Alaunos Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results

March 7, 2023

- *Generated cutting-edge translational data demonstrating safety, persistence and functionality of infused TCR-T cells in the tumor microenvironment; provides support for next generation TCR-T efforts*
- *Advancing TCR-T Library Program towards Phase 2 readiness with accelerated patient enrollment following proof-of-concept of Sleeping Beauty TCR-T in solid tumors targeting driver mutations*
- *Expanded TCR library with two new TCRs; expect to increase to 15 TCRs using hunTR® TCR discovery platform in 2023*
- *Executing against multi-pronged manufacturing strategy; completed transition from fresh to cryopreserved cell product to increase treatment flexibility and reduce manufacturing process time*
- *Company to host conference call today at 8:30 a.m. ET*

HOUSTON, March 07, 2023 (GLOBE NEWSWIRE) -- Alaunos Therapeutics, Inc. (“Alaunos” or the “Company”) (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company, today announced financial results for the fourth quarter and full year ended December 31, 2022, and provided a corporate update.

“Last year was transformative as we demonstrated leadership in the field of TCR-T cell therapies for solid tumors,” said Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. “Our early clinical data shows exciting proof of concept. As a result, we have seen significant interest from clinicians and patients in our TCR-T Library Phase 1/2 trial. In 2023, we aim to build on this momentum by increasing patient enrollment to generate additional, meaningful clinical data. Through an expansive IND amendment, we have made several critical enhancements to accelerate enrollment, improve manufacturing and expand our TCR Library. We are confident that these amendments will allow us to achieve Phase 2 readiness in 2023.”

Recent Developments and Upcoming Milestones

Actively enrolling patients in TCR-T Library Phase 1/2 trial; expect to report interim data on multiple patients in mid-2023: 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 the fourth quarter of 2022, the Company successfully dosed its third patient in the trial. The Company also made multiple enhancements to the trial IND to increase the patient screening match rate and treatment flexibility. With these enhancements, the Company expects to enroll multiple patients in the months ahead.

Translational assessments provide additional encouraging results and proof-of-concept for *Sleeping Beauty* TCR-T cell therapy: The Company is employing cutting-edge techniques to evaluate persistence, memory, exhaustion and function of infused TCR-T cells from blood and tumor specimens over time in patients treated on the TCR-T Library clinical trial. The Company has observed limited T-cell exhaustion markers such as PD-1 as well as multiple memory subsets of TCR-T cells in circulation, including T memory stem cells, which have been reported to have the greatest proliferative capacity and ability to regenerate more effector T cells. Functional TCR-T cells have been observed infiltrating solid tumors. These encouraging data corroborate clinical data, highlight the promise of TCR-T cell therapy targeting driver mutations and support next generation TCR-T cell efforts underway at the Company.

Expanded TCR library with two new TCRs, doubling potential 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 targeting frequent mutations and HLAs to its library, doubling the addressable market of its TCR-T program. This illustrates the Company’s two-pronged strategy to expand the library by adding more HLAs to the existing mutations with a TCR targeting KRAS-G12V and HLA-DRB1*07:01 and adding new mutations with a TCR targeting TP53-R273C and HLA-DPB1*04:02. In over 700 patients screened at MD Anderson Cancer Center with gastrointestinal or lung tumors, the Company has improved its match rate from 5% to 10%, including roughly one in five patients matching two TCRs in the current library providing a potential opportunity for multiplexed TCR-T cell therapy in the future.

Executing against multi-pronged strategy to optimize manufacturing process and improve treatment flexibility: The Company doubled its manufacturing capacity in 2022, allowing for production of two products simultaneously. In the fourth quarter of 2022 IND amendment, the manufacturing process was enhanced to move from fresh to cryopreserved cell product. The use of cryopreserved cell products has reduced manufacturing process time from 30 days to 26 days, a 13% decrease. This transition also allows for greater flexibility for patient scheduling and treatment and supports the Company’s expected increase in patient accruals in 2023. The Company will continue to execute its multi-pronged strategy to further optimize and reduce manufacturing time.

Expanding application of the hunTR® TCR discovery platform to add additional TCRs to the TCR Library in 2023: In November 2022, the Company presented a poster at the SITC annual meeting, highlighting its proprietary hunTR® (human neoantigen T-cell Receptor) discovery platform.

The poster highlighted the ability of hunTR® to identify neoantigen-reactive TCRs, including shared mutations that could potentially be added to the Company's TCR Library. The Company is working to expand the application of hunTR ® to screen for shared KRAS, TP53 and EGFR mutations to rapidly advance new TCR library candidates from the lab through to clinical translation. Alaunos expects to expand its TCR library to 15 TCRs by the end of 2023.

