EDAP Submits 510(k) Filing to U.S. FDA for Sonolith I-Sys

LYON, France, Dec 18, 2008 (GlobeNewswire via COMTEX News Network) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced that it has filed a 510(k) marketing application with the U.S. Food and Drug Administration (FDA) for its newly designed, high-end Sonolith I-Sys device.

Sonolith I-Sys is a novel, robotized device with the potential to become the comparative assessment benchmark of next-generation lithotripsy devices. The integrated lithotripter utilizes EDAP's patented electroconductive technology, an advanced shockwave approach that is unique to successfully disintegrating urinary stones in association with combined x-ray or ultrasound systems.

Sonolith I-Sys received CE mark approval in July 2007 and was officially launched by EDAP in late 2007. Currently also approved in Korea, Australia and Canada, urologists have benefited from the straightforward treatment preparation and ESWL procedure, which has a clear navigational platform software. The device has generated impressive enthusiasm among users in Europe by providing a superior x-ray imaging system and user friendly features associated with efficacious treatments and high standards that benefit both patients and hospitals.

Marc Oczachowski, EDAP's Chief Executive Officer, said, "We are very pleased to file our 510(k) with the FDA prior to year end 2008, a significant milestone for EDAP that is in line with our expectations. We look forward to working with the FDA towards obtaining device approval and providing U.S. physicians and patients with today's most advanced lithotripsy system."

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 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 or http://www.urotoday.com/HIFU.

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