EDAP Gains U.S. FDA 510(k) Lithotripter Clearance

Innovative Compact Sonolith(R) i-move Lithotripter Expands U.S. Market Potential

LYON, France, Aug. 3, 2011 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced it has received marketing clearance from the U.S. Food and Drug Administration (FDA) for its Sonolith i-move device, a technologically advanced compact mobile lithotripter. The U.S. FDA has cleared EDAP's Sonolith i-move device for fragmentation of kidney stones, extracorporeal shock wave lithotripsy procedures and endourology applications.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "This FDA clearance is a major milestone for EDAP and its U.S. business. The Sonolith i-move lithotripter is a technologically advanced device with modularity and mobile capability. We believe our Sonolith i-move is attractively positioned to take market share in the U.S., the second largest lithotripsy market worldwide. Our established U.S. sales and marketing organization has clearly identified potential customers within this dynamic lithotripsy market."

Marc Oczachowski added, "Our Sonolith platform offers both patients and physicians innovative efficient technology to treat urinary stones. The state-of-the-art technology and high level of innovation brought by both the Sonolith i-move and i-sys devices will enable us to renew our existing installed base of lithotripters and to maximize opportunity to take market share from the competition in the U.S."

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 Japanese approval in June 2011.

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 multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) 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® 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, expectations regarding the IDE submission to and approval by the FDA of the Ablatherm-HIFU device and the market potential for the Sonolith i-move 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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