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Bringing New Horizons to Therapy

EDAP Announces Scientific Presentation Highlighting Feasibility of Focal One® to Perform Non-thermal Histotripsy Energy Delivery at the 187th Acoustical Society of America Meeting

Nov 22, 2024

- *Early feasibility work demonstrates Focal One system's ability to generate histotripsy lesions ex vivo*

LYON, France, November 22, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced a scientific presentation which demonstrated the technical feasibility of performing non-thermal histotripsy energy delivery and generating histotripsy lesions in biological tissues *ex vivo* using the Company's Focal One® Robotic HIFU technology. The results from the study were presented on November 19th at the 187th Acoustical Society of America meeting, which is taking place virtually from November 18 - 22, 2024.

Histotripsy is a non-ionizing, non-thermal and noninvasive technique for [tissue ablation](#) that generates controlled acoustic microcavitation using microsecond ultrasound pulses leading to mechanical tissue destruction.¹ Over the last several years, the technology has been increasingly evaluated for applications in cancer as well as benign conditions.

"The results from this initial technical feasibility study demonstrate EDAP's continued commitment in driving innovation in our core focused ultrasound energy delivery technology," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "As focal therapy continues to evolve for the treatment of multiple conditions, histotripsy represents an expansion in energy-based therapies that we plan to further invest in and develop as part of our innovation roadmap. This technical milestone, in addition to our clinical development of real-time elastography to enable ablation treatment confirmation, demonstrates our commitment towards remaining the innovation leader in focal therapy."

Presentation Details:

- **Conference:** 187th Meeting of Acoustical Society of America
- **Oral Presentation:** November 19, 2024, 5:00 PM ET
- **Presentation Title:** "Feasibility Study of Histotripsy with the Clinical Device Focal One®"
- **Session:** 1pBA, Bubble-Based Therapies
- **Presenter:** Virgil Accary, M.S.

¹ Source: <https://www.sciencedirect.com/topics/medicine-and-dentistry/histotripsy>

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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