EDAP Submits U.S. FDA 510(k) Application for Marketing Clearance for Sonolith i-move

LYON, France, Aug 19, 2010 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced that it has filed its 510(k) application for marketing clearance with the U.S. Food and Drug Administration (FDA) for its new compact and stand alone lithotripter Sonolith i-move.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are actively moving forward in obtaining approval in major lithotripsy markets for our recently developed, innovative Sonolith i-move lithotripter. Our recent 510(k) application to the FDA is a clear milestone for EDAP's expansion in this field. In addition to our high-range fully integrated Sonolith I-sys lithotripter that received 510(k) marketing clearance a year ago, our compact multi-configurations Sonolith i-move device offers a wide range of urinary stones treatment options to mid-size clinics and hospitals, hence covering all lithotripsy market segments. We look forward to working with the FDA in view of approval of our Sonolith i-move, hence providing U.S. patients and physicians with the most versatile advanced treatment option."

Sonolith i-move is a compact lithotripter with a revolutionary infrared stereo-vision system for real-time, three-dimensional ultrasound localization of urinary stones. With its various modular configurations, Sonolith i-move will replace Sonolith Praktis, an earlier generation lithotripter, and complements the Company's high-end Sonolith I-sys lithotripter, an integration of x-ray and ultrasound localization systems.

Sonolith i-move received European (CE) approval in April 2010 and was simultaneously officially launched in Europe. EDAP is also actively working on clearance applications for its Sonolith i-move device in major lithotripsy markets such as Japan and South Korea.

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm(R), 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 multi-center 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 (the Sonolith(R) 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. These include statements regarding the Company's growth and expansion plans, the conclusiveness of the results of and success of its Ablatherm-HIFU clinical trials and expectations regarding the IDE submission to and approval by the FDA of the Ablatherm-HIFU device. 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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