EDAP Announces Scientific Presentation at 2024 AAGL Global Congress Comparing Focal One HIFU Versus Surgery for the Treatment of Deep Infiltrating Endometriosis

Nov 19, 2024

- *Treatment with robotic HIFU showed reduction in moderate and severe post-operative complications and reduced hospital stay compared to surgery*

LYON, France, November 19, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced a moderated scientific presentation of clinical data comparing Focal One HIFU versus surgery for the treatment of deep infiltrating endometriosis at the 2024 AAGL Global Congress, which took place from November 16-19, 2024, in New Orleans, LA. The presentation was entitled, "Evaluation of rectal endometriosis treatment with high-intensity focused ultrasound versus surgery: a retrospective multicenter study", and was delivered by Professor Gil Dubernard, Head of Gynecology Department at Croix-Rousse University Hospital, Lyon, France, and Principal Investigator.

“The comparative results from these two cohorts demonstrate that, based on its much less invasive treatment approach, robotic HIFU therapy could offer meaningful advantages over surgical intervention both with respect to reducing post-procedure complications, duration of hospital stay and improving overall patient health,” said Professor Dubernard. “I look forward to seeing robotic HIFU technology continue to advance for the treatment of rectal endometriosis, which at present, has very few treatment alternatives other than highly invasive surgical procedures.”

The objective of the study was to compare the management of rectal endometriosis with HIFU and surgery in terms of treatment-related improvements in symptoms and morbidity. The trial was designed as a comparative, retrospective, multicenter study that reviewed treatment outcomes of 120 patients issued from 2 prospective databases. The first cohort comprised 60 consecutive patients from the ENDO-HIFU-R1 Phase 2 study who underwent a High-Intensity Focal Ultrasound (HIFU) treatment of the posterior deep infiltrating endometriosis at 4 different centers. The second cohort was comprised of 60 patients from a large surgical database who had complete surgical excision of their endometriosis lesions, including digestive involvement.

Highlighted Results

- Compared to surgery, patients treated with HIFU therapy for the management of deep infiltrating rectal endometriosis nodules showed encouraging data with respect to health improvement, reduced rate of complications, shorter operating time, and reduction in length of hospital stay.
- Moderate and severe postoperative complications were significantly less frequent after HIFU treatment compared to surgery.
- These findings suggest that HIFU treatment could be an alternative to surgery in select patients with rectal endometriosis.

As previously reported, the Company’s ongoing Phase 3 trial evaluating Focal One HIFU for the treatment of deep infiltrating endometriosis continues per protocol, with more than 85% of the patients initially in the Sham treatment arm having elected to receive HIFU therapy as their symptoms returned back to their high baseline levels. This additional data continues to suggest that HIFU therapy is a safe, non-invasive treatment that has significant potential to reduce pain for women suffering from this debilitating condition. Between now and year-end, the Company expects to communicate with the FDA to discuss this data and the next steps forward for this program.

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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