

EDAP Announces Publication of Focal One® Endometriosis Study in the Journal *Ultrasound in Obstetrics & Gynecology*

Dec 19, 2019

Study confirms feasibility of using Focal One HIFU to treat rectal endometriosis

LYON, France, December 19, 2019 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in therapeutic ultrasound, today announced that Focal One data has been accepted for publication in the journal of *Ultrasound in Obstetrics & Gynecology*. Data from the Phase 1 study confirm the feasibility of using EDAP's Focal One high intensity focused ultrasound (HIFU) technology for the treatment of deep invasive endometriosis (DIE).

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.

Professor Gil Dubernard, Head of the Gynecologic Department, Croix-Rousse University Hospital, Lyon, commented, "Having our publication accepted by this renowned journal is a great recognition of our clinical investigation work on HIFU for the treatment of rectal endometriosis. We are very enthusiastic to be pioneering this non-invasive approach that will change the strategy of treatment for rectal endometriosis by combining great potential of efficacy with fewer side effects. We believe that for a number of patients, HIFU treatment will replace surgery in this indication. We now look forward to initiating the next clinical study to confirm our expectation in terms of efficacy and safety of HIFU for this indication. We are writing a new chapter in the treatment of digestive endometriosis."

Marc Oczachowski, Chief Executive Officer of EDAP, said, "We are very pleased with the acceptance for publication of these data from the endometriosis study utilizing Focal One. This is clearly a great milestone in the ongoing development of our HIFU technology and it is consistent with our vision and strategy to expand our novel therapeutic ultrasound technology into additional indications. The results from this initial study are very promising, and our clinical teams are now focused on commencing the next phase of our clinical investigation in endometriosis to further confirm its safety and efficacy."

About Croix-Rousse University Hospital

Based in Lyon, France, *Hôpital de la Croix-Rousse* is a leading complete care Institution. Among the hospital's many specialties are: infectious and tropical diseases (with a P4 room to isolate very contagious patients), a Level 3 maternity and neonatal resuscitation service and neonatology, orthopedics, hepatic transplant for adults, gynecology and breast care, and cardiology. The hospital employs 3,107 staff members, including 792 physicians.)

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market for 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 may contain 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, regulatory approvals, market acceptance and the continued market potential for our HIFU and lithotripsy devices. 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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