TScan Therapeutics to Present Updated Data from the Ongoing ALLOHA™ Phase 1 Heme Trial During Oral Session at the 66th American Society of Hematology Annual Meeting and Exposition

December 9, 2024

To date, event-free survival strongly favors the treatment arm (HR=0.30; p=0.04), and treatment-arm patients trend towards lower probability of relapse (HR=0.28; p=0.14)

No dose-limiting toxicities observed and infusions of TSC-100 and TSC-101 were well-tolerated across all three dose levels

Company to host virtual KOL event featuring Ran Reshef, M.D., M.Sc., on Tuesday, December 10, 2024, at 8:00 a.m. ET

WALTHAM, Mass., Dec. 09, 2024 (GLOBE NEWSWIRE) -- TScan Therapeutics, Inc. (Nasdaq: TCRX), a clinical-stage biotechnology company focused on the development of T cell receptor (TCR)-engineered T cell (TCR-T) therapies for the treatment of patients with cancer, today announced that updated results from the ongoing ALLOHA™ Phase 1 trial of TSC-100 and TSC-101 will be presented during an oral session at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition. TSC-100 and TSC-101 are designed to treat residual disease and prevent relapse in patients with acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and myelodysplastic syndrome (MDS) undergoing allogeneic hematopoietic cell transplantation (HCT) with reduced intensity conditioning.

“Disease relapse is the leading cause of death in patients undergoing transplant following reduced intensity conditioning and represents a significant unmet medical need,” said Chrystal U. Louis, M.D., Chief Medical Officer. “As the majority of patients enrolled in both the treatment and control arms were considered at very high risk for relapse, we are highly encouraged by the preliminary ALLOHA study results, which suggest that TSC-100 and TSC-101 have the potential to eliminate residual disease and prevent relapse in patients with AML, ALL, or MDS post-HCT.”

“We are very excited by these data and, based on these results, we intend to launch a pivotal trial in the second half of 2025,” said Gavin MacBeath, Ph.D., Chief Executive Officer. “Following recent feedback from the FDA, we believe we have a clear development path and will share our plans at our KOL event tomorrow morning.”

In the ongoing ALLOHA Phase 1 trial (NCT05473910), patients receive either TSC-100 or TSC-101 post-HCT, whereas control-arm patients receive HCT alone as per standard of care. To date, 38 patients have been enrolled in the trial and undergone HCT, with 26 in the treatment arm and 12 in the control arm. The key endpoints in the trial are safety and efficacy, with exploratory endpoints including donor chimerism and minimal residual disease (MRD) status.

Key Presentation Highlights:

- To date, event-free survival strongly favors the treatment arm (HR=0.30; p=0.04) and early trends suggest a lower probability of relapse (HR=0.28; p=0.14).
  - 2 of 26 (8%) treatment-arm patients relapsed compared to 4 of 12 (33%) control-arm patients. One treatment-arm relapse and subsequent mortality occurred in a very high-risk patient who was taken to transplant without first achieving complete remission, and the other was an extramedullary relapse in the patient’s central nervous system with no evidence of systemic relapse.
  - Median time to relapse was not evaluable in the treatment arm versus 160 days in the control arm.
  - 8 of 38 (21%) patients in the study had TP53 mutations, with 6 cases in the treatment arm and 2 cases in the control arm. Of the 4 patients in the treatment arm with these mutations who received TCR-T cell infusions, none has relapsed, and one patient has now been relapse-free for 22 months. Of the 2 patients in the control arm with mutated TP53, both relapsed within 6 months of transplant and died shortly thereafter.
- TSC-100 and TSC-101 infusions were well-tolerated at all three dose levels with no dose-limiting toxicities. Observed adverse events were similar across the treatment and control arms and were generally consistent with post-HCT adverse events.
- TSC-100 and TSC-101 TCR-T cells were detected at all timepoints in all treated patients, including those who have been on study for over a year, with clear evidence of a dose-persistence relationship.

A copy of the presentation materials will be made available on the “Publications” section of the Company’s website at tscan.com once the presentation has concluded.

