Alpha Tau Announces the Publication of its US Multicenter Pilot Skin Cancer Trial Results in JAMA Network Open

# *The trial demonstrated a 100% Complete Response rate at 12 weeks post treatment and no device-related serious adverse events or systemic toxicity reported in the 10 patients treated in the feasibility and safety study of intratumoral Alpha DaRT for the treatment of recurrent or unresectable skin cancer.*

# *CT scan data at 24 weeks post-treatment showed no evidence of recurrent disease in any of the ten patients, and no long-term toxicities were observed during the course of the study.*

JERUSALEM, May 11, 2023 (GLOBE NEWSWIRE) -- Alpha Tau Medical Ltd. ("Alpha Tau", or the “Company”) (NASDAQ: DRTS, DRTSW), the developer of the innovative alpha-radiation cancer therapy Alpha DaRT™, announced today the publication of the results of its US multicenter pilot trial in JAMA Network Open. The publication, titled “*Feasibility and Safety of Diffusing Alpha-Emitter Radiation Therapy (DaRT) for Recurrent or Unresectable Skin Cancers”*,can be accessed at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2804784>, and was authored by clinicians from Memorial Sloan Kettering Cancer Center in New York, NY, University Cancer Centers in Houston, TX and West Cancer Center in Germantown, TN.

The pilot study was designed to evaluate the feasibility of Alpha DaRT in treating ten subjects with malignant skin and superficial soft tissue tumors. The primary objectives were to explore the feasibility of delivering radiotherapy for malignant skin and superficial soft tissue tumors using Alpha DaRT, with a goal of achieving successful delivery in at least seven of the ten patients, as well as to determine the frequency and severity of acute adverse events. Secondary objectives included assessments of radiotherapy-related adverse events, tumor response, radiation safety, stability of device placement, and quality of life measures. The trial was conducted in multiple sites across the U.S. The results of the trial demonstrated that the treatment was successfully delivered to ten of ten patients, with a 100% CR observed at 12 and 24 weeks, and only mild or moderate device-related side effects reported, and with no device-related systemic toxicity reported.

Alpha Tau CEO Uzi Sofer commented, “The publication of the pilot trial results in JAMA Network Open is a moment of great pride for all of us at Alpha Tau. The trial has met its primary and secondary endpoints in demonstrating feasibility of successful delivery, exceptional efficacy and no serious adverse events or systemic toxicity during the follow-up period. These results reinforce our belief that Alpha DaRT therapy is a novel breakthrough technology with the potential to help many patients that have run out of viable treatment options. We are committed, focused, and moving quickly to enroll eligible patients in our ongoing U.S. pivotal trial, Recurrent SCC Treatment with Alpha DaRT Radiation Therapy (ReSTART), with over 12 clinical sites now open and actively recruiting patients.

Robert Den, MD, Chief Medical Officer at Alpha Tau, added, “We would like to thank all of our trial site investigators, whose excitement for the tremendous potential of the Alpha DaRT helped us recruit patients very quickly. With our Breakthrough Device Designation for the treatment of certain patients with squamous cell carcinoma, we look forward to swift accrual into our U.S. pivotal ReSTART trial, with the goal of bringing the Alpha DaRT closer to availability for patients as quickly as possible."

Christopher A. Barker, MD, Vice-Chair, Clinical Research, Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center in New York City, and lead author of the publication, commented, “We are very pleased with the results of this study. Treatment with Alpha DaRT was associated with high response rates and was very well tolerated, which is an important consideration in this group of patients. Given the promising results of this pilot trial, we look forward to the results of the pivotal ReSTART trial.”

Additional information about the ReSTART trial can be found at [https://clinicaltrials.gov/ct2/show/NCT0532325](https://clinicaltrials.gov/ct2/show/NCT05323253).

**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.

**About Alpha Tau Medical Ltd.**

Founded in 2016, Alpha Tau is an Israeli medical device 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.

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**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, projections, objectives, performance or other characterizations of future events or circumstances, 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 uncertain. Alpha Tau may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation: (i) Alpha Tau's ability to receive regulatory approval for its Alpha DaRT technology or any future products or product candidates; (ii) Alpha Tau's limited operating history; (iii) Alpha Tau's incurrence of significant losses to date; (iv) Alpha Tau's need for additional funding and ability to raise capital when needed; (v) Alpha Tau's limited experience in medical device discovery and development; (vi) Alpha Tau's dependence on the success and commercialization of the Alpha DaRT technology; (vii) the failure of preliminary data from Alpha Tau's clinical studies to predict final study results; (viii) failure of Alpha Tau's early clinical studies or preclinical studies to predict future clinical studies; (ix) Alpha Tau's ability to enroll patients in its clinical trials; (x) undesirable side effects caused by Alpha Tau's Alpha DaRT technology or any future products or product candidates; (xi) Alpha Tau's exposure to patent infringement lawsuits; (xii) Alpha Tau's ability to comply with the extensive regulations applicable to it; (xiii) the ability to meet Nasdaq's listing standards; (xiv) costs related to being a public company; (xv) changes in applicable laws or regulations; and the other important factors discussed under the caption "Risk Factors" in Alpha Tau's annual report filed on form 20-F with the SEC on March 9, 2023, and other filings that Alpha Tau may make with the United States Securities and Exchange Commission. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While Alpha Tau may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing Alpha Tau's views as of any date subsequent to the date of this press release.