



TScan Therapeutics Announces FDA Clearance of Investigational New Drug Application for TSC-203-A0201 Targeting PRAME

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TSC-203-A0201 is TScan's fourth TCR-T cell product cleared for use in its solid tumor program, designed to enable customized, multiplexed TCR-T cell therapy

WALTHAM, Mass., Aug. 29, 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 that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application for TSC-203-A0201, a TCR-T targeting PReferentially expressed Antigen in Melanoma (PRAME). In addition to being expressed in ~90% of melanomas, PRAME is also frequently expressed in various other solid tumors, including ~90% of head & neck cancers and ~50% of non-small cell lung cancers. TSC-203-A0201 is specific for patients with HLA type A*02:01, which represents over 40% of people in the U.S. TSC-203-A0201 is the fourth TCR-T cleared for clinical development in the Company's solid tumor program, following TSC-200-A0201, TSC-204-A0201, and TSC-204-C0702, which target human papillomavirus 16 (HPV16) presented on HLA type A*02:01, and MAGE-A1 presented on HLA types A*02:01 and C*07:02, respectively.

All four TCR-T cell products are designed to be used in combination with each other and are being developed under a single master clinical trial protocol. Each agent is an enhanced, autologous T cell therapy product that includes the cancer antigen-specific TCR, along with CD8 α / β to engage helper T cells and a dominant negative form of TGF β receptor II to promote T-cell persistence. Patients are administered specific combinations of TCR-T cell agents based on which targets and HLAs are expressed in their tumors. In the Phase 1 clinical trial, each agent will first be tested singly at two dose levels to establish safety, and then will be eligible to be combined with any other TCR-T cell product.

"We are thrilled to have a multiplexing strategy that allows us to customize treatments tailored to each patient's tumor biology, particularly utilizing targets that are expressed in prevalent cancers such as melanoma, lung, and head and neck cancers," said Debora Barton, M.D., Chief Medical Officer. "More importantly, customizable treatments may be crucial to achieve durable responses, overcome tumor heterogeneity, and resistance that develops from either target or HLA loss, which are commonly observed in these tumor types. A screening protocol to identify eligible patients has already been initiated and clinical trial start-up activities are underway to initiate clinical development for all four TCR-Ts in the ImmunoBank. We are excited about the potential to help patients with these prevalent solid tumors, where a high unmet need for effective treatments remains, and are on-track to treat the first patient with a TScan TCR-T and report preliminary data by the end of 2023."

"TScan continues to make great progress towards our vision of delivering enhanced, multiplexed TCR-Ts to a broad patient population," said Gavin MacBeath, Ph.D., Chief Executive Officer. "The IND clearance of TSC-203-A0201, the fourth TCR-T cell product cleared for our T-Plex solid tumor program, highlights the strength of our discovery platform and the potential of cell therapy to treat patients with a wide variety of solid tumors. PRAME is a particularly important target, as it is very frequently expressed in solid tumors and recent clinical trials targeting PRAME have shown promising results. In parallel, we are increasing our discovery efforts to further expand the number of therapeutic TCRs suitable for clinical development, and we anticipate additional IND filings for our solid tumor program this year and next."

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 solid tumor programs and the presentation of data, 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, 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; 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 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

Joyce Allaire
LifeSci Advisors, LLC
Managing Director
617-435-6602
jallaire@lifesciadvisors.com