TScan Therapeutics Presents Preliminary Phase 1 Clinical Results on TSC-100 and TSC-101 at the American Society of Gene & Cell Therapy 26th Annual Meeting

May 17, 2023

Poster highlights Phase 1 results following treatment with TSC-100 and TSC-101 after hematopoietic cell transplantation

Company to host a virtual KOL event featuring Monzr M. Al Malki, M.D., to discuss highlights from the meeting and preliminary data today, Wednesday, May 17th at 5:30 p.m. ET

WALTHAM, Mass., May 17, 2023 (GLOBE NEWSWIRE) -- TScan Therapeutics, Inc. (Nasdaq: TCRX), a clinical-stage biopharmaceutical company focused on the development of T cell receptor (TCR)-engineered T cell therapies (TCR-T) for the treatment of patients with cancer, today announced a poster presentation highlighting preliminary data from the Phase 1 umbrella clinical trial evaluating TSC-100 and TSC-101 targeting minor histocompatibility antigens (MiHA) HA-1 and HA-2, respectively, to treat residual disease and prevent relapse following hematopoietic cell transplantation (HCT) using reduced intensity conditioning (RIC) in patients with acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), or acute lymphocytic leukemia (ALL) at the American Society of Gene & Cell Therapy (ASGCT) 26th Annual Meeting 2023.

TScan has developed two lead TCR-T cell therapy candidates, TSC-100 and TSC-101, that express TCRs targeting MiHAs HA-1 and HA-2, respectively, both presented by HLA-A*02:01. The goal is to select HCT patients who are HA-1 or HA-2 positive, with donors who are mismatched on either the MiHA or HLA-A*02:01. In this context, TSC-100 and TSC-101 are designed to eliminate all recipient hematopoietic cells, including malignant cells, that persist post-transplant, while leaving donor-derived cells unaffected. Both products are being developed in patients with AML, ALL, and MDS undergoing allogeneic haploidentical HCT with RIC, with the goal of preventing disease relapse. Approximately 42% of patients with these diseases relapse within two years of RIC transplant, at which point there are limited treatment options and poor prognosis. The longer-term objective is to enable more patients to maintain prolonged remission after receiving HCT with RIC, which is a more tolerable conditioning regimen than myeloablative conditioning.

“We continue to make meaningful progress in our Phase 1 umbrella trial with preliminary data presented at ASGCT demonstrating notable differences following treatment with both of our TCR-T cell therapy candidates,” said Debora Barton, M.D., Chief Medical Officer. “In a p53-mutated MDS patient who received TSC-101 infusion, we observed T cell expansion between 14 and 21 days post-treatment and observed markers of T cell activation and proliferation. Particularly encouraging, this patient had 100% donor chimerism post-transplant with no detectable patient-derived hematopoietic cells with sensitivity limit of 0.13%, and no dose-limiting toxicities. Our Phase 1 study is rapidly enrolling and TSC-101 is advancing into the second dose level. We are on track to reach the recommended Phase 2 dose for TSC-100 and TSC-101 and report interim clinical data for the program by the end of 2023.”

Gavin MacBeath, Ph.D., acting Chief Executive Officer and Chief Scientific and Operating Officer added: “We are very excited to progress to the second dose level for TSC-101 after seeing encouraging results from the patient at this first dose level. We are hopeful to continue to produce robust clinical outcomes as we progress our Phase 1 trial and remain excited about the potential clinical benefits our engineered T cells may have in difficult-to-treat patient populations.”

The Phase 1 umbrella trial is a multi-arm, i3+3 study evaluating TSC-100, TSC-101, and standard of care HCT alone (control arm) in patients with AML, ALL or MDS. Patients enrolled in Dose Level 1 (DL1) receive either TSC-100 or TSC-101 upon count recovery after HCT at approximately day 21. Patients enrolled in Dose Level 2 (DL2) will receive the same dose of TSC-100 or TSC-101 approximately 21 days post-transplant, followed by a second dose administered 40 days after the initial dose, provided there are no safety issues. The trial design also includes a third dose level (DL3), where the second dose is escalated 4-fold.

