UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported) December 9, 2024

TSCAN THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40603**	**82-5282075**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

830 Winter Street **Waltham, Massachusetts**	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (857) 399-9500

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Voting Common Stock, $0.0001 par value per share	TCRX	The Nasdaq Global Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 9, 2024, TScan Therapeutics, Inc. (the "Company") issued a press release regarding updated data from its ongoing ALLOHA™ Phase 1 trial of TSC-100 and TSC-101 to be presented during an oral session at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition. A copy of the press release is furnished as Exhibit 99.1 hereto. The Company also announced a virtual key opinion leader (KOL) event featuring Ran Reshef, M.D., M.Sc., to be held on Tuesday, December 10, 2024, at 8:00 a.m. ET to discuss the data presented at ASH, updates regarding a potential registrational path for the program following its initial meeting with the U.S. Food and Drug Administration, future plans to expand the program, in addition to an update on the Company's PLEXI-T™ Phase 1 solid tumor trial. A copy of the KOL event slide presentation is furnished as Exhibit 99.2 hereto. The presentation will also be available on the investor relations section of the Company's website at https://ir.tscan.com. Information contained on the Company's website is not incorporated by reference into this Current Report on Form 8-K, and you should not consider any information on, or that can be accessed from, the Company's website as part of this Current Report on Form 8-K.

The information under this Item 7.01, including Exhibits 99.1 and 99.2 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing. The Company undertakes no obligation to update, supplement or amend the material attached hereto as Exhibits 99.1 and 99.2.

Item 8.01 Other Events.

Heme Malignancies Program.

Updated Phase 1 Trial Results.

In the ongoing ALLOHA Phase 1 trial (NCT05473910), patients receive either TSC-100 or TSC-101 post-hematopoietic cell transplantation (HCT), whereas control arm patients receive HCT alone as per standard of care. To date, 38 patients have been enrolled in the trial and have undergone HCT, with 26 in the treatment arm and 12 in the control arm. Key endpoints in the trial include safety and efficacy, and exploratory endpoints include donor chimerism and minimal residual disease (MRD) status.

To date, the preliminary results from the ongoing ALLOHA™ Phase 1 trial indicated that TSC-100 and TSC-101 demonstrated the potential to treat residual disease and prevent relapse in patients with acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL) or myelodysplastic syndromes (MDS) undergoing allogeneic hematopoietic cell transplantation (HCT) with reduced intensity conditioning (RIC):

- Event-free survival strongly favors the treatment arm (Hazard Ratio (HR)=0.30; p=0.04) and early trends suggest a lower probability of relapse (HR=0.28; p=0.14).
    - 2 of 26 (8%) treatment-arm patients have relapsed compared to 4 of 12 (33%) control-arm patients.
        - One treatment-arm relapse and subsequent mortality occurred in a high-risk patient who was taken to transplant without first achieving complete remission; and
        - The other treatment-arm relapse was an extramedullary relapse in the patient's central nervous system with no evidence of systemic relapse.
    - Median time to relapse was not evaluable in the treatment arm versus 160 days in the control arm.
    - 8 of 38 (21%) patients in the study had TP53 mutations, with 6 cases in the treatment arm and 2 cases in the control arm. Of the 4 patients in the treatment arm who received TCR-T cell infusions, none has relapsed, and one patient has now been relapse-free for 22 months. Of the 2 patients in the control arm with mutated TP53, both relapsed within 6 months of transplant and died shortly thereafter.

- TSC-100 and TSC-101 infusions across both arms were well-tolerated at all three dose levels with no dose-limiting toxicities. Observed adverse events generally consistent with post-HCT adverse events.
- TSC-100 and TSC-101 TCR-T cells were detected in all treated patients, including all timepoints for those who have been on study for over a year, with clear evidence of a dose-persistence relationship.

Pivotal Study Design.

Through a meeting with the FDA, the Company obtained feedback on the potential registrational pathway following the Phase 1 ALLOHA trial. Based on this feedback, the Company believes that for a registrational trial: (1) the following proposed patient population is acceptable: AML, MDS, and ALL undergoing allo-HCT with RIC, (2) relapse-free survival (RFS) will be an appropriate primary endpoint to support full approval and (3) use of an external control arm using data from Center for International Blood and Marrow Transplant Research (CIBMTR) will be acceptable to support full approval. The Company has decided to pursue an initial registrational path for TSC-101 as it captures almost all HLA-A*02:01-positive patients, and accordingly the Company believes that it is not necessary to include TSC-100 or a companion diagnostic in its upcoming trial. Subject to any further feedback from regulatory authorities or updates to streamline trial execution, the Company expects that the design of a potential registrational trial, which it anticipates launching in the second half of 2025, will include the following elements:

- Subjects: Patients with AML, MDS, ALL undergoing transplant with RIC.
- Donors: Haploidentical and mismatched unrelated donors.
- Enrollment: TSC-101 vs matched controls (1:3)
- Primary endpoint: Relapse-free survival
- Key secondary endpoint: Overall survival, time to relapse and event-free survival
- Exploratory endpoint: Minimal residual disease, complete chimerism rates
- Full approval: the study is designed with a HR of 0.60, 85% power and approximately 140 subjects in the treatment arm. The primary endpoint requires 184 total relapse and death events to assess efficacy
- Study readout: anticipated in approximately 24 months.

