EDAP Receives Japanese Approval for Sonolith I-Sys

Enters Largest Global Lithotripsy Market

LYON, France, Mar 9, 2010 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that the Japanese Administration has granted marketing approval of its newly designed, high-end Sonolith I-Sys lithotripsy device.

The lithotripsy market in Japan ranks number one worldwide in both total lithotripsy sales volume and installed base. Physicians in Japan have been historically quick to adopt new innovative, high-end devices. As the latest device to enter the Japanese market, the Sonolith I-Sys is an easy to use and effective tool that delivers benefits to both patients and physicians. With unique, integrated and robotized features, Sonolith I-Sys fully addresses the Japanese lithotripsy market demands for new high-end technologies.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "Japan is the largest global lithotripsy market and the latest key territory we have received approval for Sonolith I-Sys. This approval is a major milestone and further validates EDAP's position as a major worldwide player in the lithotripsy field, with Sonolith I-Sys approved in all lithotripsy markets in the world. We are very enthusiastic with the Japanese approval of our Sonolith I-sys lithotripter. We are convinced that our innovative, high-end device perfectly suits the Japanese lithotripsy market and will allow us to successfully address the strong demand of major clinical centres and University hospitals. We are all the more excited as the approval coincides with the upcoming annual Japanese Urology Association (JAU) Congress, to be held in Morioka on April 27-30, 2010. At the event, our Sonolith I-sys will be highlighted and introduced as the latest innovative lithotripsy device."

Marc Oczachowski continued, "The Japanese marketing approval will significantly contribute to our business development efforts in Japan as our sales and marketing team is already focusing its efforts in aggressively promoting our device to the medical community."

Sonolith I-Sys has been actively promoted in Europe and the U.S. territory and is now available for sale in Japan. In 2007, Sonolith I-Sys lithotripsy device received initial marketing approval in Europe. As part of EDAP's strategy to introduce Sonolith I-Sys to leading global lithotripsy markets, the device successfully obtained marketing clearance by the U.S. FDA in August 2009 and the Japanese Administration in March 2010.

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, 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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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