EDAP Announces First Pancreatic Cancer Patient Treated with Proprietary HIFU Technology

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AUSTIN, Texas, January 8, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced that the first patient has been treated in a phase I/II PULS Trial sponsored by the Centre Léon Bérard, Lyon, France, evaluating proprietary High Intensity Focused Ultrasound (HIFU) technology for the treatment of pancreatic tumors.

“The initiation of the PULS Trial represents a major milestone in efforts to develop a new and innovative approach for treating this devastating disease with such poor prognosis,” said Professor Aurélien Dupré, MD, PhD, Surgical Oncologist, Centre Léon Bérard, and Principal Investigator of the PULS Trial. “For patients diagnosed with locally advanced pancreatic cancer, the standard treatment is chemotherapy with or without radiotherapy. The low proportion of patients who can benefit from surgery and the scarcity of alternative therapies make the development of new treatments vital and urgent. HIFU has the potential to provide a solution for these patients. This first procedure was performed and completed as planned and the patient was discharged and sent home without complications.”

“We are proud to share this noteworthy achievement as part of our on-going commitment to innovation and improving the lives of patients across a diverse spectrum of disease states,” said Ryan Rhodes, Chief Executive Officer of EDAP. “This first treatment milestone is the result of a strong collaboration between our product and clinical development teams as well as our strategic research and clinical partnerships. This demonstrates our on-going technical and clinical leadership in applying focused ultrasound therapy in areas of significant unmet need.”

The PULS Trial is a phase I/II, multicenter study for patients with locally advanced and unresectable pancreatic tumors. The Phase I aims at evaluating the tolerance of intraoperative High Intensity Focused Ultrasound (HIFU) intervention on the pancreatic lesion. The phase II aims at evaluating the preliminary efficacy of the HIFU intervention.

The five-year survival rate across all stages of pancreatic cancer is 11.5% based on data from 2012-2018. The National Cancer Institute’s projected new cases in the U.S. for 2022 is 62,210 and its projected number of annual deaths is 49,830. Pancreatic cancer still has the lowest rate of early detection and remains the most difficult cancer to treat versus all other major types of cancer. Despite the 5.5% improvement of relative 5-year survival rate compared to a decade ago, pancreatic cancer has become the third leading cause of cancer deaths trailing only lung and colorectal cancers.[1]

[1] Source: https://seenamagowitzfoundation.org/pancreatic-cancer-statistics/

About EDAP TMS SA
A recognized leader in the robotic energy-based therapies, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various conditions using ultrasound technology. By combining the latest technologies in imaging, robotics and precise non-invasive energy delivery, EDAP TMS introduced the Focal One® in Europe and in the U.S. as the leading prostate focal therapy controlled by urologists with the potential to expand to multiple indications beyond prostate cancer. For more information on the Company, please visit www.focalone.com.

HIFU technology addressing pancreatic tumors has been developed in cooperation with LabTAU (*Laboratory of Therapeutic Applications of Ultrasound*) a joint research unit under the academic authorities of Claude Bernard University Lyon 1, INSERM and Centre Léon Bérard.

About the Centre Léon Bérard
The Centre Léon Bérard is a member of the Unicancer network, which brings together 18 French cancer centers and one affiliated facility. It is recognized as a regional, national and international reference center for oncology. Based in Lyon, France's 2nd largest city, the CLB's mission is threefold: care, research and teaching, with the constant aim of improving the quality and accessibility of care for cancer patients. This care comprises patient diagnosis, treatment, care, rehabilitation, screening and prevention, as well as innovation (with teams dedicated to basic, translational and clinical research) and education. The DRCI (Clinical Research and Innovation Department) manages over 200 active clinical trials per year including ~25 trials sponsored by CLB. Actually, the CLB is the 3rd French Cancer Centre in terms of patient recruitment into clinical trials, and 2nd in terms of percentage of active patients included in clinical trials (20%). More than 2 000 patients are enrolled each year in clinical trials. It offers a single site for all diagnostic examinations, treatments and follow-up care during and after the disease. It welcomes over 42,000 patients each year for hospitalization, consultation or examination, and 6,000 new tumors are diagnosed. The Center employs over 2,200 people, including 280 doctors, 600 researchers and 800 caregivers. For more information on the Centre Léon Bérard, please visit: https://www.centreleonberard.fr/en.

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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