EDAP Announces Positive Results from Phase 2 Study Evaluating Therapeutic High-Intensity Focused Ultrasound (HIFU) for the Treatment of Rectal Endometriosis

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Focal One® HIFU treatment resulted in significant improvements in endometriosis symptoms and quality of life (QoL)

Positive safety profile with 96.7% of patients with no or non-significant adverse events

Data was presented at the Paris Santé Femmes Major Gynecology French Congress on Friday, January 27

Company intends to initiate randomized, double-blind, SHAM-controlled study in 2Q 2023

LYON, France, January 31, 2022 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, today announced positive clinical results from the Endo-HIFU-R1 Phase 2 study evaluating the safety of therapeutic high-Intensity focused ultrasound (HIFU) for the treatment of rectal endometriosis. Results from the study were presented by study coordinator, Pr. Gil Dubernard of Croix Rousse University Hospital (Lyon, France), on Friday, January 27, at the *Paris Santé Femmes French Congress*[1] (Lille, France).

Endo-HIFU-R1 is a Phase 2 study designed to evaluate the safety of HIFU treatment of rectal endometriosis with EDAP's Focal One® Robotic HIFU device. The study enrolled 60 patients across four centers in France between August 2020 and March 2022. Results from the study are based upon a six-month follow-up evaluation post-HIFU treatment.

"These encouraging results validate the safety of Focal One HIFU treatment in this difficult and challenging endometriosis population," said Marc Oczachowski, Chairman and Chief Executive Officer of EDAP TMS. "Positive data from the Endo-HIFU-R1 study represent an important milestone for EDAP and also underscore the potential of Focal One Robotic HIFU as a promising new treatment modality for patients suffering from this debilitating pathology. We would like to thank all of the patients and clinical investigators who participated in this important study. Based on these results, EDAP TMS intends to confirm the efficacy of Focal One HIFU treatment in rectal endometriosis by initiating a randomized, double-blind controlled study in the second quarter of 2023."

"Surgery is typically done to excise or ablate the lesions and surrounding fibrotic tissue in patients with significant rectal endometriosis, which is often associated with post-surgical morbidities, including up to 15% of such patients who will present Clavien 3 complications requiring a second surgical or radiological procedure under anesthesia," said Pr. Gil Dubernard, Study Coordinator of the Endo-HIFU-R1. "Based on the positive safety results from the Endo-HIFU-R1 study, the hyper-accurate mapping of targeted lesions made possible through use of this HIFU-based therapy may represent a viable treatment approach that could lead to decreased post-operative morbidity rates compared to traditional surgical intervention. In addition, according to these encouraging results, we believe that the use of HIFU for the treatment of rectal endometriosis could be considered as an alternative to rectal surgery. In a few months, this mini-invasive approach should be offered in case of failure of hormonal treatment instead of surgery. I look forward to seeing this technology advance further into clinical testing."

Endo-HIFU-1R Study Results

Treatment with Focal One HIFU showed a positive safety profile with 96.7% of patients with no or non-significant adverse events (Clavien 1), 3.3% of treated patients presenting Clavien 2 complications and zero patients presenting Clavien 3 complications. The study also evaluated the effect of HIFU treatment on endometriosis symptoms and Quality of Life (QoL). Results show a significant decrease of the symptoms level (acute pelvic pain, dyspareunia, diarrhea, constipation, rectal bleeding, false urges, tenesmus, rectal spams, posterior pelvic pain and asthenia) from the first post-treatment evaluation (at one month), and the reduction of symptoms was maintained at three and six months following HIFU treatment.

With respect to QoL measurement, a significant improvement was also observed from the first month after HIFU treatment and maintained at three and six months after treatment for almost all evaluated criteria: physical functioning, role limitation due to emotional problems, energy – fatigue, emotional well-being, social functioning, bodily pain, general health, and on physical and mental global score components.

The study also blindly evaluated the evolution of nodule volume via MRI, and a significant reduction of the volume of lesions was observed at six months.

About Endometriosis

Endometriosis is a chronic, progressive disease affecting nearly 10-12% of women of reproductive age. The disease is characterized by tissue resembling the lining of the uterus growing outside the uterine cavity. This extraneous endometrial tissue may commonly occur in the peritoneum or in pelvic and extra-pelvic organs such as the bowels, appendix, bladder, diaphragm muscle and thoracic cavity. The space between the uterus and the rectum, known as the Douglas pouch, is one of the most frequent and symptomatic sites of endometriosis leading to rectal endometriosis.[2]

[1] Paris Santé Femmes is a National Event gathering experts and obstetric surgeons community in France (https://paris-sante-femmes.fr/).

2 Source: https://drseckin.com/rectal-endometriosis/

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. 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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