Next Steps.

The Company currently intends to focus on the following next steps for its heme malignancies program: (1) continue to enroll ALLOHA Phase 1 study using commercial manufacturing process at the Company, (2) transfer commercial process to a third-party contract development and manufacturing organization (CDMO), (3) work to reach final agreement with FDA on its pivotal trial design and (4) initiate registrational trial with clinical supply manufactured at CDMO.

Market Opportunity.

The Company believes that if there is an increased use of reduced intensity conditioning with haploidentical donors and mismatched unrelated donors it would have the potential to expand the addressable market of its TCR-T therapy candidates, both in the United States and in Europe. The positive data from the Company's ALLOHA trial could potentially accelerate such changes in clinical practice and increase the total addressable market. The Company believes that the addressable market can also be expanded with the introduction of additional TCR-Ts that target other HLA types. TCRs for additional HLA types will target epitopes on CD45, a universal source of antigens for heme malignancies.

Solid Tumor Program.

TScan is building and expanding the ImmunoBank of T cell receptors (TCRs) to enable enhanced, multiplex TCR-engineered T cell (TCR-T) therapy, which is designed to address the heterogeneity of solid tumors:

- The solid tumor program will focus on immune-rich cancers with high unmet need, with T-Plex enrollment focusing on the following key indications: non-small cell lung cancer (NSCLC), sarcoma, head and neck cancer, and cervical cancer, and anal cancer.

- To date, eight patients have been infused with singleplex TCR-T.
- Early evidence of anti-tumor activity was observed.
- One TCR-T (TSC-203-A0201, which targets PRAME) has advanced through dose level 2 and is now eligible for T-Plex. A second TCR-T (TSC-200-A0201, which targets HPV16) is anticipated to clear dose level 2 before mid-December and will soon be eligible for T-Plex.
- TScan has successfully manufactured its first T-Plex product.
- TScan is progressing multiple TCRs through early does levels, which is expected to enable TScan to investigate multiplexed therapy in 2025.
- Investigational new drug filing for a TCR targeting MAGE-A4 on HLA-A*02:01 (TSC-202-A0201) was submitted, which if cleared is expected to increase T-Plex eligibility.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press release, dated December 9, 2024
99.2	Presentation, dated December 10, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that are based on the Company's beliefs and assumptions and on information currently available to the Company on the date of this Current Report. These forward-looking statements involve substantial risks and uncertainties. Any statements in this Current Report on Form 8-K other than statements of historical fact, including statements about the Company's future expectations, plans and prospects, constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's financial and operating results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements, including the factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that the Company files with the Securities and Exchange Commission. Any forward-looking statements represent the Company's views only as of the date of this Current Report on Form 8-K. The Company anticipates that subsequent events and developments may cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law even if new information becomes available in the future.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TScan Therapeutics, Inc.

Date: December 10, 2024

By: /s/ Gavin MacBeath
Gavin MacBeath
Chief Executive Officer

TScan Therapeutics to Present Updated Data from the Ongoing ALLOHA™ Phase 1 Heme Trial During Oral Session at the 66th American Society of Hematology Annual Meeting and Exposition

To date, event-free survival strongly favors the treatment arm (HR=0.30; p=0.04), and treatment-arm patients trend towards lower probability of relapse (HR=0.28; p=0.14)

No dose-limiting toxicities observed and infusions of TSC-100 and TSC-101 were well-tolerated across all three dose levels

Company to host virtual KOL event featuring Ran Reshef, M.D., M.Sc., on Tuesday, December 10, 2024, at 8:00 a.m. ET

WALTHAM, Mass., Dec. 9, 2024 — TScan Therapeutics, Inc. (Nasdaq: TCRX), a clinical-stage biotechnology company focused on the development of T cell receptor (TCR)-engineered T cell (TCR-T) therapies for the treatment of patients with cancer, today announced that updated results from the ongoing ALLOHA™ Phase 1 trial of TSC-100 and TSC-101 will be presented during an oral session at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition. TSC-100 and TSC-101 are designed to treat residual disease and prevent relapse in patients with acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and myelodysplastic syndrome (MDS) undergoing allogeneic hematopoietic cell transplantation (HCT) with reduced intensity conditioning.

“Disease relapse is the leading cause of death in patients undergoing transplant following reduced intensity conditioning and represents a significant unmet medical need,” said Chrystal U. Louis, M.D., Chief Medical Officer. “As the majority of patients enrolled in both the treatment and control arms were considered at very high risk for relapse, we are highly encouraged by the preliminary ALLOHA study results, which suggest that TSC-100 and TSC-101 have the potential to eliminate residual disease and prevent relapse in patients with AML, ALL, or MDS post-HCT.”

“We are very excited by these data and, based on these results, we intend to launch a pivotal trial in the second half of 2025,” said Gavin MacBeath, Ph.D., Chief Executive Officer. “Following recent feedback from the FDA, we believe we have a clear development path and will share our plans at our KOL event tomorrow morning.”

