EDAP Announces First Patients Treated in Phase I/II Study Evaluating Focal One Robotic HIFU for the Treatment of Benign Prostatic Hyperplasia (BPH)

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LYON, France, October 1, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced that the first patients have been treated in a Phase I/II study evaluating the Company's proprietary Focal One ® robotic high-intensity focused ultrasound (HIFU) technology for the treatment of benign prostatic hyperplasia (BPH).

"We've been offering targeted HIFU ablation to prostate cancer patients for more than 15 years," said Harry Toledano, MD, Head of the Urology Department of Martigues Hospital in Martigues, France. "Based on this large experience and the follow-up of hundreds of prostate cancer patients with their functional outcomes, we believe that the HIFU energy precisely delivered by Focal One has the potential to improve BPH symptoms with minimal side effects allowing a quick return to normal activities for a significant number of patients. We are enthusiastic to co-lead the first phase of this important clinical trial with our colleagues from Edouard Herriot Hospital – Lyon University and are looking forward to offering a new option to our BPH patients."

"We are excited to initiate this important clinical study evaluating Focal One robotic HIFU for the treatment of BPH, a condition which impacts millions of men each year," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "While there are other treatment options available for treating BPH, there remains a significant need for much less invasive treatment approaches that can preserve and protect the integrity of the urethra and other critical structures. We believe Focal One is ideally positioned to deliver this type of treatment solution, and this clinical approach in addressing BPH represents a logical next step in expanding our technology beyond the application in prostate cancer. We also believe this study will serve as a foundation for initiating a BPH clinical study in the United States next year."

The Phase I/II study is a company-sponsored, prospective, multicenter clinical trial designed as a two-part study. Part 1 of the Phase I/II study will take place at two leading academic prostate treatment centers in France with a recognized expertise in the treatment of BPH as well as in the use of Focal One HIFU technology. Part 1 is designed to define the optimal treatment parameters to effectively treat BPH and its related symptoms with minimal side effects. Part 2 of the study will expand patient enrollment across a larger number of treatment centers in order to validate the safety and efficacy of the parameters as defined in Part 1 of the study.

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, us.hifu-prostate.com and www.focalone.com.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933 (the "Securities Act") or Section 21E of the U.S. Securities Exchange Act of 1934, which may be identified by words such as "believe," "can," "contemplate," "could," "plan," "intend," "is designed to," "may," "might," "potential," "objective," "target," "project," "predict," "forecast," "ambition," "guideline," "should," "will," "estimate," "expect" and "anticipate," or the negative of these and similar expressions, which reflect our views about future events and financial performance. 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 and distribution divisions, as well as risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics like the COVID 19 pandemic, or other public health crises, and their related impact on our business operations, including their impacts across our businesses or demand for our devices and services.

Other factors that may cause such a difference may also 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.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

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