Alaunos Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results

March 30, 2022

- *Phase 1/2 TCR-T Library trial targeting KRAS, TP53 and EGFR mutations across six solid tumor indications; first patient consented and is expected to dose in 2Q 2022*
- *Extended CRADA with the National Cancer Institute focused on evaluating Alaunos' TCR-T Library in a personalized TCR-T program*
- *The Company has successfully identified proprietary TCRs under the hunTR™ platform*

HOUSTON, March 30, 2022 (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, 2021.

"Over the course of 2021 we successfully restructured to refocus Alaunos on advancing our novel TCR-T platform for the treatment of solid tumors," commented Kevin S. Boyle, Sr., Chief Executive Officer. "We are very pleased to announce that we've consented our first patient for treatment in our Phase 1/2 TCR-T Library trial at MD Anderson. We anticipate treating our first patient in the second quarter and will continue to focus in 2022 on generating meaningful clinical data."

James Huang, Chair of Alaunos, stated, "I am very pleased by the transformation of Alaunos over the past six months under Kevin's leadership. As we prepare to enter the clinic, I am confident in his ability to lead the Company through its next phase of development. I believe that now is the right time for me to transition from Executive Chair to Chair of the board. I look forward to our continued collaboration on the board to guide Alaunos towards success."

Recent Developments and Upcoming Milestones

TCR-T Library Clinical Program: In January 2022, the Company announced that its Phase 1/2 TCR-T Library trial targeting KRAS, TP53, and EGFR mutations across six solid tumor indications is open for enrollment. The Company also announced that it had amended the study's investigational new drug (IND) application to include an additional four TCRs, for a total of 10 evaluable TCRs across KRAS, TP53, and EGFR mutations.

The study will be conducted at MD Anderson Cancer Center and will be an open label, dose escalation study, with patients to be treated in one of three dosing cohorts: 5×10^9, 40×10^9, or 10×10^{10} TCR-T cells. The trial will enroll 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. The primary endpoint of the study is to identify the maximum tolerated dose or recommended phase 2 dose. The Company has consented the first patient and expects to dose the first patient in the second quarter of 2022. Additional information about the study is available at www.clinicaltrials.gov using the identifier: NCT05194735.

human neoantigen T-cell Receptor Platform (hunTR™): The Company's robust and innovative TCR discovery engine has successfully identified proprietary TCRs under this platform. With further development and testing, the Company intends to further expand its TCR library with a selected group of these proprietary TCRs.

Filed patent for mbIL-15: In February 2022, the Company filed an international patent application related to its membrane bound IL-15 TCR T cell program, which covers vectors expressing mbIL-15 with TCRs that target hotspot mutations in solid tumors, including KRAS, TP53 and EGFR. The Company plans to showcase new preclinical data from this program at a major scientific conference later this year. The Company intends to file an IND application for this program in 2023.

Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute: In March 2022, the Company announced that it had extended its CRADA with the NCI for the evaluation of its TCR-T cells targeting solid tumors, which was established in January 2017. The agreement has been extended through January 9, 2023 and will focus on evaluating Alaunos' TCR-T Library in a personalized TCR program.

Fourth Quarter Ended December 31, 2021 Financial Results

Research and Development Expenses: Research and development expenses were $8.2 million for the fourth quarter of 2021, compared to $14.0 million for the fourth quarter of 2020, a decrease of approximately 41%. The decrease was primarily due to reduced employee related expenses and lower program-related costs as a result of the winding down of the Company's Controlled IL-12 and CAR-T programs.

General and Administrative Expenses: General and administrative expenses were $2.1 million for the fourth quarter of 2021, compared to $8.8 million for the fourth quarter of 2020, a decrease of approximately 76%. The decrease was primarily due to reduced professional services and employee related expenses.

Net Loss: Net loss was $11.8 million, or $(0.05) per share, for the fourth quarter of 2021, compared to a net loss of $22.8 million, or $(0.11) per share, for the same period in 2020.

Cash and Cash Equivalents: As of December 31, 2021, Alaunos had approximately $76.1 million in cash and cash equivalents. The Company anticipates its cash runway will be sufficient to fund operations into the second quarter of 2023.

Full Year 2021 Financial Results

Research and Development Expenses: Research and development expenses were $49.6 million for the full year ended December 31, 2021, compared to $52.7 million for the full year ended December 31, 2020. The decrease in research and development expenses was primarily due to reduced program-related costs of $9.2 million as a result of the winding down of the Company's Controlled IL-12 and CAR-T programs. The decrease was partially offset by an increase of $4.3 million in employee related expenses, including a $2.2 million severance charge related to the Company's strategic restructuring in the third quarter of 2021, and a $1.8 million increase in facilities and other related expenses primarily related to our expanded facilities in Houston.

General and Administrative Expenses: General and administrative expenses were $27.6 million for the full year ended December 31, 2021, compared to $27.7 million for the full year ended December 31, 2020. The decrease in general and administrative expenses was primarily due to reduced professional services of $4.4 million, partially offset by a $4.3 million increase in employee related expenses, including a $1.3 million severance charge related to the Company's strategic restructuring in the third quarter of 2021.

Net loss: Net loss was $78.8 million, or $(0.37) per share for the full year ended December 31, 2021, compared to a net loss of $80 million, or $(0.38) per share for the full year ended December 31, 2020.

Conference Call and Webcast

Alaunos will host a conference call and webcast today, March 30, 2022 at 8:30am ET. Participants should dial 844-309-0618 (United States) or 661-378-9465 (International) with the conference code 9091406. A live webcast may be accessed using the link here, or by visiting the "Investors" section of the Alaunos website at www.alaunos.com. After the live webcast, the event will be archived on Alaunos' website for approximately 90 days after the call.

About Alaunos Therapeutics, Inc.
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 unique cancer mutation hotspot TCR library, targeting common tumor-related mutations in key oncogenic genes including *KRAS*, *TP53* and *EGFR*. The Company has clinical and strategic collaborations with The University of Texas MD Anderson Cancer Center and 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 Company's cash runway, and the timing of the Company's research and development programs, including the anticipated dates for filing INDs, enrolling and dosing patients in and the expected timing for announcing preclinical data and results 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 Form 10-K 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)	(Audited)
	2021	2020	2021	2020
Collaboration revenue	$ -	$ -	$ 398	$ -
Operating expenses:				
Research and development	$ 8,217	$ 13,971	$ 49,643	$ 52,696
General and administrative	2,090	8,803	27,564	27,665
Property and equipment and right-of-use asset impairment	740	-	740	-
Total operating expenses	11,047	22,774	77,947	80,361

Loss from operations	(11,047)	(22,774)	(77,549)	(80,361)
Other income (expense), net	(744)	2	(1,202)	385
Net loss	(11,791)	(22,772)	(78,751)	(79,976)
Basic and diluted net loss per share	$ (0.05)	$ (0.11)	$ (0.37)	$ (0.38)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	214,662,338	213,028,832	214,399,074	209,636,456

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

	(Audited) 2021	(Audited) 2020
Cash and cash equivalents	$ 76,054	$ 115,069
Working capital	$ 62,790	$ 112,221
Total assets	$ 94,865	$ 146,345
Total stockholders' equity	$ 58,057	$ 123,982