In the ongoing ALLOHA Phase 1 trial (NCT05473910), patients receive either TSC-100 or TSC-101 post-HCT, whereas control-arm patients receive HCT alone as per standard of care. To date, 38 patients have been enrolled in the trial and undergone HCT, with 26 in the treatment arm and 12 in the control arm. The key endpoints in the trial are safety and efficacy, with exploratory endpoints including donor chimerism and minimal residual disease (MRD) status.

Key Presentation Highlights:

- To date, event-free survival strongly favors the treatment arm (HR=0.30; p=0.04) and early trends suggest a lower probability of relapse (HR=0.28; p=0.14).
    - 2 of 26 (8%) treatment-arm patients relapsed compared to 4 of 12 (33%) control-arm patients. One treatment-arm relapse and subsequent mortality occurred in a very high-risk patient who was taken to transplant without first achieving complete remission, and the other was an extramedullary relapse in the patient’s central nervous system with no evidence of systemic relapse.
    - Median time to relapse was not evaluable in the treatment arm versus 160 days in the control arm.
    - 8 of 38 (21%) patients in the study had TP53 mutations, with 6 cases in the treatment arm and 2 cases in the control arm. Of the 4 patients in the treatment arm with these mutations who received TCR-T cell infusions, none has relapsed, and one patient has now been relapse-free for 22 months. Of the 2 patients in the control arm with mutated TP53, both relapsed within 6 months of transplant and died shortly thereafter.

- TSC-100 and TSC-101 infusions were well-tolerated at all three dose levels with no dose-limiting toxicities. Observed adverse events were similar across the treatment and control arms and were generally consistent with post-HCT adverse events.
- TSC-100 and TSC-101 TCR-T cells were detected at all timepoints in all treated patients, including those who have been on study for over a year, with clear evidence of a dose-persistence relationship.

A copy of the presentation materials will be made available on the "Publications" section of the Company's website at tscan.com once the presentation has concluded.

Virtual Key Opinion Leader (KOL) Event

The Company will host a virtual KOL event featuring Ran Reshef, M.D., M.Sc., on Tuesday, December 10, 2024, at 8:00 a.m. ET to discuss the data presented at ASH, updates with regards to a potential registrational path for the program following its initial meeting with the U.S. Food and Drug Administration, as well as future plans to expand the program, in addition to an update on the Company's PLEXI-T™ Phase 1 solid tumor trial.

Dr. Reshef is the Professor of Medicine and Director of the Cellular Immunotherapy Program at Columbia University Irving Medical Center. Details for attending the event can be found here.

About TScan Therapeutics, Inc.

TScan is a clinical-stage biotechnology company focused on the development of T cell receptor (TCR)-engineered T cell (TCR-T) therapies for the treatment of patients with cancer. The Company's lead TCR-T therapy candidates are in development for the treatment of patients with hematologic malignancies to prevent relapse following allogeneic hematopoietic cell transplantation (the ALLOHA™ Phase 1 heme trial). The Company has developed and continues to expand its ImmunoBank, the Company's repository of therapeutic TCRs that recognize diverse targets and are associated with multiple HLA types, to provide customized multiplex TCR-T therapies for patients with a variety of cancers (the PLEXI-T™ Phase 1 solid tumor trial). The Company is currently enrolling patients into both clinical programs.

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 clinical updates of the ALLOHA Phase 1 heme trial, presentation of data, opening of expansion cohorts, and initiation of registrational trials; the Company's plans, progress, and timing relating to the Company's solid tumor program, including, screening,

enrolling, and dosing patients, presentation of data, and submission of additional INDs to expand the ImmunoBank; the progress of the hematologic malignancies and solid tumor programs being indicative or predictive of the success of each program; the engagement of CDMO being indicative of successful initiation or support of manufacturing activities or execution of definitive agreements; 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 ability to fund its operating plan with its existing cash, cash equivalents, and marketable securities; and the Company's goals, strategy and anticipated financial performance. 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; TScan's recently approved INDs being indicative or predictive of bringing TScan closer to its goal of providing customized TCR-T therapies to treat patients with cancer; the timing of the launch, initiation, progress, expected results and announcements of TScan's preclinical studies, clinical trials and its research and development programs; TScan's ability to enroll patients for its clinical trials within its expected timeline; 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 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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Exhibit 99.2

KOL Event

December 10, 2024

TSCAN THERAPEUTICS

Disclaimers and forward-looking statements

This presentation and the accompanying discussion contain 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 Tscan Therapeutics, Inc. (the "Company" or "TScan")'s plans, progress, and timing relating to the Company's hematologic malignancies programs, 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 presentation 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 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, subsequent Quarterly Reports on Form 10-Q and any other filings that TScan has made or may make with the SEC in the future.

