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Alpha Tau Successfully Treats First Patient in its U.S. Multi-Center Pancreatic Cancer Clinical Trial

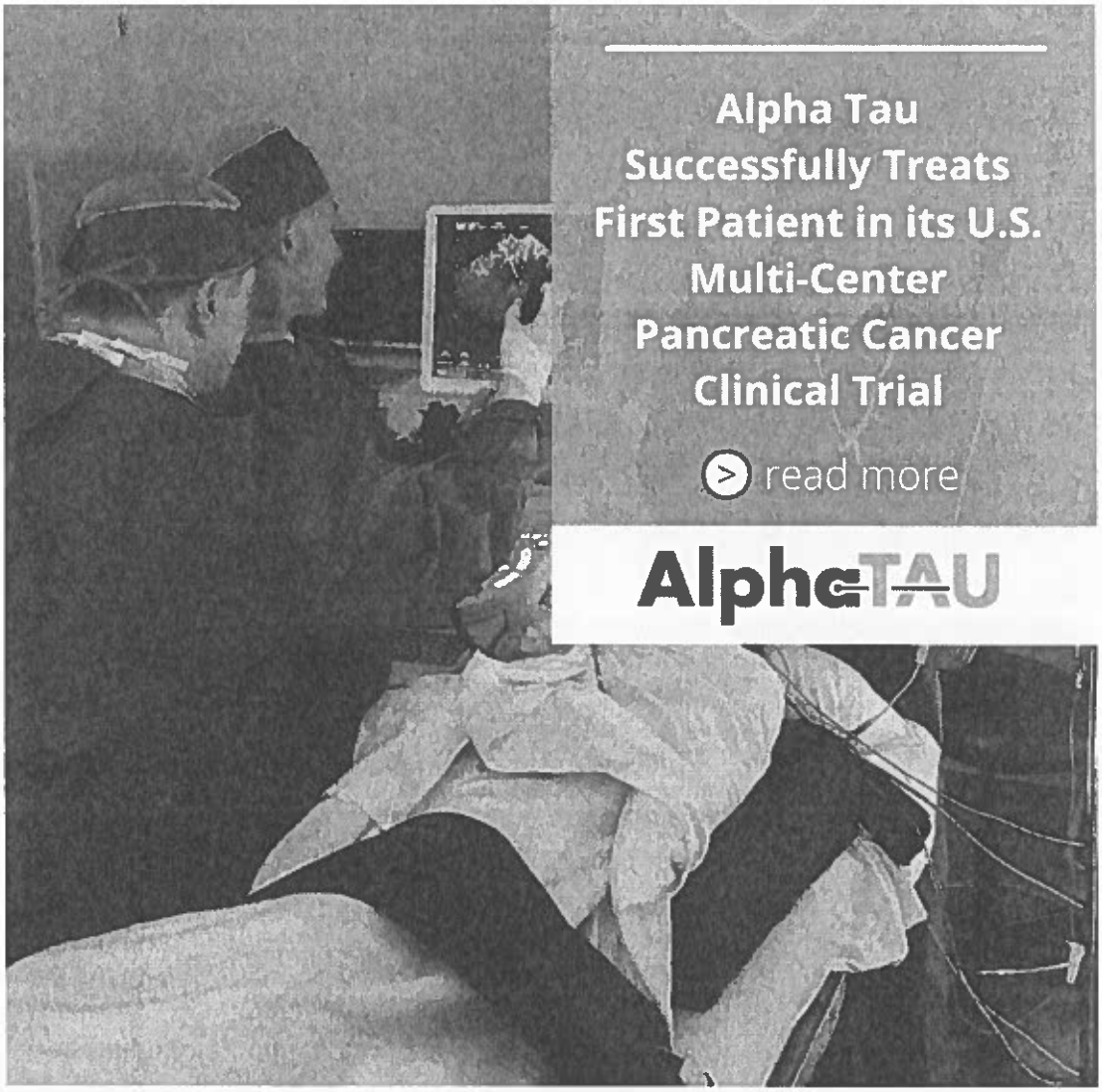
– First patient treatment marks successful initiation of multi-center pilot study in Alpha DaRT U.S. pancreatic cancer program –

– Study explores Alpha DaRT® combined with chemotherapy in patients with newly diagnosed unresectable locally advanced or metastatic pancreatic adenocarcinoma –

– Up to 87% of newly diagnosed pancreatic cancer patients are considered inoperable at diagnosis and face a dismal prognosis, with limited benefit from existing therapies –

– This pilot study is a key part of Alpha Tau's broader strategy to bring Alpha DaRT to cancer patients with some of the highest unmet needs –

JERUSALEM, Sept. 02, 2025 (GLOBE NEWSWIRE) -- Alpha Tau Medical Ltd. (Nasdaq: DRTS, DRTSW) ("Alpha Tau"), the developer of the innovative alpha-radiation cancer therapy Alpha DaRT® today announced that the first patient has been treated in its U.S. multi-center pancreatic cancer pilot study, known as *IMPACT* (Intratumoral Pancreatic Alpha Combination Trial), evaluating the safety, feasibility, and efficacy of Alpha DaRT in combination with chemotherapy for patients with newly diagnosed unresectable locally advanced or metastatic pancreatic adenocarcinoma.



