EDAP Reports on its Great Success at European Association of Urology Congress

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LYON, France, March 27 /PRNewswire-FirstCall/ -- EDAP TMS S.A. (NASDAQ: EDAP), the global leader in High Intensity Focused Ultrasound (HIFU) treatment of prostate cancer and the international leader in the development, production, and distribution of a wide portfolio of minimally invasive medical devices primarily for the treatment of urological diseases announced success at the recent European Association of Urology Congress in Berlin. Significant EDAP and Ablatherm-HIFU activities included:

- The largest and most thorough HIFU clinical activity and exposure in the official EAU Congress program
- More than 300 doctors attended the company's live treatment broadcast
- Multiple on-site treatment sessions for small groups conducted each day at top Berlin hospitals including Franziskus Krankenhaus and Charite Berlin
- The HIFU Symposium with more than 130 participants affirmed specifically Ablatherm-HIFU use as a primary alternative for selected patients not suitable for surgery or with failure after radiotherapy based on EDAP's specific long-term results covering 10 years validating the efficacy and safety of the Ablatherm device.
- Experience data up to 10 years of follow up confirms patient success at top levels with minimal side effects. EDAP is the only HIFU company to offer not only this level of clinical data, but also to provide clear repeatability of results at multiple center studies.

Marc Oczachowski, COO of EDAP, stated, "Our mission at the EAU Congress was to credibly and professionally further Ablatherm-HIFU's already convincing lead in HIFU technology by moving strongly toward standard of care status. We clearly achieved this goal, and urologists in Europe are seeing HIFU in a new and positive light based on EDAP's long-term confirmed data. Our live treatment session was certainly a conference highlight as well as a convincing opportunity demonstrating why EDAP is the global leader in prostate cancer HIFU. We conducted numerous treatment sessions at top Berlin area hospitals bringing highly interested urologists directly into the treatment theater for an undeniable demonstration of our device's unparalleled capabilities. In concert with the ongoing progression of clinical data EDAP continues to unveil now covering more than 10 years of active therapy, there is no doubt HIFU is establishing itself as a new treatment choice and a standard of care for localized prostate cancer."

Symposium Furthers Ablatherm-HIFU as Only Device Achieving Standard of Care Status

Pr. Gunnar Aus, of Goteberg, Sweden, Chairman of the "EAU Guidelines Office" in charge of establishing guidelines for the use of new therapies in Europe and Chairman of the official HIFU Symposium set the EAU Congress tone for HIFU in his opening remarks. In its introduction, after reviewing all different options, Pr. Aus clearly reminded doctors that active therapy shows significantly reduced risk overtime compared to watchful waiting.

Pr. Aus highlighted the importance of long-term clinical data to support the use of HIFU as a first-line therapy for patients not suitable for radical prostatectomy and as a salvage treatment for patients after radiotherapy failure. The Symposium then moved to discuss EDAP data demonstrating the capabilities only attributable to the Ablatherm-HIFU device and its clear clinical protocols proven over many years at multiple centers.

In one presentation, Pr. G. Conti of Como, Italy presented long-term results of Ablatherm after External Beam Radiation Therapy failure showing 73% success based on negative biopsies. Further demonstrating Ablatherm-HIFU as a favored curative option for low and intermediate risk patients are the low complication rates related to HIFU on this very specific population with dedicated parameters implemented exclusively on Ablatherm-HIFU since 2002. As a concluding remark to this presentation, Pr. Aus strongly recommended that patients failing external beam radiation have to be treated as soon as possible using a second-line therapy, thus increasing their chance of success.

The next three presentations were based on long-term data, all with a minimum of five years follow-up and reaching as far as 10 years of experience data. Dr F.G. Murat of HEH in Lyon, presented a long term results study of 140 low and intermediate risk patients. Ablatherm efficiency on long-term results showed an overall survival rate at 90% at 5 years, 83% at 8 years with no death related to HIFU. Also confirming the validity of Ablatherm-HIFU, 86% of the patients did not require any form of a salvage treatment at 5 Yrs and 79% at 8 years.

Concluding, Dr. Murat stated: "HIFU is a valid indication for localized prostate cancer in patients not suitable or refusing surgery as it allows a high tumor local control and a long-term efficacy comparable to other non-surgical options. We confirmed that, based on long term results, it can now be considered as a real alternative to radiation or any other non-invasive treatment."

The panel acknowledged the fact that these long term results come up equivalent to other mature treatment options, including radiation, even though the results were obtained on the first Ablatherm-HIFU prototypes, greatly refined since. Further improvement in the equipment and treatment's

parameters allows for more precise imaging, updated treatment programs to provide more thorough HIFU application, detailed protocols for differing patient cases and reduction in side effects through treatment refinement.

Long term side effect data, presented by Dr. A. Blana of Regensburg, Germany, included patient studies. Results showed that at last evaluation, none of the patients had severe incontinence and only 5.7% had light incontinence, only 21% were fully impotent after HIFU therapy. In his conclusion, Dr. Blana reiterated these long-term results confirmed the absence of severe adverse reactions such as rectal urethral fistula, urinary incontinence, blood transfusion requirements, treatment related death and no unexpected late complications arising post treatment.

In his presentation, Dr. Brown, from Stockport, UK, analyzed the possibility of early feedback based on the PSA level reached in the following four months after treatment, and use it as a surrogate endpoint of the long term efficacy, greatly improving patient visibility. Dr. Brown concluded the early feedback provided by nadir PSA on the outcome of the treatments was a strong advantage as compared to radiation therapies. This predictive endpoint also confirms the progress achieved in terms of efficacy with EDAP's latest commercial devices including all the most recent developments, as short-term results significantly improved.

"This EAU Congress clearly confirms Ablatherm-HIFU's place in the treatment protocol for localized prostate cancer," said Oczachowski. "Only EDAP can provide clear and compelling long-term data showing efficacy and repeatability across centers. Further, only Ablatherm-HIFU has the global installation base to demonstrate its efficacy in top regional centers near practicing urologists seeking to adopt this technology into their practices. Our marketing efforts will lay the path for HIFU adoption in Europe. We look forward to reporting continued success in these efforts."

All Symposium presentations will be soon available on UROTODAY web site http://www.urotoday.com.

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. 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. The company is also developing this technology for the potential 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 Magnolia Investor Relations at (972) 801-4900, the Corporate Investor Relations Dept at +33 (0)4 78 26 40 46 or see the Company's Web sites at http://www.edap-tms.com and http://www.hifu-planet.com.

To sign up for alerts please visit http://www.b2i.us/irpass.asp?BzID=1053&to=ea&s=0

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 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 yet FDA approved or marketed in the United States.

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