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TSCAN THERAPEUTICS

Agenda

- Ran Reshef, M.D., M.Sc., Director of Translational Research, Blood and Marrow Transplantation Program, Columbia University Irving Medical Center
  - Results from ALLOHA™ Phase 1 trial study of TSC-100 and TSC-101 in patients with acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and myelodysplastic syndrome (MDS)
- Gavin MacBeath, Ph.D., Chief Executive Officer
  - Pivotal trial design and heme development strategy
  - Market opportunity
  - Expansion opportunities
- Q&A
- Solid tumor program update and strategy for 2025
- Q&A

TSCAN THERAPEUTICS

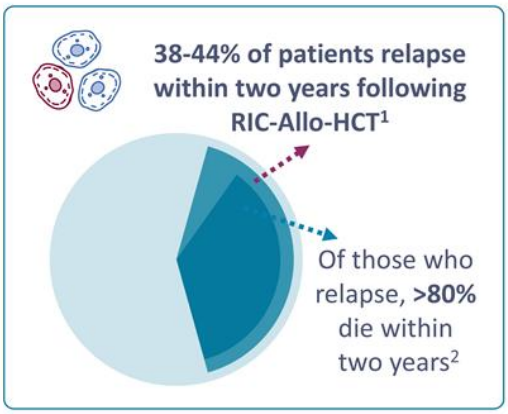
TSC-100 and TSC-101 Demonstrate the Potential to Reduce Relapse Rates and Increase Relapse-free Survival in Patients with AML, ALL, or MDS Undergoing Allogeneic HCT with Reduced Intensity Conditioning (RIC): Preliminary Results from the Phase 1 ALLOHA Trial

Monzr M. Al Malki, MD[1], Alla Keyzner, MD[2], Uday Popat, MD[3], Yi-Bin Chen, MD, MS[4],Hyung C Suh, MD, PhD[5], Tania Jain, MD[6], Melhem M. Solh, MD[7], Anson Snow, MD[8], Saar Gill, MD, PhD[9], Lohith Gowda, MD[10], Joseph Uberti, MD, PhD[11], Erica Buonomo, PhD[12], Yun Wang, PhD[12], Nancy Nabilsi, PhD[12], Timothy White[12], Cuong Nguyen[13], Jim Murray[12], Gavin MacBeath, PhD[12], Chrystal Louis, MD, MPH[12], Shrikanta Chattopadhyay, MD[12], Michelle Matzko, MD, PhD[12] and Ran Reshef, MD, MSc[14]

(1)City of Hope, Duarte, CA, (2)Icahn School of Medicine at Mount Sinai, New York, NY, (3)MD Anderson Cancer Center, Houston, TX, (4)Massachusetts General Hospital, Boston, MA, (5)John Theurer Cancer Center, Hackensack University Medical Center, Hackensack, NJ, (6)Johns Hopkins University, Baltimore, MD, (7)Northside Hospital Cancer Institute, Atlanta, GA, (8)Lineberger Comprehensive Cancer Center, University of Carolina at Chapel Hill, Chapel Hill, NC, (9)Abramson Cancer Center and Hospital of the University of Pennsylvania, Philadelphia, PA, (10)Yale Cancer Center and Yale School of Medicine, New Haven, CT, (11)Karmanos Cancer Center/ Wayne State University, Detroit, MI, (12)TScan Therapeutics, Waltham, MA, (13)Biostatistical Consulting, Lexington, MA, (14)Herbert Irving Comprehensive Cancer Center, Columbia University, New York, NY

