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EDAP Announces Positive 24 Month Interim Results of French Urology Association (AFU) Sponsored Clinical Study comparing HIFU to Radical Prostate Surgery

January 14, 2021

- Results on 3,329 patients demonstrate significant difference in efficacy in favor of HIFU versus Radical Prostatectomy (RP)
- HIFU treatment also resulted in meaningful benefits in both urinary and erectile function versus RP showing superior quality of life preservation capability

LYON, France, January 14, 2021 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy based therapies, announced today positive 24 month interim results from the "HIFU" study comparing outcomes from high intensity focused ultrasound (HIFU) versus radical prostatectomy (RP) in a population of prostate cancer patients. This study is sponsored by the French Association of Urology (AFU) and supported by the French Ministry of Health. The results were presented at the AFU Congress in November 2020.

The study is a multicenter, prospective, non-randomized, comparative and non-inferiority study of HIFU vs. RP in men with primary prostate cancer. Between 2015 and 2019, the study enrolled 3,364 patients in 42 public and private hospitals in France: 1,988 treated with HIFU and 1,376 with RP, the current standard-of-care surgical approach. In terms of cancer characteristics, the two groups are comparable, with a majority of ISUP Grade Group 2 and equivalent median PSAs at baseline.

The results of the interim analysis show a significantly better 24-month recurrence-free survival (i.e., the rate of salvage treatment by external beam radiotherapy and/or hormone therapy) for the patients treated with HIFU compared to the patients undergoing surgery ($p < 0.001$). Additionally, urinary continence was significantly better ($p < 0.005$) and erectile function was significantly less impacted for the patients undergoing HIFU compared to those in the RP arm, despite the fact that the patients in the HIFU arm are more than 10 years older on average (current French guidelines), and therefore naturally more likely to suffer from these issues.

Pascal Rischmann, MD, Professor of Urology at Toulouse University Hospital, former President of AFU and co-principal investigator of the study, commented: "This is very exciting for the French Association of Urology to see this ambitious project come to fruition after several years and thousands of patients enrolled across the country. We have been pioneering HIFU for the treatment of prostate cancer for years and were convinced about its potential for many of our patients. If these results are confirmed at the end of the follow-up period, which we are cautiously optimistic, it will constitute a major milestone in making HIFU a standard option for a significant portion of men with localized prostate cancer."

Marc Oczachowski, Chairman and Chief Executive Officer of EDAP, commented: "We are very pleased with these interim results which were derived from a large cohort of patients who were treated at a significant number of clinical sites across France. These results are all the more relevant as this study was initiated and sponsored by a recognized national organization, AFU, further confirming the superiority of HIFU. This is a clear validation of HIFU technology and we believe this incremental clinical evidence will drive accelerating adoption going forward."

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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Source: EDAP TMS S.A.