EDAP Announces Approval for Phase II Study Evaluating High Intensity Focused Ultrasound (HIFU) for Deep Invasive Endometriosis

August 25, 2020

- Multicenter study to commence in September in France
- Reinforces company's recent shift in strategic focus toward development of additional high-value HIFU tissue ablation indications

LYON, France, August 25, 2020 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, today announced that the company has received approval from French health authorities to initiate a Phase II multicenter clinical trial evaluating its Focal One® HIFU to treat deep rectal endometriosis.

In this Phase II multicenter study, a single patient group of 38 women with a confirmed diagnosis of deep rectal endometriosis will be treated in a total of five major hospitals in France, and both safety and efficacy will be assessed. This study is planned to commence in September at the Croix-Rousse University Hospital and expand to four additional sites. Pr. Gil Dubernard will serve as lead investigator. Based on the results from this Phase II study, if positive, the company plans to initiate a Phase III, randomized, placebo-controlled study to confirm these outcomes.

In a prior Phase I clinical study, also conducted by Pr. Dubernard, 20 women were observed to benefit from Focal One. The detailed outcomes of the study were published in *Ultrasound in Obstetrics & Gynecology Journal* in December 2019.

"Endometriosis, particularly the deep invasive form, can be a painful and debilitating disease that is very much in need of new treatment options," stated Pr. Dubernard. "Based on our earlier findings in a Phase I trial, I believe HIFU holds great promise as an effective and minimally-invasive treatment. This trial will raise awareness of the potential of HIFU across many high-need indications in France and elsewhere, and I am very eager to begin treating patients as we work to get data as efficiently as possible."

"The initiation of this endometriosis trial is consistent with our recent strategic focus to further expand our HIFU pipeline into new indications," noted Marc Oczachowski, Chairman and Chief Executive Officer of EDAP TMS. "As a leading innovator in the field of HIFU ablation, we see it as our mission to make this technology to the broadest possible patient population. We are grateful to Pr. Dubernard for continuing to champion our company and our technology and we look forward to the completion of this important study. In the meantime, our HIFU R&D efforts continue to expand as we look to explore HIFU's broader clinical utility."

Endometriosis affects nearly 10% of women of childbearing age, which is approximately 176 million women worldwide. Digestive endometriosis affects 20% of these women. It is one of the most symptomatic forms of the disease, mostly when the rectum is involved, and is responsible for a significant decline in quality of life. The symptoms of endometriosis include pain during menstrual cycles and ovulation, defecation during or after sexual intercourse, infertility, and can impact general physical, mental, and social wellbeing. When medical treatments are ineffective, surgical resection remains the standard despite significant adverse events. Focal One HIFU, as a minimally invasive ablative procedure, may prove to be a real benefit for these women who have no effective therapeutic options today.

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market for almost 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for urology 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 2013 in Europe and in 2018 in the US as the answer to all requirements for ideal prostate tissue ablation as a complement to the existing FDA-cleared Ablatherm® Robotic HIFU and Ablatherm® Fusion. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS exclusively utilizes the latest generation of shock wave source in its Sonolith® range of ESWL systems. 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 sustained activity of our lithotripsy business, 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.