Relapse after hematopoietic cell transplant remains an unmet need

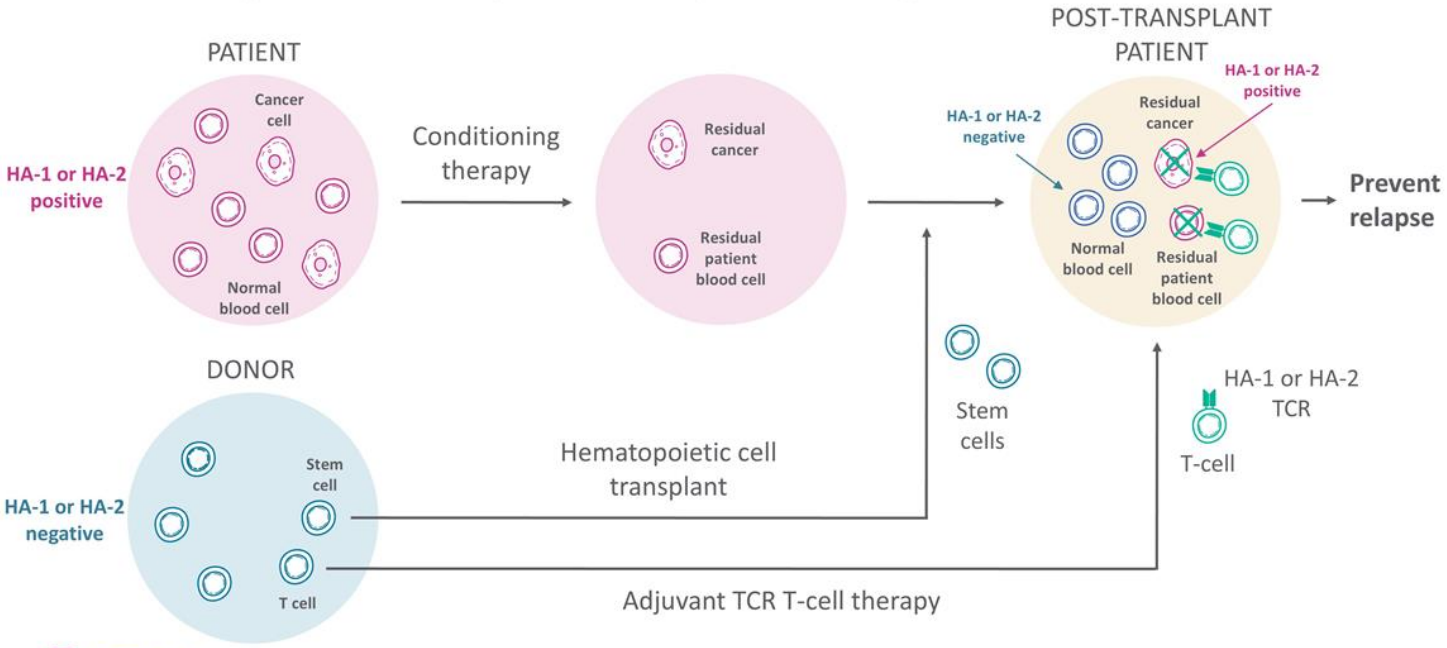
- Allogeneic hematopoietic cell transplantation (HCT) can cure some patients with AML, ALL or MDS
- Advances in reduced intensity conditioning (RIC-HCT) regimens as well as GvHD prophylaxis with post-transplant cyclophosphamide (PTCy) have expanded patient access to HCT by markedly improving treatment-related morbidity and mortality
- However, **relapse remains the leading cause of death post-HCT** and is therefore a significant unmet medical need
- TSC-100 and TSC-101 are donor-derived engineered TCR-T cells designed to selectively eliminate any residual patient-derived hematopoietic cells after HCT by targeting the hematopoietically-restricted antigens HA-1 and HA-2, respectively
- The ALLOHA Study (TSCAN-001, NCT05473910) is a Phase 1, multi-center, biologically controlled study evaluating TSC-100 in HA-1 and TSC-101 in HA-2 positive adult patients with AML, ALL, or MDS undergoing RIC-HCT



TSCAN THERAPEUTICS

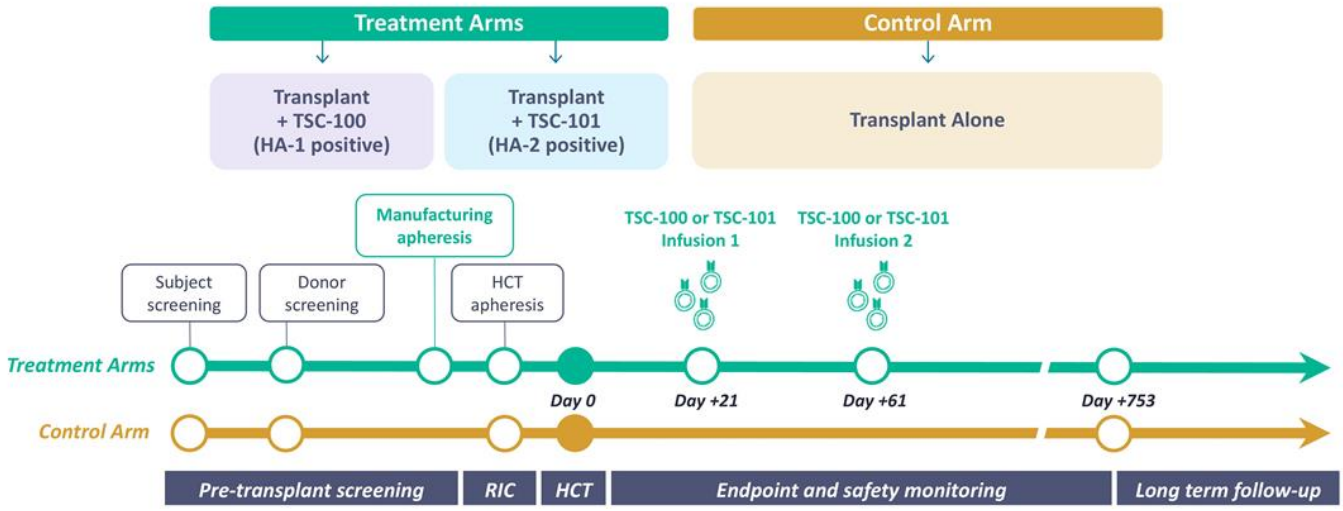
1. CIBMTR analysis of AML, ALL, MDS allogeneic transplants with reduced intensity conditioning (RIC) between 2017-2019 with 2-year follow-up
2. Schmid, Blood 2012, Spyridonidis, Leukemia 2012, Schmid, Haematologica 2018

TSC-100 and TSC-101 are adjuvant engineered TCR-T cells designed to eliminate residual recipient cells and prevent relapse following HCT



