# TScan Therapeutics Announces FDA Clearance of Investigational New Drug Application for TSC-100 for the Treatment of Hematologic Malignancies

January 24, 2022

*– Phase 1 trial of TSC-100 expected to initiate in the first half of 2022 –*

*– IND for TSC-101 on hold pending additional assessment of the risk of off-tumor reactivity –*

WALTHAM, Mass., Jan. 24, 2022 (GLOBE NEWSWIRE) -- TScan Therapeutics, Inc. (Nasdaq: TCRX), a 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 that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application to evaluate TSC-100 for the treatment of patients with hematologic malignancies who are undergoing allogeneic hematopoietic cell transplantation (HCT). The target of TSC-100 is the minor histocompatibility antigen HA-1, which is a lineage-specific antigen found on blood cells. The Company will now submit the clinical protocol to Institutional Review Boards (IRB) for the initial study sites and expects to begin dosing patients in the first half of 2022.

TSC-101 is targeted to the lineage-specific blood cell antigen HA-2, which is a novel target for cell therapy. The Company received a brief communication from the FDA indicating that the TSC-101 IND has been placed on hold pending additional assessment of the risk of off-tumor reactivity for TSC-101. The Company expects to receive further written communication from the FDA in the near future and plans to work with the agency to resolve its questions as quickly as possible.

“FDA clearance of our IND application for TSC-100 is an important milestone for our lead liquid tumor program as it marks the first clinical-stage product candidate to advance from our pipeline of therapies geared to treat unmet needs in major cancer indications,” said David Southwell, President and Chief Executive Officer. “We are excited about the potential of both TSC-100 and TSC-101 to prevent relapse in leukemia patients following HCT. We are looking forward to initiating our Phase 1 multi-arm clinical trial in the first half of this year, with preliminary data expected in the second half of 2022. We will be opening the TSC-101 arm upon FDA clearance of the TSC-101 IND.”

“FDA clearance of our TSC-100 IND is significant as it allows us to move forward with the umbrella clinical protocol for our hematologic cancer study,” said Gavin MacBeath, Chief Scientific Officer. “This is a great accomplishment for our organization and validation of our TCR discovery platform. Importantly, the INDs for TSC-100 and TSC-101 were based on our proprietary T-Integrate cell engineering platform, which includes our advanced non-viral vector and our in-house GMP manufacturing capabilities. We intend to use this same platform to develop enhanced TCR-T cell therapies for our solid tumor program.”

With the acceptance of the IND for TSC-100 in hematologic malignancies, TScan plans to initiate a multi-arm Phase 1 umbrella trial designed to evaluate TSC-100 compared to standard-of-care in patients who are undergoing allogeneic HCT. Pending acceptance from the FDA regarding the IND for TSC-101, the Company will then initiate the TSC-101 arm of this trial in the same patient population. Primary endpoints include safety and dose-finding, and secondary and exploratory endpoints include relapse rate versus standard-of-care as well as qualitative biological readouts including minimal residual disease and kinetics of donor chimerism. Once the recommended Phase 2 dose has been identified, the study will transition to Phase 2 to assess relapse rates of treated patients versus the standard-of-care arm.

**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 liquid tumor TCR-T therapy candidates, TSC-100 and TSC-101, are in development for the treatment of patients with hematologic malignancies to eliminate residual leukemia and prevent relapse after hematopoietic stem 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 most extensive collection of known and novel solid tumor targets across different HLA types in the TCR field.

**Forward-Looking Statements**

This press release may contain forward-looking statements and information within the meaning of The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as “may,” “will,” “could,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “seeks,” “endeavor,” “potential,” “continue” or the negative of such words or other similar expressions can be used to identify forward-looking statements. The express or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation risks set forth under the caption “Risk Factors” and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of TScan's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although TScan believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither TScan nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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