

EDAP TMS SA
Form 6-K
March 02, 2004

EDAP TMS S.A. AND HEALTHTRONICS SURGICAL SERVICES, INC. ANNOUNCE FINALIZATION OF
AGREEMENT FOR ABLATHERM® IN THE U.S.A.

- Allows HealthTronics to Pursue PMA Approval and Grants Distribution Rights in the U.S.A. -

Vaulx-en-Velin, France and Marietta, GA, March 1, 2004 -- 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, and **HealthTronics Surgical Services, Inc. (Nasdaq: HTRN)**, a leading provider of minimally invasive surgical services for the urologic and orthopaedic communities, today announced that the two companies finalized a distribution agreement for Ablatherm in the United States.

The distribution agreement is based on a letter of intent entered into by both companies in December 2003. The distribution agreement grants 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 grants HealthTronics exclusive distribution rights in the United States, when and if a PMA is granted by the FDA. The Ablatherm, which is currently being utilized at 42 sites, has successfully treated more than 4,500 patients in Europe.

The final agreement between the two companies includes the issuance of warrants by EDAP TMS to HeathTronics in consideration for providing services related to pursuing a PMA from the FDA. The issuance of warrants was approved by the shareholders of EDAP TMS at an extraordinary shareholder meeting held January 29, 2004. The warrants issued to HealthTronics vest at various times based on certain milestones related to the PMA process and based on certain lithotripsy purchase expectations.

Philippe Chauveau, Chairman and Chief Executive Officer of EDAP TMS S.A. commented, "We are very excited to announce that we have finalized our agreement with a U.S. partner for our HIFU technology. In HealthTronics, we feel we have found a partner who will champion HIFU in the United States and will work to bring this technology to the people who will benefit the most from it, the hundreds of thousands of men who are diagnosed each year with localized prostate cancer."

Argil J. Wheelock, M.D., Chairman and Chief Executive Officer of HealthTronics Surgical Services, commented, "Our partnership with EDAP offers us the opportunity to introduce a very exciting new prostate cancer treatment modality to the United States. After discussions with several well-known urologists in Europe and observing several cases, I am convinced that HIFU has great potential to play an important role in the treatment of prostate cancer. In Europe, HIFU has been shown to be clinically effective and very cost efficient. Several prominent urologists in the United States have already expressed a strong interest in participating in our FDA clinical trials. These factors, along with our previous experience in getting products and treatments through the FDA process, gives me confidence that we will be successful in getting HIFU with the Ablatherm approved for use in the United States. We believe that this agreement will benefit patients, third party payers, urologists and our shareholders."

About the Companies:

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.

HealthTronics Surgical Services, Inc. is one of the nation's leading providers of non-invasive and minimally invasive surgical services for certain urologic and orthopaedic conditions. The Company provides technical and administrative services to physicians, hospitals and ambulatory surgery centers using extracorporeal shock wave devices. The two primary services offered by HealthTronics are lithotripsy extracorporeal shock wave treatment, which is a procedure for treating kidney stones in a non-invasive manner, and Orthotripsy(r) extracorporeal shock wave surgery, which is a procedure for treating orthopaedic soft tissue disorders in a non-invasive manner. The Company has operations in approximately 45 states in the United States.

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.;

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