TSCAN THERAPEUTICS

Multi-arm Phase 1 trial for TSC-100 & TSC-101 in subjects with AML, ALL, and MDS



Key eligibility criteria

- Age ≥18 years
- Undergoing first allo-HCT for ALL, AML, MDS
- Subject positive for HA-1 (or HA-2) with a haploidentical HA-1 (or HA-2) negative donor
- Eligible for RIC-HCT followed by PTCy for GvHD prophylaxis

Key endpoints

- Safety: Dose limiting toxicities, adverse events
- Efficacy
- Exploratory endpoints: Donor chimerism, minimal residual disease

TSCAN THERAPEUTICS

ALL, acute lymphoblastic leukemia; AML, acute myeloid leukemia; MDS, myelodysplastic syndromes; GvHD, graft vs host disease; RIC-HCT, reduced intensity conditioning hematopoietic cell transplantation

Majority of subjects in the treatment and control arms are at high risk for relapse

		TSC-100	TSC-101	Any TSC	Control
Subjects Enrolled and assigned		14	12	26	13
Subjects Transplanted (efficacy data cohort)		14	12	26	12
Subjects Infused (safety data cohort)		10	12	22	N/A*
Median Time of Follow Up, months		4.0 (0-19)	6.4 (1-21)	5.1 (0-21)	7.1 (1-25)
Age, Median (Range)		69 (39-76)	66 (52-74)	67 (39-76)	66 (23-74)
Sex, Male (n, %)		10 (71%)	7 (58%)	17 (65%)	6 (46%)
Underlying Disease	ALL	2	2	4	0
	AML	10	7	17	8
	MDS	2	3	5	5
Genetics/ cytogenetics	**TP53 mutated**	**4**	**2**	**6**	**2**
	FLT3 mutation	2	0	2	5
	Adverse Risk**	11	10	21	8
Pre-HCT MRD Positive		8	5	13	7
MRD positive or adverse risk genetics		11/14	10/12	21/26	10/13

*Control subjects that received transplant are included in the safety data cohort

**Adverse risk is defined as having either a IPSS-M mutation if the subject has MDS or European Leukemia Network (ELN) high risk genetics or cytogenetics for AML; ELN 2022 high risk genetics/ cytogenetics include mutated ASXL1, BCOR, EZH2, RUNX1, SF3B1, SRSF2, STAG2, U2AF1, ZRSR2, TP53, -5/ del(5q)/, -7,-17/ abn(17p), t(6;9), t(v;11q23.3), t(9;22), t(8;16), inv(3) or t(3;3), t(3q26.2;v), monosomal or complex karyotype (for AML); IPSS-M mutations are reported in Bernard et al, NEJM Evid, 2022 (for MDS)

***MRD measured by flow cytometry (lower limit of detection 0.1-1%) or NGS (lower limit of detection 0.05-0.1% in myeloid and 0.001-0.01% in lymphoid malignancies).

TSCAN THERAPEUTICS

As of Nov 20, 2024 data cut

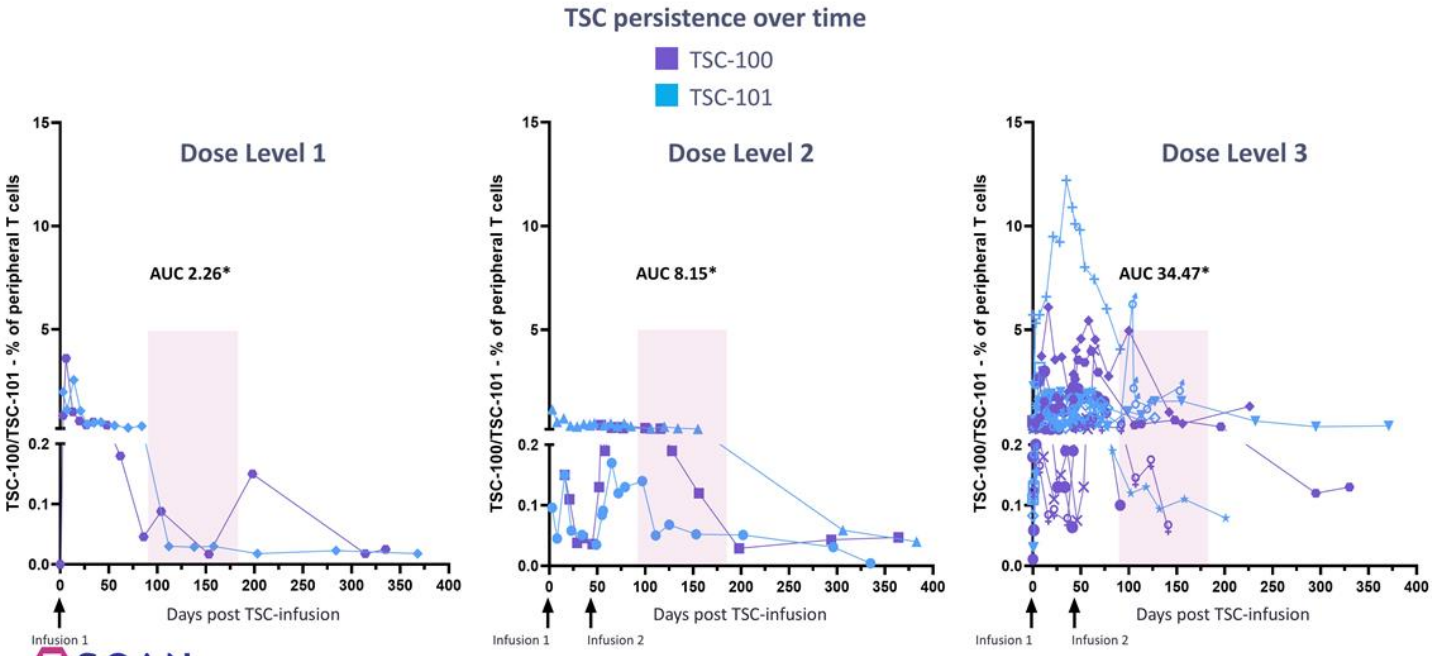
Subjects treated at all three dose levels with no dose-limiting toxicities

