EDAP Announces FDA Breakthrough Device Designation for Focal One® in the Treatment of Deep Infiltrating Rectal Endometriosis

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Focal One HIFU has potential to address large market impacting thousands of women each year

LYON, France, March 4, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, announced today that its Focal One platform has been granted Breakthrough Device designation by the US Food and Drug Administration (FDA) for the treatment of deep infiltrating endometriosis (DIE). In June 2018, the FDA cleared Focal One Robotic Focal HIFU for the ablation of prostatic tissue.

“Receiving Breakthrough Device designation from the FDA represents a major milestone and reinforces our commitment to expand the use of Focal One Robotic HIFU technology to treat other patient conditions beyond prostate disease,” said Ryan Rhodes, Chief Executive Officer of EDAP TMS. “This designation reflects the FDA’s recognition that deep infiltrating endometriosis remains a significant unmet medical need in women’s health with few treatment alternatives. By expanding our proprietary robotic HIFU technology, we aim to provide women with a safe and effective treatment option that is significantly less invasive and less morbid than conventional surgical approaches.”

By definition, the FDA’s Breakthrough Device designation is granted to products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. This unique program is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review. The Focal One system being granted a Breakthrough Device designation underscores the significance of this innovative development for DIE patients.

Rectal endometriosis induces lesions associated with painful symptoms that can seriously alter quality of life for many women. Focal One HIFU is a non-invasive, robotic ablative procedure using a high-intensity ultrasound probe to deliver tissue devitalization through use of acoustic cavitation and thermal ablation.

In January 2022, EDAP reported positive results from the Phase 2 Endo-HIFU-1R study (N=60) evaluating Focal One HIFU for the treatment of deep infiltrating rectal endometriosis, and this data was included in EDAP’s submission in consideration for receiving Breakthrough Device designation from the FDA. The study evaluated the effect of HIFU treatment on endometriosis symptoms and Quality of Life (QoL). Results showed a significant decrease of the evaluated symptoms (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, noting a significant reduction of the volume of lesions observed at six months. Results from the study also 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.

In February 2024, EDAP announced the completion of enrollment in a Phase 3 study evaluating Focal One HIFU therapy for the treatment of deep infiltrating rectal endometriosis. The ongoing Phase 3 study (NCT05755958) is a comparative, randomized, double blind trial, with the primary objective of evaluating acute pelvic pain levels in 60 patients. Patients enrolled in the study are being followed for three months comparing HIFU treatment to a sham group. The last patient was treated in January 2024. Study results are expected in the second half of 2024.

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.[1]

[1] 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 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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