase II/III clinical trial under an Investigational Device Exemption granted by the FDA, the ENLIGHT U.S. clinical study. The Company also is developing this technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment 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, http://www.hifu-planet.com and http://www.pcaresearch.com.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements that involve risks and uncertainties. These include statements regarding the company's growth and expansion plans. Such statements are based on management's current expectations and are subject to a number of uncertainties 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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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