Dose Level	Planned Day of Infusion Post HCT		TSC 100 N=10	TSC 101 N=12
	+21	+61		
DL1	5×10^6 TCR-T cells/kg	N/A	1	1
DL2	5×10^6 TCR-T cells/kg	5×10^6 TCR-T cells/kg	1	2
DL3	5×10^6 TCR-T cells/kg	20×10^6 TCR-T cells/kg	8	9

TSCAN THERAPEUTICS

As of Nov 20, 2024 data cut

TSC-100 and TSC-101 TCR-T cells detected for over one year with increased persistence seen at highest dose level (DL3)



*AUC of TSC-100/TSC-101 between Day 90-180 (Geometric mean(geometric CV)): DL1: 2.26(47.2%); DL2 and sDL2: 8.15(42.2%); DL3 and sDL3: 34.47(97.7%). Dose did not meet target dose criteria in supplemental dose level cohorts (sDL)

As of Nov 20, 2024 data cut

Adverse events of special interest were low grade and manageable

Adverse Event of Special Interest*	TSC-100 n=10	TSC-101 n=12	Any TSC n=22	Control n=12
Any Acute GvHD**	5 (50%)	6 (50%)	11 (50%)	4 (33%)
Grade II - IV	0 (0%)	2 (17%)	2 (9%)	3 (25%)
Grade III - IV	0 (0%)	1 (8%)	1 (5%)	2 (17%)
Any CRS	4 (40%)	8 (67%)	12 (57%)	6 (50%)
Grade 1 - 2	4 (40%)	8 (67%)	12 (57%)	6 (50%)
Grade 3 - 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Treatment-emergent CRS	1 (10%)	1 (8%)	2 (9%)	NA
Grade 1 - 2	1 (10%)	1 (8%)	2 (9%)	NA
Grade 3 - 4	0 (0%)	0 (0%)	0 (0%)	NA
Any ICANS	0 (0%)	0 (0%)	0 (0%)	0 (0%)

- Balanced Grade II – IV acute GvHD between treatment and control arms
- No cases of moderate or severe chronic GvHD
  - One case each of mild chronic GvHD in the treatment and control arms
- Two episodes of low-grade CRS reported post TSC infusions
  - One Grade 1 event (TSC-100) and one Grade 2 event (TSC-101)
- No cases of ICANS

*MAGIC grading used for acute GvHD, NIH consensus grading for chronic GvHD, and ASTCT grading used for CRS or ICANS
**Acute GvHD through 180 days post HCT
CRS: Cytokine release syndrome; ICANS: Immune effector cell-associated neurotoxicity syndrome

TSCAN THERAPEUTICS

As of Nov 20, 2024 data cut

Grade ≥3 treatment emergent adverse events are consistent with transplantation

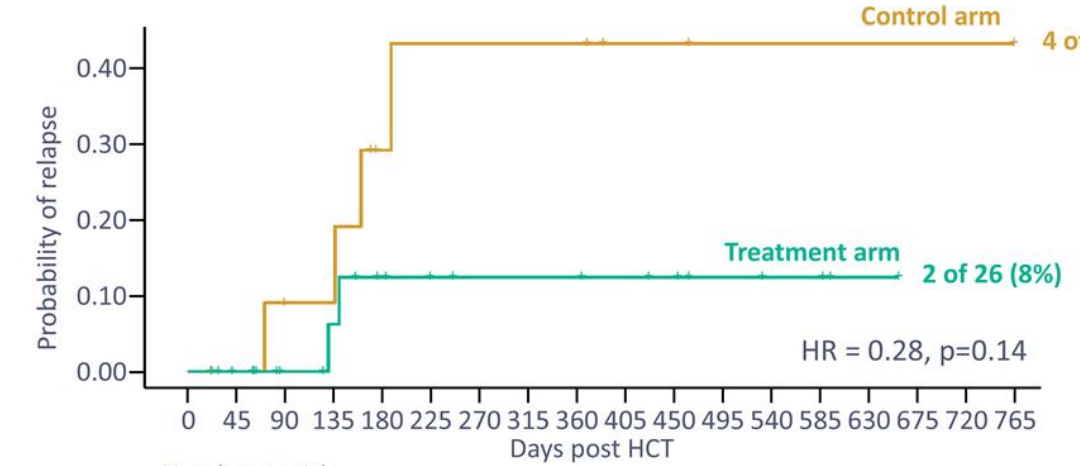
Events in >5% of subjects	Any TSC n=22	Control n=12
Anemia	7 (31.8)	2 (16.7)
Platelet count decreased	4 (18.2)	3 (25.0)
Neutrophil count decreased	3 (13.6)	1 (8.3)
Pneumonia	3 (13.6)	1 (8.3)
Sepsis	3 (13.6)	0
Decreased appetite	2 (9.1)	0
Rash maculo-papular	2 (9.1)	0
Hypertension	1 (4.5)	1 (8.3)
Hypokalemia	1 (4.5)	1 (8.3)
Hypoxia	1 (4.5)	1 (8.3)
Pancytopenia	1 (4.5)	1 (8.3)
Acute graft vs host disease*	1 (4.5)	2 (16.7)
Neck pain	0	2 (16.7)
Alanine aminotransferase increased	0	1 (8.3)
Aspartate aminotransferase increased	0	1 (8.3)
Gamma-glutamyltransferase increased	0	1 (8.3)
Muscular weakness	0	1 (8.3)
Pneumonia respiratory syncytial viral	0	1 (8.3)

