TScan Therapeutics Announces FDA Clearance of Investigational New Drug Application for TSC-101 for the Treatment of Hematologic Malignancies

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Study start-up activities now ongoing for all three arms of the Phase 1 umbrella trial of TSC-100 and TSC-101

WALTHAM, Mass., May 31, 2022 (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 that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application to evaluate TSC-101 for the treatment of patients with hematologic malignancies who are undergoing allogeneic hematopoietic cell transplantation (HCT). The target of TSC-101 is the minor histocompatibility antigen HA-2, which is a lineage-specific antigen expressed on blood cells. TScan believes that TSC-101 is the first clinical program to target the HA-2 antigen. As previously announced, TScan's IND for TSC-100, which targets the minor histocompatibility antigen HA-1, was cleared by the FDA in January 2022. TSC-100 and TSC-101 are designed to address different subsets of patients undergoing allogeneic HCT.

Study start-up activities are now ongoing for all three arms of TScan's umbrella Phase 1 clinical trial, which includes active treatment arms for TSC-100, TSC-101, as well as a control arm using current standard-of-care for HCT patients. TScan expects to enroll the first patient in the middle of the year.

"This marks TScan's second IND clearance in our leukemia program. Our TCRs against both HA-1 and HA-2 antigens are aimed at reducing the risk of relapse following HCT, thereby enabling increased use of more tolerable conditioning regimens to allow more leukemia patients to be cured by transplantation," said David Southwell, President and Chief Executive Officer. "With the FDA clearance of TSC-101, we will now proceed with all components of our planned multi-arm Phase 1 clinical trial, with preliminary data from all three arms of the trial expected by the end of 2022."

"We look forward to fully opening the Phase 1 umbrella trial for our leukemia program," said Gavin MacBeath, Chief Scientific Officer. "The trial will include patients positive for either the HA-1 or HA-2 antigens, with remaining patients receiving standard-of-care in the control arm. 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 will use this same platform to develop enhanced TCR-T cell therapies for our solid tumor program, with IND filings beginning later this year."

Primary endpoints in TScan's HCT trial include safety and dose-finding, and secondary and exploratory endpoints include relapse rate versus standard-of-care as well as quantitative biological readouts including minimal residual disease and kinetics of donor chimerism.

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 leukemia 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 Company's repository of therapeutic TCRs that recognize diverse targets and are associated with multiple HLA types in order 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 structure, timing and success of the Company's planned clinical trials, the potential benefits of any of the Company's proprietary platforms or current or future product candidates in treating patients, and the Company's goals, strategy, business plans and focus, among other things. 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; the timing of the initiation, progress and expected results of TScan's preclinical studies, clinical trials and its research and development programs; 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 the effect of the COVID-19 pandemic, including mitigation efforts and political, economic, legal and social effects, on any of the foregoing or other aspects of TScan's business or operations; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 12, 2022, and 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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