

EDAP TMS SA
Form 6-K
April 11, 2005

HIFU with Ablatherm Now Available in Canada

For Patients with Prostate Cancer

Lyon, France, April 11, 2005 -- EDAP TMS S.A. (Nasdaq: EDAP)

today announced its highly effective, non-invasive treatment for prostate cancer is now available to North American patients through a clinical installation in Toronto, Canada.

Prostate cancer is the leading cancer among North American men and is second only to lung cancer as the cause of cancer-related deaths in North American males. It is estimated that approximately 250,000 new cases of prostate cancer are diagnosed in North America each year.

EDAP TMS and Maple Leaf HIFU Company have entered into an exclusive sales agreement allowing Maple Leaf to market the Ablatherm in Canada and develop access to Ablatherm-HIFU technology throughout the Canadian territory.

The Ablatherm-HIFU prostate cancer treatment is now being offered at the Don Mills Surgical Unit in Toronto. The Don Mills Surgical Unit is a private surgical facility that is licensed by the Province of Ontario and under the direction of Dr. William Orovan, a board certified urologist and chair of the Department of Surgery, McMaster University. Additionally, Dr. Orovan is the former president of the Ontario Medical Association.

Ablatherm-HIFU is an effective treatment for patients with localized prostate cancer whose disease is confined to the prostate gland itself, referred to as clinical stage T1 or T2. Ablatherm-HIFU can also be performed on patients who have undergone radiation treatment in the past and experienced recurrent cancer. The HIFU procedure provides these patients with a treatment option when few others remain.

Ablatherm-HIFU is approved for use in Canada and throughout Europe where it has more than 8 years of patient follow-up data. While the technology does not currently have United States FDA approval, clinical trials are expected to begin soon. Ablatherm-HIFU is a proven technology developed and perfected in Europe with clinical experience now exceeding 7,000 treatments. This procedure offers a safe and effective alternative to more radical treatments such as surgery or radiation, currently the primary treatment methods. European studies have shown that as a curative option Ablatherm-HIFU has had success rates up to 93%, with five years of follow-up. Ablatherm-HIFU can be repeated and does not exclude patients from undergoing other treatment options if their cancer is found to be more aggressive or recurring.

"This clinically proven treatment is a revolutionary advance in the ongoing fight against Prostate Cancer," said Dr. John Warner, a Memorial Sloan-Kettering trained uro-oncologist practicing in Vancouver, Canada. "We are excited to finally bring the Ablatherm HIFU treatment to North America so many more can discover its benefits."

Ablatherm-HIFU is a non-invasive, precise, and targeted procedure that delivers a beam of high intensity focused ultrasound to the prostate. Under spinal anesthesia, the Ablatherm-HIFU probe is placed into the rectum through which the focused ultrasound waves are directed into the cancerous prostate tissue without damage to the intervening tissue. This causes a rapid rise in temperature inside the prostate cells to 85 degrees Celsius, destroying the cancerous

cells. The procedure is completed in 2 to 3 hours without blood loss or exposure to radiation.

"We are pleased and excited to bring this technology to Canada after so many years of success in Europe," said Hugues de Bantel, Chief Executive Officer of EDAP TMS. "Ablatherm-HIFU is a proven alternative to existing treatments for prostate cancer with a low occurrence of side effects, thus preserving patients quality of life. This offers men an opportunity to treat prostate cancer without significant side effects impacting their lifestyle. We believe Canada represents a significant and important opportunity to bring this treatment technology and its benefits to men suffering from prostate cancer in North America."

David Lowy, President of Maple Leaf HIFU Company, added, "We are proud to be the first to bring this innovative technique, proven in Europe for years, to North American patients suffering from prostate cancer. We anticipate that many patients will choose to be treated in Toronto with Ablatherm-HIFU and avoid surgery or radiotherapy. "

About EDAP TMS S.A.

EDAP TMS S.A. 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. The company is also developing this technology for the treatment of certain other types of tumors. EDAP TMS S.A. also produces and commercializes medical equipment for treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy (ESWL).

For more information on the Company, contact the Investor Relations Dept. by phone at +33 (0)4 78 26 40 46.

About Maple Leaf HIFU Co.

Maple Leaf HIFU Co. is a privately held Canadian medical services company offering treatments using Ablatherm-High Intensity Focused Ultrasound treatments for localized prostate cancer.

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.