TScan Therapeutics Announces 2024 Clinical Plans and Highlights Recent Progress

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Reported positive initial data from Phase 1 heme program at the 65th American Society of Hematology (ASH) Annual Meeting

Clearance of INDs for four TCR-Ts, including a TCR-T for PRAME, in support of use of multiple TCRs in combination for the solid tumor clinical trial

Entered a collaboration with Amgen to identify novel targets in Crohn's Disease

Closed underwritten public offering with gross proceeds of $140.6 million, funding operations into 2026

WALTHAM, Mass., Jan. 04, 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 therapies (TCR-T) for the treatment of patients with cancer, today announced its 2024 clinical pipeline plans and highlighted recent corporate achievements.

"2023 was a pivotal year for TScan, most recently marked by the Phase 1 heme malignancies data presented at the ASH Annual Meeting on six treatment arm patients and four control arm patients. We are encouraged to see complete donor chimerism and MRD negativity achieved and maintained in all six treated patients, with a median follow-up of over six months," said Gavin MacBeath, Ph.D., Chief Executive Officer. "Over the course of the year we also continued to build our ImmunoBank for the treatment of solid tumors. We have now cleared INDs for four TCRs, including TCRs for PRAME, HPV16, and MAGE-A1, and have regulatory clearance to treat patients with multiple TCRs sequentially in our Phase 1 study. Additionally, we submitted INDs for two additional TCRs in December and the 30-day review period with the FDA is ongoing. We look forward to dosing the first patient in the Phase 1 solid tumor clinical study in the first quarter and reporting clinical data, initially on patients treated with singleplexed therapy, and then on patients treated with multiplexed therapy, in 2024."

"The data from our heme program presented at ASH is a true testament to the progress we made over the past year. We have now enrolled and dosed patients up to the third and final dose level with no DLTs observed to date and no safety signals thus far, indicating that the third dose level will likely be the recommended Phase 2 dose," added Debora Barton, M.D., Chief Medical Officer. "We plan to activate additional sites and provide clinical updates at major medical meetings throughout the year. Upon establishing the recommended Phase 2 dose, we plan to open expansion cohorts at that dose to further characterize safety and evaluate translational and efficacy endpoints."

2023 Key Achievements and Recent Company Highlights

Heme Malignancies Program: TScan's two lead TCR-T cell therapy candidates, TSC-100 and TSC-101, are designed to treat residual disease and prevent relapse in patients with acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), or myelodysplastic syndromes (MDS) undergoing hematopoietic cell transplantation (HCT) (NCT05473910).

- Recently presented initial Phase 1 clinical results at the 65th American Society of Hematology (ASH) Annual Meeting. Highlights from the poster included:
    - No relapses have occurred in six of six treatment-arm patients, four with follow-up past six months; one of four control-arm patients relapsed at six months and two others required clinical intervention for increasing mixed chimerism.
    - No patient-derived hematopoietic cells were detected in six of six treatment-arm patients, indicating complete elimination of target cells, versus zero of four control-arm patients.
    - An AML patient with detectable disease post-transplant converted to no detectable disease following treatment with TSC-101.
    - Patients were enrolled up to the third and final dose level in both treatment arms with no dose limiting toxicities.

Solid Tumor Program: TScan continues to build the ImmunoBank, a collection of therapeutic TCRs that target different cancer-associated antigens presented on diverse HLA types. TScan's strategy is to treat patients with multiple TCR-Ts sequentially to overcome tumor heterogeneity and prevent resistance that may arise from either target or HLA loss (screening protocol: NCT05812027) (treatment protocol: NCT05973487).

- Continued to build the ImmunoBank with U.S. Food and Drug Administration (FDA) clearance of five investigational new drug applications (INDs):
    - T-Plex IND supports the sequential use of multiple TCRs to deliver customized, multiplexed TCR-T cell therapies based on target and HLA expression.
    - TSC-200-A0201 targets HPV16 on HLA type A*02:01.
    - TSC-203-A0201 targets PReferentially expressed Antigen in MElanoma (PRAME) on HLA type A*02:01.
    - TSC-204-A0201 and TSC-204-C0702 target melanoma-associated antigen 1 (MAGE-A1) on HLA types A*02:01

and C*07:02, respectively.
    - Filed INDs in December 2023 for TSC-201-B0702 targeting melanoma-associated antigen C2 (MAGE-C2) on HLA type B*07:02 and TSC-204-A0101 targeting MAGE-A1 on HLA type A*01:01; 30-day review period ongoing.

- Presented six posters at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting. Notable highlights include TScan's solid tumor Phase 1 trial design supporting a separate screening protocol to identify patients ahead of disease progression, and the disclosure of the previously undisclosed target of TSC-201-B0702 as MAGE-C2.

Corporate and Financial Highlights:

- Appointed Gavin MacBeath, Ph.D., as Chief Executive Officer and as a member of the Board of Directors.
- Appointed Justin McCue, Ph.D., as Chief Technology Officer.
- Appointed Barbara Klencke, M.D., and R. Keith Woods to the Board of Directors.
- Entered into a collaboration with Amgen to identify novel targets in Crohn's Disease. TScan received $30 million upfront and is eligible to earn over $500 million in success-based milestones as well as tiered single-digit royalty payments.
- Closed underwritten public offering with gross proceeds of $140.6 million, funding operations into 2026.
- TScan named as a Top Place to Work for two consecutive years by The Boston Globe.

Upcoming Anticipated Milestones

Heme Malignancies Program:

- Plans to complete Phase 1 dosing and report clinical and translational data in 2024, and two-year relapse data in 2025.
- Plans to open expansion cohorts at the recommended Phase 2 dose level to further characterize safety and evaluate translational and efficacy endpoints.
- Expects to initiate registration trial in 2025.

Solid Tumor Program:

- Initiated Phase 1 solid tumor clinical study and expects to dose the first patient in the first quarter of 2024.
- Expects to report initial multiplexed therapy data for its first combinations of TCR-Ts under T-Plex, as well as response data for singleplex cohorts, in 2024.
- Plans to continue to build ImmunoBank with additional IND filings throughout 2024.
- Long-term duration data for multiplexed therapy anticipated in 2025.

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 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 the completion of Phase 1 dosing, reporting of data, opening expansion cohorts, and initiation of registrational trial; the Company's plans, progress, and timing relating to the Company's solid tumor program, including dosing of patients, reporting of data, and filing of INDs; 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; the Company's beliefs about operating expenses and that it will have capital to fund the Company into 2026; 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 execute on upcoming anticipated milestones into 2026; 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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