Key Poster Highlights:

Phase 1 umbrella clinical trial evaluating TSC-100 and TSC-101 targeting MiHAs HA-1 and HA-2, respectively, to treat residual disease and prevent relapse following HCT using RIC in patients with AML, MDS or ALL

Two control arm patients have been enrolled and received standard of care (SOC) (HCT alone):

- Both control arm patients have medium-risk MDS and experienced incomplete donor chimerism (presence of patient-derived cells) following transplant
- One patient is now in early stages of relapse: after 100 days, patient-derived cells are still observed and increasing

TSC-101 treatment arm (n=1 high-risk MDS with p53 mutation):

- DL1 administered 21 days after transplant
  - Engineered T cells showed expansion between 14-21 days after infusion
  - Detectable markers of activation and proliferation observed
- Twenty-one days after treatment and 42 days after transplant, donor chimerism was at 100% (no detectable patient-derived hematopoietic cells with sensitivity limit of 0.13%)

- Minimal residual disease (MRD) assessment: p53 mutation was not detected post-transplant in bone marrow and peripheral blood samples, with sensitivity limit of 0.01%
- No DLTs observed
- Study advancing to DL2

TSC-100 treatment arm (n=1 T-cell ALL):

- DL1 administered 28 days after transplant
- T cell expansion occurred on Day 7 with detectable markers of T cell activation and proliferation

Two assays are used to detect the action of T cells:

- MRD: SOC assays measuring remaining malignant cells use flow cytometry, which has a sensitivity of ~0.1%
  - High sensitivity assay based on next-generation sequencing (NGS) and droplet digital PCR is also used in this study, with a sensitivity of 0.01%
- Chimerism: SOC STR assays have ~1% sensitivity
  - Study is using the high-sensitivity NGS-based Alloheme assay, with a sensitivity of ~0.13%

A copy of the poster can be accessed on the "Publications" section of the Company's website at www.tscan.com.

Virtual KOL Event

The Company will share highlights from its poster presented at ASGCT, featuring Monzr M. Al Malki, M.D, Associate Profession, Division of Leukemia, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope, on Wednesday, May 17th at 5:30 p.m. ET to discuss the presentation and results from the ongoing Phase 1 study of TSC-100 and TSC-101 to treat residual disease and prevent relapse following HCT using RIC in patients with AML, MDS and ALL. To register for the event, please click here. A replay will be available on the "Events and Presentations" section of the Company's website at ir.tscan.com.

About TScan Therapeutics, Inc.

TScan is a clinical-stage biopharmaceutical company focused on the development of T cell receptor (TCR)-engineered T cell therapies (TCR-T) for the treatment of patients with cancer. The Company's lead TCR-T therapy candidates, TSC-100 and TSC-101, are in development for the treatment of patients with hematologic malignancies to eliminate residual disease and prevent relapse after allogeneic hematopoietic cell transplantation. The Company is also developing multiplexed TCR-T therapy candidates for the treatment of various solid tumors. The Company has developed and continues to build its ImmunoBank, the Company's repository of therapeutic TCRs that recognize diverse targets and are associated with multiple HLA types, to provide customized multiplexed TCR-T therapies for patients with a variety of solid tumors.

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 patient enrollment, reaching recommended Phase 2 dose for TSC-100 and TSC-101, and interim clinical data; the structure, timing and success of the Company's planned preclinical development and clinical trials; the potential benefits of any of the Company's proprietary platforms, multiplexing, or current or future product candidates in treating patients; and the Company's goals, focus, and strategy. 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," "advance," "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 approved INDs and enrollment of patients in its study being indicative or predictive of bringing TScan closer to its goal of providing customized TCR-T therapies to treat patients with cancer; the partnership with Amgen being indicative or predictive of the value of TScan's target discovery platform outside of oncology; the timing of the launch, initiation, progress and expected results and announcements of TScan's preclinical studies, clinical trials and its research and development programs; TScan's timeline regarding its filing of INDs for its TCRs throughout the year, 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.

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