Alaunos Therapeutics Announces Early Clinical Data Showing Objective Clinical Response Using its TCR-T Cell Therapy

Sep 06, 2022

- First patient dosed achieved a confirmed objective partial response
- Second patient dosed at second dose level; cleared 28-day safety window
- Data to be presented on Friday, September 30 at 8:30am ET in a proffered presentation at the *CRI-ENCI-AACR Sixth International Cancer Immunotherapy Conference (CICON)*

HOUSTON, Sept. 06, 2022 (GLOBE NEWSWIRE) -- Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company, today announced early clinical findings from its ongoing TCR-T Library Phase 1/2 trial.

"We are excited to announce early findings from our TCR-T Library trial. This is the first time that an objective clinical response has been observed in a solid tumor cancer in connection with non-viral TCR-T cell therapy," said Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. "We believe this reinforces our approach targeting shared tumor-specific hotspot mutations using our non-viral *Sleeping Beauty* technology. We look forward to presenting additional details at the CICON conference on September 30."

The TCR-T Library Phase 1/2 trial is an open label, dose escalation study being conducted at The University of Texas MD Anderson Cancer Center. The trial is enrolling patients with non-small cell lung, colorectal, endometrial, pancreatic, ovarian, and bile duct cancers that have a matching human leukocyte antigen (HLA) and hotspot mutation pairing in Alaunos' TCR library. The first patient dosed was diagnosed with non-small cell lung cancer with a KRAS G12D mutation, matching one of the ten TCRs within the Company's TCR library. The patient received TCR-T cells, which were produced using *Sleeping Beauty* at the Company's in house cGMP manufacturing facility. The patient had a confirmed objective partial response. The Company has dosed a second patient in the study, diagnosed with colon cancer, who has been treated at the second dose level and has cleared the 28-day safety window.

"While cell therapies have demonstrated success in hematological cancers, there remains a significant unmet medical need for effective and cost-efficient cell therapies for patients with solid tumors, which account for nearly 90% of all cancer diagnoses. These early clinical findings show the potential for the first time that we may be able to use a non-viral TCR-T cell therapy to achieve measurable regression in solid tumors," added Marcelo V. Negrao, MD, Department of Thoracic-Head & Neck Medical Oncology, Division of Cancer Medicine at MD Anderson. "We are encouraged by these findings, and we look forward to continuing enrollment in the study."

Data is scheduled to be presented during a proffered talk at CICON, which is being held in New York, NY from September 28 – October 1, 2022.

Details of the presentation are as follows:

Title: Objective clinical response by KRAS mutation-specific TCR-T cell therapy in previously treated advanced Non-small cell lung cancer
Presenter: Marcelo V. Negrao, MD, Department of Thoracic-Head & Neck Medical Oncology, Division of Cancer Medicine at MD Anderson
Date and Time: Friday, September 30, 2022, 8:30am ET
Session Title: Session 6: Cellular Therapies: Engineering T cells

About Alaunos Therapeutics
Alaunos is a clinical-stage oncology-focused cell therapy company, focused on developing T-cell receptor (TCR) therapies based on its proprietary, non-viral *Sleeping Beauty* gene transfer technology and its TCR library targeting shared tumor-specific hotspot mutations in key oncogenic genes including *KRAS*, *TP53* and *EGFR*. The Company has a clinical and strategic collaboration with the National Cancer Institute. For more information, please 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 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 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.

Investor Relations Contact:
Alex Lobo
Stern Investor Relations
alex.lobo@sternir.com