

EDAP TMS SA
Form 6-K
December 16, 2003

EDAP TMS S.A. ANNOUNCES A LETTER OF INTENT WITH HEALTHTRONICS ON ABLATHERM® IN THE U.S.A.

- Agreement to Allow Right to Pursue PMA Approval and Grants Distribution Rights -

- Company Plans to Call a Meeting of its Shareholders to Approve Key Portion of the Agreement -

Vaulx-en-Velin, France, December 15, 2003-- EDAP TMS S.A. (Nasdaq: EDAP)

, a global leader in the development, marketing and distribution of a portfolio of minimally-invasive medical devices for the treatment of urological diseases, today announced that it has entered into a letter of intent with HealthTronics Surgical Services, Inc. ("HealthTronics") (Nasdaq: HTRN). This letter of intent outlines terms that would grant HealthTronics the right to begin clinical trials with the Ablatherm, a medical device that utilizes High Intensity Focused Ultrasound ("HIFU") to provide minimally invasive treatment of prostate cancer, to obtain Pre-Market Approval ("PMA") from the Food and Drug Administration ("FDA") and would grant HealthTronics exclusive distribution rights in the United States, when and if, a PMA is granted by the FDA. The letter of intent is subject to the negotiation and execution of definitive agreements between EDAP TMS and HealthTronics.

The final agreement between the two companies will include the issuance of warrants by EDAP TMS S.A. to HealthTronics in consideration for providing services related to pursuing a PMA from the FDA. Certain aspects of the proposed transaction will require the approval of the shareholders of EDAP TMS at an extraordinary shareholder meeting prior to the execution of a final agreement. The Board of Directors anticipates calling such a meeting to be held at the end of January 2004. Shareholders of EDAP TMS S.A. will receive details of the resolutions to be voted on as soon as the Board has finalized the meeting and record dates.

Philippe Chauveau, Chairman and Chief Executive Officer of EDAP TMS S.A. commented, "We are pleased to announce that we are moving forward with a partnership in the United States for our HIFU technology. We look forward to discussing this partnership with our shareholders as we progress towards the shareholders meeting at the end of January, 2004." Argil J. Wheelock, M.D., Chairman and Chief Executive Officer of HealthTronics Surgical Services, Inc. commented, "We are very pleased to have reached preliminary terms with EDAP and look forward to finalizing a definitive agreement and moving forward with the project."

EDAP TMS S.A. is the global leader in the development, production, marketing and distribution of a portfolio of minimally invasive medical devices primarily for the treatment of urological diseases. The Company currently produces and markets devices for the minimally invasive treatment of localized prostate cancer, using High Intensity Focused Ultrasound (HIFU) and the treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy (ESWL). The Company also produces and markets in Japan and Italy devices for the non-surgical treatment of benign Prostate Hyperplasia (BPH) using Microwave Thermotherapy (TUMT). The Company is also developing HIFU for the treatment of certain other types of tumors. For more information, in the U.S., contact EDAP Technomed Inc., the Company's U.S. subsidiary located in Atlanta, GA, by phone at (770) 446-9950.

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This press release contains, in addition to historical information, 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 the 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.