EDAP and Avenda Health Launch World's First AI-Assisted Focal One® Robotic HIFU Procedures

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- *First Unfold AI®-Assisted Focal One procedures successfully performed at the UCLA School of Medicine*
- *FDA-cleared Unfold AI enables urologists to provide tailored, patient-specific Robotic HIFU ablation for prostate cancer patients*
- *EDAP and Avenda Health to present Unfold AI-Assisted Focal One simulated procedures at the 2024 Joint Meeting of the Focal Therapy Society & Society of Urologic Robotic Surgeons in Washington, DC September 19-21, 2024*

LYON, France, September 19, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, and Avenda Health ("Avenda"), a leading AI healthcare company, today announced a collaboration agreement for the purpose of offering personalized prostate cancer care, utilizing Avenda's groundbreaking AI technology, Unfold AI, to launch the world's first AI-assisted Focal One robotic high-intensity focused ultrasound (HIFU) procedures.

Avenda Health's Unfold AI is a multimodal AI decision support platform cleared by the U.S. Food and Drug Administration (FDA) that brings "superhuman" abilities to cancer surgeons and oncologists to power the future of cancer care. Unfold AI builds 3D patient-specific cancer maps that reveal invisible tumor extent and enables physicians to avoid leaving cancerous tissue behind while sparing healthy surrounding tissue. By leveraging Unfold AI's planning with the Focal One robotic HIFU platform, EDAP and Avenda believe that urologists can provide a more tailored, patient-specific HIFU ablation procedure for their prostate cancer patients.

"Incorporating AI technology into the diagnostics and treatment planning for patients with prostate cancer enables urologists to more accurately pinpoint the presence of tumor cells," said Wayne G. Brisbane, M.D., Assistant Professor of Urology at The University of California Los Angeles David Geffen School of Medicine. "Having performed the first Focal One procedures utilizing data from Unfold AI, the seamless integration of these two technologies can precisely guide the ablation for optimized oncologic control without damaging healthy surrounding structures, hence minimizing the risk of side effects."

"We are pleased to enter into this collaboration with the Focal One team" said Shyam Natarajan, Ph.D., Chief Executive Officer of Avenda Health. "Unfold AI is a highly complementary technology that when combined with Focal One robotic HIFU, will enable urologists to map cancer effectively so that the entire tumor can be confidently eradicated. This exciting collaboration with Focal One represents a unique opportunity for Avenda to introduce our groundbreaking AI-technology to a broad community of leaders in the field of prostate cancer to further improve outcomes."

"We are excited to announce this unique and important collaboration with the highly talented team at Avenda Health during Prostate Cancer Awareness Month and congratulate Dr. Brisbane on successfully completing the first Unfold-AI assisted Focal One procedures," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "The combination of Avenda's Unfold AI patient-specific cancer map with Focal One's proprietary HIFUsion ® software significantly augments a surgeon's ability to combine existing diagnostic information and deep-learning algorithms to assist the urologist in creating a personalized precise treatment plan. AI-assisted procedures therefore represent an important and strategic next step in the evolution of the Focal One platform that will help us remain at the forefront of delivering the most advanced treatment solutions for patients with prostate cancer."

About Avenda Health
Avenda Health is creating a more personalized future of prostate cancer care. Using deep learning, Avenda Health software maps a patient's cancer in 3D, giving physicians precise information and the confidence to make care decisions. Dedicated to bringing this cutting-edge technology to all practices and physicians treating prostate cancer patients, Avenda Health aims to improve outcomes, preserve quality of life, and create a new standard of cancer care.

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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