EDAP Announces First Patients Treated in Phase 2 Study of Focal One for the Treatment of Deep Invasive Endometriosis

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· First patients already treated as recruitment accelerates

LYON, France, September 3, 2020 -- EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced that the first two patients have been treated in the company's Phase 2 clinical trial assessing Focal One® High Intensity Focused Ultrasound (HIFU) as a potential treatment for deep rectal endometriosis. A total of 38 women will be enrolled in the study and treated at five major hospitals and assessed over a six-month follow-up period. Follow-up of these patients will evaluate the safety and efficacy of HIFU for this pathology. Additional patients continue to be enrolled.

Pr. Gil Dubernard, Head of the Gynecologic Department, Croix-Rousse University Hospital, Lyon, and lead investigator, commented, “The first two patient treatments were completed this past Tuesday, and additional HIFU treatment session with study subjects are already scheduled for next week. We are very pleased to have commenced enrollment and treatments so soon after receiving regulatory approval. Many women suffer from this debilitating condition, which bodes well for the rapid recruitment of the additional subjects needed to conduct this important study.”

“We had been carefully planning an efficient development path for endometriosis, and this allowed us to begin treating patients almost immediately after receiving approval from health authorities. We are very excited with the pace of recruitment so far and the number of potential candidates gives us confidence that we can continue to advance development of Focal One in this indication and, if successful, bring it to market in a timely manner,” added Marc Oczachowski, Chairman and Chief Executive Officer of EDAP TMS.

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.

Company Contact
Blandine Confort
Investor Relations / Legal Affairs
EDAP TMS SA
+33 4 72 15 31 50
bconfort@edap-tms.com

Investor Contact
Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com

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