TScan Therapeutics Announces FDA Clearance of Investigational New Drug Application for TSC-200-A0201 Targeting HPV16 to Treat Solid Tumors

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TSC-200-A0201 is TScan's third cleared IND for the T-Plex solid tumor program supporting the use of multiple TCRs in combination to deliver customized, multiplexed TCR-T cell therapies based on target and HLA expression

WALTHAM, Mass., June 06, 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-Ts) 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-200-A0201, a TCR-T targeting human papillomavirus 16 (HPV16). TSC-200-A0201 is the third TCR cleared for clinical development in the Company's ImmunoBank following TSC-204-A0201 and TSC-204-C0702, which target MAGE-A1 presented on HLA types A*02:01 and C*07:02, respectively.

T-Plex serves as the primary IND for TScan's solid tumor program, enabling customized combinations of enhanced TCR-Ts to be administered to patients based on the targets and HLAs expressed in their tumors. The specific TCRs for each patient will be chosen from the Company's ImmunoBank, consisting of high-affinity, naturally occurring TCRs that recognize a variety of prevalent cancer-specific targets and are associated with various common HLA types.

TSC-200-A0201 targets HPV16, which is an oncogenic virus that is responsible for approximately 57% of cervical cancers and approximately 21% of head and neck squamous cell carcinomas.

"Our multiplexing strategy is unique in that it allows us to be more inclusive of patients with a variety of tumor types and supports combination therapy, the most successful approach to treating solid tumors," said Debora Barton, M.D., Chief Medical Officer. "We believe that the delivery of customized treatments tailored to each patient's tumor biology is critical for achieving durable responses in patients with solid tumors, by overcoming resistance due to tumor heterogeneity, and target and HLA loss. Clinical trial start-up activities are ongoing, and we anticipate initial data for the most advanced TCRs in this program by the end of this year."

Gavin MacBeath, Ph.D., Chief Executive Officer, continued: "We now have three cleared INDs for TCR-Ts in our T-Plex solid tumor program, representing further progress in our drive to build the ImmunoBank and deliver multiplexed TCR-T to a broad patient population with a high unmet medical need. This IND clearance is further validation of the strength of our discovery platform to identify therapeutic TCRs suitable for clinical development. We are continuing to build our ImmunoBank and anticipate additional IND filings in 2023 and 2024."

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.

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