TScan Therapeutics Receives FDA's Regenerative Medicine Advanced Therapy (RMAT) Designation for its Two Lead TCR-T Therapy Candidates for the Treatment of Heme Malignancies

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RMAT designation granted for both TSC-100 and TSC-101 for the treatment of patients with AML, ALL, and MDS undergoing allogeneic HCT with reduced intensity conditioning

WALTHAM, Mass, May 29, 2024 (GLOBE NEWSWIRE) -- TScan Therapeutics, Inc. (Nasdaq: TCRX), a clinical-stage biopharmaceutical 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 the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to TSC-100 and TSC-101, the Company's two lead TCR-T therapy candidates for the treatment of heme malignancies (NCT05473910).

"We are delighted to receive FDA RMAT designation for both candidates in our heme program designed to treat patients with acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and myelodysplastic syndrome (MDS) undergoing allogeneic hematopoietic cell transplantation (HCT) with reduced intensity conditioning, based on encouraging initial data from the ALLOHA trial," said Chrystal U. Louis, M.D., Chief Medical Officer. "This is an important milestone that recognizes the transformative potential of our engineered TCR-T therapy candidates, TSC-100 and TSC-101, in multiple difficult-to-treat cancers. We look forward to working closely with the FDA in our ongoing commitment to deliver life-changing therapies to patients."

Established under the 21st Century Cures Act, RMAT designation is a dedicated program designed to expedite the drug development and review processes for promising pipeline products, including gene and cell therapies. A regenerative medicine therapy is eligible for RMAT designation if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or therapy has the potential to address unmet medical needs for such a disease or condition. Like Breakthrough Therapy designation, RMAT designation provides the benefits of intensive FDA guidance on efficient drug development, including the ability for early interactions with FDA to discuss surrogate or intermediate endpoints, potential ways to support accelerated approval and satisfy post-approval requirements, potential priority review of an Investigational New Drug (IND) application, and other opportunities to expedite development and review.

TScan has developed two lead TCR-T therapy candidates, TSC-100 and TSC-101, that target minor histocompatibility antigens HA-1 and HA-2, respectively. TScan is prospectively selecting HLA A*02:01-positive transplant patients who are either HA-1- or HA-2-positive, with donors who are negative for these antigens. In this context, TSC-100 and TSC-101 are designed to eliminate all recipient hematopoietic cells, including malignant, pre-malignant or normal cells, that persist post-transplant, while leaving donor-derived cells unaffected. Approximately 40% of patients with AML, ALL, and MDS who undergo allogeneic haploidentical HCT with reduced intensity conditioning relapse within two years of transplant, at which point there are limited treatment options and poor prognosis. The goal of this program is to increase the cure-rate for patients receiving HCT.

On May 13, 2024, the Company provided an update on its Phase 1 heme malignancies program. The update included additional follow-up on all eight treatment-arm patients as well as data on two additional control-arm patients. With a median follow-up of >10 months, all eight patients treated with TSC-100 or TSC-101 remain relapse-free with no detectable disease. No dose-limiting toxicities were observed. In contrast, two of eight control-arm patients relapsed approximately six months post-transplant and one of these patients died approximately three months later. A third control-arm patient required clinical intervention because of concerns of impending relapse, and a fourth control-arm patient died post-transplant.

About TScan Therapeutics, Inc.

TScan is a clinical-stage biopharmaceutical 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 candidates, TSC-100 and TSC-101, are in development for the treatment of patients with hematologic malignancies to prevent relapse following allogeneic hematopoietic cell transplantation. The Company is also developing TCR-T candidates for the treatment of various solid tumors. 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 therapeutic TCR-Ts for patients with a variety of cancers.

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 any discussions with regulatory authorities related to TSC-100 and TSC-101 and any expectations regarding the benefits of RMAT designation; the progress of the hematologic malignancies programs being indicative or predictive of the success of such program; 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 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," "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.

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