



EDAP Announces Publication of Positive Pre-clinical Results Using Intraoperative HIFU Ablation of the Pancreas in the Journal *Cancers*

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Represents first step towards a potential clinical treatment of locally advanced pancreatic cancer

LYON, France, January 13, 2022 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, today announces the publication of positive pre-clinical results using intraoperative high intensity focused ultrasound (HIFU) ablation of the pancreas in the peer-reviewed journal *Cancers*.

The paper, entitled, *Intraoperative HIFU Ablation of the Pancreas Using a Toroidal Transducer in a Porcine Model. The First Step towards a Clinical Treatment of Locally Advanced Pancreatic Cancer*, describes a pre-clinical study designed to assess the feasibility of using HIFU under Doppler guidance to treat the pancreatic parenchyma and tissues surrounding the superior mesenteric vessels *in vivo*, in an animal model.

Pancreatic adenocarcinoma is among the most aggressive of all cancers. Regardless of treatment, the overall 5-year survival rate for patients with locally advanced pancreatic adenocarcinoma ("LAPA") is less than 5%. A HIFU approach could help in the treatment of such pathology that is inaccessible by other known therapeutic methods. Apart from palliative chemotherapy, no other curative options have been proven effective for the treatment of LAPA.

During the study, HIFU treatments were performed using an intraoperative HIFU probe which caused irreversible tissue necrosis in only a few seconds by producing sufficiently strong heat in the focal area. This study is the first step toward the launch of a Phase I study to evaluate the safety and feasibility of such a HIFU approach in patients with LAPA and to further confirm these encouraging results.

"The possibility of treating the pancreas using HIFU holds great promise for the treatment of locally advanced pancreatic cancers. If clinically successful, chemotherapy followed by HIFU treatment could rapidly become a novel treatment option of LAPA," concluded the paper's authors.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "We are very excited with these pre-clinical results and the promise they demonstrate for HIFU as a viable treatment for pancreatic cancer and other severe pathologies with low overall survival rates and no effective treatment options. We are proud of the ongoing work of the EDAP research team, who, together with Inserm and Centre Leon Bérard, are advancing the development of HIFU to offer patients a potentially effective treatment alternative for these difficult to treat cancers."

The full text of the paper can be found [here](#).

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>, and us.hifu-prostate.com.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements. 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 device, as well as the length and severity of the recent COVID-19 outbreak, including its impacts across our businesses on demand for our devices and services. Factors that may cause such a difference also may 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.

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