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Bringing New Horizons to Therapy

EDAP Announces Presentation of Multiple Abstracts Favorably Comparing HIFU to Surgery at the American Urological Association 2021 Annual Meeting

September 14, 2021

Data demonstrate superiority of HIFU versus radical prostatectomy among prostate cancer patients

LYON, France, September 14, 2021 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, today announced that the company's Focal One and ExactVu technologies were featured in several poster presentations at the American Urological Association (AUA) 2021 Annual Meeting, which was held virtually from September 10-13. EDAP was a Gold sponsor of the event.

Details of two noteworthy presentations are as follows:

Title: Focal Ablation Versus Radical Prostatectomy for Intermediate-Risk Prostate Cancer: Interim Analysis of a Randomized Controlled Trial

Lead author: Eduard Baco, MD, Oslo University Hospital, Norway

Summary: This is the first randomized controlled clinical trial comparing focal therapy with robotic surgery. The data suggest that at one-year post treatment, Focal One achieved good oncological efficacy while preserving erectile function and urinary continence better than radical prostatectomy.

Title: High-Intensity Focused Ultrasound (HIFU) vs Radical Prostatectomy (RP) in the Curative Treatment of ISUP 1-2 Localized Prostate Cancer: Oncological Intermediate Results of the HIFI Study

Lead author: Pascal Rischmann, MD, Toulouse University Hospital, France

Summary: In this prospective comparative study sponsored by the French Association of Urology and financed by the French Ministry of Health, 3364 patients (HIFU: 1988, radical prostatectomy: 1376) were prospectively included across 42 French treatment centers. The intermediate results presented show a salvage-treatment-free survival rate significantly higher in the HIFU arm (97.5%) compared to the radical prostatectomy arm (90.3%).

"The data from these studies presented at this year's AUA Annual Meeting once again strongly support high intensity focused ultrasound as an alternative to far more invasive radical prostatectomy," stated Marc Oczachowski, Chairman & Chief Executive Officer of EDAP. "In terms of both efficacy and long-term survival, Focal One offers patients a superior treatment option without the debilitating side effects associated with surgery. Data such as these, together with the growing roster of healthcare institutions in the US and elsewhere who champion our technology and the progress we are making securing reimbursement, are key to our long-term growth and we are pleased to add to the expanding body of evidence at this prestigious urology conference showing the many benefits of HIFU."

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various pathologies using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® in Europe and in the U.S. as an answer to all requirements for ideal prostate tissue ablation. With the addition of the ExactVu™ Micro-Ultrasound device, EDAP TMS is now the only company offering a complete solution from diagnostics to focal treatment of Prostate Cancer. EDAP TMS also produces and distributes other medical equipment including the Sonolith® i-move lithotripter and lasers for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <http://www.edap-tms.com>, and us.hifu-prostate.com.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device, as well as the length and severity of the recent COVID-19 outbreak, including its impacts across our businesses on demand for our devices and services. Factors that may cause such a difference also may include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F.

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