Alaunos Therapeutics Highlights Strategic Priorities and Anticipated Portfolio Milestones for 2023

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- *Announcing addition of two new TCRs to the library, estimated to double the addressable market; plans to further expand TCR library using hunTR® TCR discovery platform*
- *Increasing patient enrollment to advance TCR-T Library Program towards Phase 2 using high value TCRs targeting common hotspot mutations in six solid tumor indications*
- *Executing against multi-pronged strategy to expand and optimize manufacturing capabilities and processes towards commercial scalability*
- *Advancing our mbIL-15 program towards an anticipated IND filing in the second half of 2023*

HOUSTON, Jan. 09, 2023 (GLOBE NEWSWIRE) -- Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company today highlights its expected milestones and strategic priorities for 2023.

"Achieving the first-in-human objective clinical response in a patient with a solid tumor using a non-viral TCR-T cell therapy made for an exciting 2022. We believe we are well positioned to increase the pace of enrollment in 2023 and with the addition of two new TCRs to our library we have doubled the potential addressable market of our therapy," commented Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. "In December we treated our third patient, a pancreatic patient, with a KRAS-G12V mutation. The year ahead will focus on increasing patient enrollment with an aim towards advancing the program to Phase 2 readiness. We are excited about our progress to date and as leaders in the TCR-T cell therapy space we look forward to bringing the promise of our therapies to even more patients in need."

Anticipated 2023 Milestones and Strategic Priorities

Expand TCR library using hunTR® TCR discovery platform to increases addressable market: In the fourth quarter of 2022, the Company submitted an IND amendment to the U.S. Food and Drug Administration (FDA) adding two new TCRs to its clinical trial targeting frequent mutations and HLAs, with the potential to double the addressable market of its TCR-T program. The addition of these new TCRs highlights our strategy to add both more HLAs to existing mutations (KRAS-G12V and HLA-DRB1*07:01) and new mutations within our targeted gene families (TP53-R273C and HLA-DPB1*04:02). In 2023, the Company expects to further expand its library with exclusively owned TCRs targeting recurrent hotspot mutations in *KRAS*, *TP53* and *EGFR*.

Advance TCR-T library program to Phase 2 readiness: The Company continues to actively enroll patients in its TCR-T Library Phase 1/2 trial targeting *KRAS*, *TP53*, and *EGFR* hotspot mutations across six solid tumor indications. In September 2022, the Company announced the first objective clinical response from a TCR-T cell therapy using non-viral *Sleeping Beauty* targeting solid tumors. The Company successfully dosed its third patient in the trial in December 2022 and expects to enroll multiple patients in the first half of 2023. Alaunos anticipates providing an interim data update by mid-2023 as it works towards advancing the program into Phase 2.

Optimize manufacturing process towards commercial scalability: The Company continues to execute on its multi-pronged strategy to expand manufacturing capacity and efficiency. The Company doubled its manufacturing capacity in 2022 allowing for production of two products simultaneously. The Company also filed an IND amendment to move from fresh to cryopreserved product and expects to begin implementing this change in the first half of 2023. The use of cryopreserved cell products will reduce manufacturing process time from 30 days to 26 days, a 13% decrease, while increasing flexibility for patient scheduling and treatment. The Company has ongoing initiatives to optimize the process and further reduce the manufacturing time.

Explore next generation TCR-T cell therapy approaches to deepen clinical responses: The Company is advancing its mbIL-15 TCR-T cell therapy program towards an IND filing anticipated in the second half of 2023. The Company believes mbIL-15 has the potential to increase the survival of TCR-T cells in the harsh tumor microenvironment and deepen clinical responses. In addition, Alaunos continues to conduct translational assessments of treated patients to guide next generation TCR-T therapy approaches including potential combination and multiplexed TCR-T cell therapies.

Cash Position and Financial Guidance

Alaunos ended the fourth quarter of 2022 with unaudited cash and cash equivalents of approximately $39.1 million and restricted cash of approximately $13.9 million. Based on current operating plans, the Company expects its operating cash flow for 2023 to be between approximately $35 million and $40 million. The Company expects to have sufficient cash resources to fund research and development programs and operations into Q4 2023.

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.

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 cash runway and forecast operating cash flow, 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 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