Alaunos Therapeutics to Present Early Data from TCR-T Library Phase 1/2 Trial at 2023 American Society of Clinical Oncology Annual Meeting

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- *TCR-T cell therapy shows first-in-human response for non-viral TCR-T therapy; effectively targets high frequency TP53 and KRAS driver mutations across multiple solid tumor indications*
- *Treatment was well tolerated with a manageable safety profile and persistence of TCR-T cells in peripheral blood observed in all three treated patients at last follow-up*
- *Proof-of-concept demonstrated for non-viral* Sleeping Beauty *cell engineering platform in effective manufacturing of TCR-T cell therapies with all products achieving >90% TCR positivity*
- *Data to be presented on Saturday, June 3, at 8:00 a.m. CT*

HOUSTON, May 25, 2023 (GLOBE NEWSWIRE) -- Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") (Nasdaq: TCRT), a leading T-cell receptor (TCR) cell therapy company advancing a clinical-stage pipeline of therapeutics for solid tumors, today announced that the Company will present early translational data from the first three patients treated in its ongoing TCR-T Library Phase 1/2 trial at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 2-6, 2023, at the McCormick Place Convention Center in Chicago.

"Demonstrating our first objective clinical response in solid tumors using non-viral TCR-T cell therapy establishes proof-of-concept of our *Sleeping Beauty* cell engineering platform's potential to generate safe, persistent and effective TCR-T therapies," said Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. "We believe our innovative non-viral approach targeting high-frequency driver mutations is the most promising approach for treating solid tumors. We are encouraged by our ability to manufacture cell products with high viability, purity and TCR positivity that have exhibited persistence and tumor infiltration in patients. We remain confident in the promise of our TCR-T platform to weaponize the immune system and revolutionize the treatment of solid tumors."

The poster will highlight early clinical and translational data on the first three patients with refractory solid tumors expressing *KRAS* or *TP53* mutations who received *Sleeping Beauty* TCR-T cells at one of two dose levels, DL1 (0.9×10^{10} TCR-T cells) and DL2 (6.4×10^{10} TCR-T cells and 5.8×10^{10} TCR-T cells). Manufactured TCR-T cells exhibited greater than 90% TCR positivity, viability and purity, underscoring the ability of the Company's non-viral, universal manufacturing process to create TCR-T cells in multiple indications with different TCRs.

Overall, the TCR-T cell therapy was observed to be well-tolerated and presented a manageable safety profile, with no dose-limiting toxicities or immune effector cell-associated neurotoxicity syndrome observed and only one instance of grade three cytokine release syndrome, which was resolved with administration of tocilizumab.

Anti-tumor activity was seen in two patients, as previously reported, including one patient with non-small cell lung cancer (NSCLC) who achieved partial response with six-month progression-free survival, and one colorectal cancer patient who achieved a best overall response of stable disease at six weeks with three-month progression-free survival. The third patient, a 60-year-old gentleman with advanced, chemotherapy-refractory stage IV pancreatic cancer, experienced progressive disease. TCR persistence and tumor infiltration were observed in patients at last follow-up and out to seven months post-infusion in the NSCLC patient.

Maria Pia Morelli, M.D., Ph.D., Assistant Professor, Department of Gastrointestinal Medical Oncology at The University of Texas MD Anderson Cancer Center and presenter of the poster, added, "TCR-T cell therapy has shown early promise as a potential cancer treatment. There remains a significant unmet medical need for new, patient-specific therapies for people living with difficult-to-treat solid tumor cancers. These early data are encouraging as they showed an objective clinical response and persistence alongside a favorable safety and tolerability profile in patients who have not responded to prior lines of therapy. These data support continued evaluation of driver-mutation reactive TCR-T cells for the treatment of solid tumors, and we look forward to continuing enrollment in the trial."

The data will be presented during a poster session at the 2023 ASCO Annual Meeting on Saturday, June 3, 2023, between 8:00 – 11:00 a.m. CT. The full abstract is now available on the ASCO conference website.

Alaunos expects to provide an interim data update on multiple new patients in the third quarter of 2023 and anticipates establishing a recommended Phase 2 dose by year-end 2023.

About the TCR-T Library Phase 1/2 Trial
The TCR-T Library Phase 1/2 trial is an open-label, dose-escalation trial being conducted at MD Anderson. The trial is actively enrolling patients with NSCLC, colorectal, endometrial, pancreatic, ovarian and bile duct cancers that have a matching human leukocyte antigen (HLA) whose tumors contain at least one of the targeted driver mutations in *KRAS*, *TP53* and *EGFR*. Additional information about the trial is available at www.clinicaltrials.gov using the identifier NCT05194735.

About Alaunos Therapeutics, Inc.
Alaunos Therapeutics is a leader in the science of T-cell receptor (TCR) cell therapy working to revolutionize solid cancer treatment and outcomes. The clinical-stage company's TCR T-cell therapy (TCR-T) is one of the most advanced TCR programs targeting driver mutations in solid tumors with an ongoing Phase 1/2 trial of its TCR-T product candidates across six solid cancers. Alaunos is powered by two proprietary platforms: its elegantly efficient non-viral *Sleeping Beauty* cell engineering platform; and its hunTR® discovery platform, which is expanding its industry-leading library of TCRs against high-frequency driver mutations. Alaunos is a part of an ongoing collaboration with the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), working to advance the science of TCR therapy. For more information, visit www.alaunos.com.

Forward-Looking Statements Disclaimer
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," "believes" or other words or terms of similar meaning. These statements include, but are not limited to, statements regarding the Company's business and strategic plans, the anticipated outcome of preclinical and clinical studies by the Company or its third-party collaborators, the Company's manufacturing capabilities and the timing of the Company's research and development programs, including the expected timeline for enrolling and dosing patients, submitting and receiving approvals on INDs and similar regulatory submissions and the timing and forums for announcing data from the Company's clinical trials. Although the management team of Alaunos believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Alaunos, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, among other things, changes in the Company's operating plans that may impact its cash expenditures; the uncertainties inherent in research and development, future clinical data and analysis, including whether any of Alaunos' product candidates will advance further in the preclinical research or clinical trial process, including receiving clearance from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies to conduct clinical trials and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indication; the strength and enforceability of Alaunos' intellectual property rights; and competition from other pharmaceutical and biotechnology companies; the impacts related to or resulting from recent bank failures and other economic and industry volatility; the potential delisting of the Company's common stock from the Nasdaq Stock Market LLC, as well as risk factors discussed or identified in the public filings with the Securities and Exchange Commission made by Alaunos, including those risks and uncertainties listed in the most recent periodic report filed by Alaunos with the Securities and Exchange Commission. Alaunos is providing this information as of the date of this press release, and Alaunos does not undertake any obligation to update or revise the information contained in this press release whether as a result of new information, future events, or any other reason.

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