Pancreatic cancer is the third leading cause of cancer-related death in the United States, with approximately 66,000 new cases diagnosed annually. Tragically, up to 87% of these patients are considered inoperable at diagnosis due to either locally advanced disease or distant metastases. These patients face a dismal prognosis, with limited benefit from existing systemic therapies.

Uzi Sofer, CEO of Alpha Tau, stated, "With the vast majority of pancreatic cancer patients deemed inoperable at diagnosis, the need for innovation is urgent. The initiation of the IMPACT trial in the U.S. marks an important step by exploring how Alpha DaRT, with its ultra-high dose and localized alpha radiation, might complement chemotherapy in treating this terrible disease. This pilot study is a key part of our broader strategy to bring Alpha DaRT to cancer patients with some of the highest unmet needs."

The first patient was treated for unresectable pancreatic cancer at the University Cancer Centers in Houston by a multidisciplinary team including the Principal Investigator, Radiation Oncologist Dr. Mark D'Andrea MD FACRO and Gastroenterologist Dr. Isaac Raijman MD.

Dr. D'Andrea noted, "The Alpha DaRT sources are designed to emit powerful alpha particles that travel only a short range in tissue. This is ideal for pancreatic tumors, which are surrounded by critical structures. Its biological effectiveness may offer a new way to achieve local control in a conformal manner in one session, instead of a more lengthy treatment seen with conventional radiation therapy. It also offers the potential for activation of a systemic response of the treatment outside of the initial treated area. This trial gives us the opportunity to further evaluate this novel modality in the treatment of one of the most deadly and challenging cancers we face."

Dr. Raijman added that the "Alpha DaRT sources were delivered into the pancreatic tumor under real-time endoscopic ultrasound guidance, enabling a seamless and accurate delivery through a minimally invasive approach. This non-surgical technique makes it possible to reach deeply located tumors with precision, and with potentially less side effects. This is an exciting time for endoscopists

to explore a new and promising interventional option for the treatment of such a devastating disease."

"This study incorporates a thoughtful design based on our pre-clinical work to explore the integration of Alpha DaRT with chemotherapy in both locally advanced and metastatic pancreatic cancer," commented Dr. Robert Den, MD, Chief Medical Officer of Alpha Tau. "We are focused on generating high-quality clinical data on safety and early efficacy to inform our future development path. Our goal is to eventually offer patients a localized treatment option with the potential to enhance both local control and overall outcomes. This trial builds on Alpha Tau's expanding clinical program aimed at solid tumors with limited local treatment options and aligns with the company's mission to develop curative technologies that deliver alpha radiation precisely where it matters most."

About the IMPACT Study

The IMPACT study aims to enroll up to 30 patients, comprising 15 patients with inoperable locally advanced disease and 15 patients with metastatic disease, across multiple centers in the U.S., Canada and Israel.

Eligible patients must have newly diagnosed, histologically confirmed pancreatic adenocarcinoma and must be inoperable, non-irradiated, and either chemotherapy-naïve or within the first four cycles of their initial chemotherapy regimen. Patients who have undergone prior surgery or received radiation are excluded.

Patients will continue receiving their standard-of-care chemotherapy throughout the study (mFOLFIRINOX), and Alpha DaRT sources will be implanted into the primary tumor using ultrasound-guided endoscopy. Follow-up will continue up to 6 months after enrollment.

The primary objectives of the study are to assess the feasibility of Alpha DaRT source implantation and to evaluate its safety and tolerability, specifically monitoring for Grade 3 or higher adverse events related to the device. Secondary objectives include evaluating local tumor response using RECIST criteria and/or volumetric imaging, measuring time to local progression, monitoring progression-free survival and overall survival, and collecting patient-reported outcomes related to pain control. In addition, patients with inoperable locally advanced disease will be evaluated based on the percentage of patients who become surgically resectable after treatment with Alpha DaRT. Additional information about the IMPACT trial can be found at https://clinicaltrials.gov/study/NCT06698458.

About Alpha Tau Medical Ltd.

Founded in 2016, Alpha Tau is an Israeli oncology therapeutics company that focuses on research, development, and potential commercialization of the Alpha DaRT for the treatment of solid tumors. The technology was initially developed by Prof. Itzhak Kelson and Prof. Yona Keisari from Tel Aviv University.

About Alpha DaRT®

Alpha DaRT (Diffusing Alpha-emitters Radiation Therapy) is designed to enable highly potent and conformal alpha-irradiation of solid tumors by intratumoral delivery of radium-224 impregnated sources. When the radium decays, its short-lived daughters are released from the sources and disperse while emitting high-energy alpha particles with the goal of destroying the tumor. Since the alpha-emitting atoms diffuse only a short distance, Alpha DaRT aims to mainly affect the tumor, and to spare the healthy tissue around it.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. When used herein, words including "anticipate," "being," "will," "plan," "may," "continue," and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, including with respect to clinical trials, the IMPACT study and the safety, feasibility, and efficacy of Alpha DaRT, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Alpha Tau's current expectations and various assumptions. Alpha Tau believes there is a reasonable basis for its expectations and beliefs, but they are inherently