Virtual Key Opinion Leader (KOL) Event

The Company will host a virtual KOL event featuring Ran Reshef, M.D., M.Sc., on Tuesday, December 10, 2024, at 8:00 a.m. ET to discuss the data presented at ASH, updates with regards to a potential registrational path for the program following its initial meeting with the U.S. Food and Drug Administration, as well as future plans to expand the program, in addition to an update on the Company’s PLEXI-T™ Phase 1 solid tumor trial.

Dr. Reshef is the Professor of Medicine and Director of the Cellular Immunotherapy Program at Columbia University Irving Medical Center. Details for

attending the event can be found here.

About TScan Therapeutics, Inc.

TScan is a clinical-stage biotechnology company focused on the development of T cell receptor (TCR)-engineered T cell (TCR-T) therapies for the treatment of patients with cancer. The Company's lead TCR-T therapy candidates are in development for the treatment of patients with hematologic malignancies to prevent relapse following allogeneic hematopoietic cell transplantation (the ALLOHA™ Phase 1 heme trial). The Company has developed and continues to expand its ImmunoBank, the Company's repository of therapeutic TCRs that recognize diverse targets and are associated with multiple HLA types, to provide customized multiplex TCR-T therapies for patients with a variety of cancers (the PLEXI-T™ Phase 1 solid tumor trial). The Company is currently enrolling patients into both clinical programs.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, express or implied statements regarding the Company's plans, progress, and timing relating to the Company's hematologic malignancies program, including clinical updates of the ALLOHA Phase 1 heme trial, presentation of data, opening of expansion cohorts, and initiation of registrational trials; the Company's plans, progress, and timing relating to the Company's solid tumor program, including, screening, enrolling, and dosing patients, presentation of data, and submission of additional INDs to expand the ImmunoBank; the progress of the hematologic malignancies and solid tumor programs being indicative or predictive of the success of each program; the engagement of CDMO being indicative of successful initiation or support of manufacturing activities or execution of definitive agreements; the Company's current and future research and development plans or expectations; the structure, timing and success of the Company's planned preclinical development, submission of INDs, and clinical trials; the potential benefits of any of the Company's proprietary platforms, multiplexing, or current or future product candidates in treating patients; the Company's ability to fund its operating plan with its existing cash, cash equivalents, and marketable securities; and the Company's goals, strategy and anticipated financial performance. TScan intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as, but not limited to, "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan," "on track," or similar expressions or the negative of those terms. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions, and uncertainties. The express or implied forward-looking statements included in this release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of TScan's TCR-T therapy candidates; TScan's expectations regarding its preclinical studies being predictive of clinical trial results; TScan's recently approved INDs being indicative or predictive of bringing TScan closer to its goal of providing customized TCR-T therapies to treat patients with cancer; the timing of the launch, initiation, progress, expected results and announcements of TScan's preclinical studies, clinical trials and its research and development programs; TScan's ability to enroll patients for its clinical trials within its expected timeline; TScan's plans relating to developing and commercializing its TCR-T therapy candidates, if approved, including sales strategy; estimates of the size of the addressable market for TScan's TCR-T therapy candidates; TScan's manufacturing capabilities and the scalable nature of its manufacturing process; TScan's estimates regarding expenses, future milestone payments and revenue, capital requirements and needs for additional financing; TScan's expectations regarding competition; TScan's anticipated growth strategies; TScan's ability to attract or retain key personnel; TScan's ability to establish and maintain development partnerships and collaborations; TScan's expectations regarding federal, state and foreign regulatory requirements; TScan's ability to obtain and maintain intellectual property protection for its proprietary platform technology and our product candidates; the sufficiency of TScan's existing capital resources to fund its future operating expenses and capital expenditure requirements; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of TScan's most recent Annual Report on Form 10-K and any other filings that TScan has made or may make with the SEC in the future. Any forward-looking statements contained in this release represent TScan's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, TScan explicitly disclaims any obligation to update any forward-looking statements.

Contacts

Heather Savelle
TScan Therapeutics, Inc.
VP, Investor Relations
857-399-9840
hsavelle@tscan.com

Maghan Meyers
Argot Partners
212-600-1902
TScan@argotpartners.com