Completed $15.0 million follow-on public offering of common stock to extend cash runway: In November 2022, Alaunos raised $15.0 million in gross proceeds from a follow-on offering of 24.2 million shares of its common stock in a challenging financing environment for biotechs. Alaunos intends to use the net proceeds from the offering to fund the continued development of the product candidates in its pipeline, and for working capital, capital expenditures and general corporate purposes.

Fourth Quarter Ended December 31, 2022 Financial Results

Research and Development Expenses: Research and development expenses were $5.6 million for the fourth quarter of 2022, compared to $8.2 million for the fourth quarter of 2021, a decrease of approximately 32%. The decrease was primarily due to lower program-related costs of $1.3 million, a $0.9 million decrease in employee-related expenses due to reduced headcount and a $0.4 million decrease in consulting expenses.

General and Administrative Expenses: General and administrative expenses were $2.9 million for the fourth quarter of 2022, compared to $2.1 million for the fourth quarter of 2021, an increase of approximately 40%. The increase was primarily due to higher professional services fees of $0.8 million.

Net Loss: Net loss was $9.2 million, or $(0.04) per share, for the fourth quarter of 2022, compared to a net loss of $11.8 million, or $(0.05) per share, for the same period in 2021.

Cash, Cash Equivalents and Restricted Cash: As of December 31, 2022, Alaunos had approximately $53.0 million in cash balances, which includes restricted cash of approximately $13.9 million. Based on current operating plans, the Company expects its operating outflows, excluding debt service costs, 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 the fourth quarter of 2023.

Full Year 2022 Financial Results

Collaboration Revenue: Collaboration revenue was $2.9 million for the full year ended December 31, 2022, compared to $0.4 million for the full year ended December 31, 2021. The increase in collaboration revenue was primarily due to the achievement of sales-based milestones of darinaparsin in Japan pursuant to a license and collaboration agreement with Solasia Pharma K.K., which was largely offset by a one-time corresponding $2.5 million Research and Development expense.

Research and Development Expenses: Research and development expenses were $25.0 million for the full year ended December 31, 2022, compared to $49.6 million for the full year ended December 31, 2021. The decrease in research and development expenses was primarily due to lower program-related costs of $9.7 million, a $15.5 million decrease in employee-related expenses due to reduced headcount, a $1.4 million decrease in consulting expenses and a $0.5 million decrease in lease expense. These decreases were partially offset by a one-time $2.5 million expense to MD Anderson under the terms of our License Agreement, which was associated with the achievement of sales-based milestones of darinaparsin in Japan.

General and Administrative Expenses: General and administrative expenses were $13.1 million for the full year ended December 31, 2022, compared to $27.6 million for the full year ended December 31, 2021. The decrease in general and administrative expenses was primarily due to lower employee-related expenses of $12.3 million as a result of reduced headcount, a $1.9 million decrease in professional services fees and a $0.2 million decrease in lease expense.

Net loss: Net loss was $37.7 million, or $(0.17) per share for the full year ended December 31, 2022, compared to a net loss of $78.8 million, or $(0.37) per share for the full year ended December 31, 2021.

Conference Call and Webcast

Alaunos will host a conference call and webcast today, March 7, 2023, at 8:30 a.m. ET. Participants may access the live webcast using the link here or by visiting the "Investors" section of the Alaunos website at www.alaunos.com. To participate via telephone, please register in advance at this link. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. The event will be archived on the Company's website for approximately 30 days after the call.

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 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.

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Alaunos Therapeutics, Inc.
Statement of Operations
(In thousands except per share data)

	Three Months Ended December 31 (Unaudited)		Year Ended December 31 (Audited)	
	2022	2021	2022	2021
Collaboration revenue	$ 11	$ -	$ 2,922	$ 398
Operating expenses:				
Research and development	$ 5,607	$ 8,216	$ 25,018	$ 49,643
General and administrative	2,925	2,095	13,142	27,564
Gain on lease modification	-	-	(133)	-
Property and equipment and right-of-use assets impairment	-	740	-	740
Total operating expenses	8,532	11,051	38,027	77,947
Loss from operations	(8,521)	(11,051)	(35,105)	(77,549)
Interest expense	(888)	(745)	(3,154)	(1,189)
Other income (expense), net	250	2	529	(13)
Net loss	(9,159)	(11,794)	(37,730)	(78,751)
Basic and diluted net loss per share	$ (0.04)	$ (0.05)	$ (0.17)	$ (0.37)
Weighted average common shares outstanding, basic and diluted	223,406,148	214,662,338	217,130,311	214,399,074

Alaunos Therapeutics, Inc.
Selected Balance Sheet Data
(In thousands)

	December 31 (Audited)	
	2022	2021
Cash and cash equivalents	$ 39,058	$ 76,054
Restricted cash	$ 13,938	$ -
Working capital, excluding restricted cash	$ 15,695	$ 62,790
Total assets	$ 64,937	$ 94,865
Total stockholders' equity	$ 38,555	$ 58,057