*Acute graft vs host disease (GvHD) includes one patient with events of acute GvHD, acute GvHD in skin, GvHD in skin and one with GvHD of the GI tract

TSCAN THERAPEUTICS

As of Nov 20, 2024 data cut

TCR-T infusion is associated with fewer relapses



Number at risk

Control arm	12	11	9	9	5	4	4	4	4	2	2	1	1	1	1	1	1
Treatment arm	26	23	17	15	12	10	8	8	8	7	6	4	3	3	1	0	0	0

Cumulative number of events

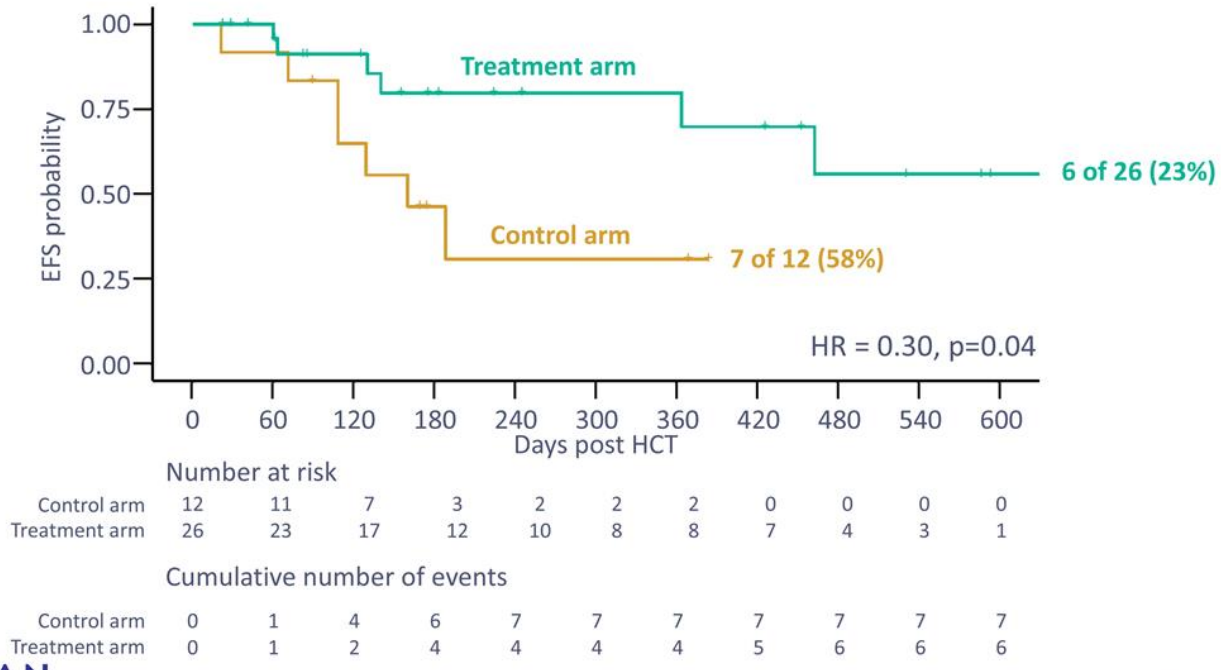
Control arm	0	0	1	1	3	4	4	4	4	4	4	4	4	4	4	4	4
Treatment arm	0	0	0	1	2	2	2	2	2	2	2	2	2	2	2	2	2

TSCAN THERAPEUTICS

CoxPH Ratio = 0.275, CI = (0.05, 1.502), p = 0.136; Log–rank p = 0.1105

Updated to include 2 events in the treatment arm reported after the Nov 20, 2024 data cut

Event-free survival (EFS) favors the treatment arm



Number at risk

Control arm	12	11	7	3	2	2	2	0	0	0	0
Treatment arm	26	23	17	12	10	8	8	7	4	3	1

Cumulative number of events

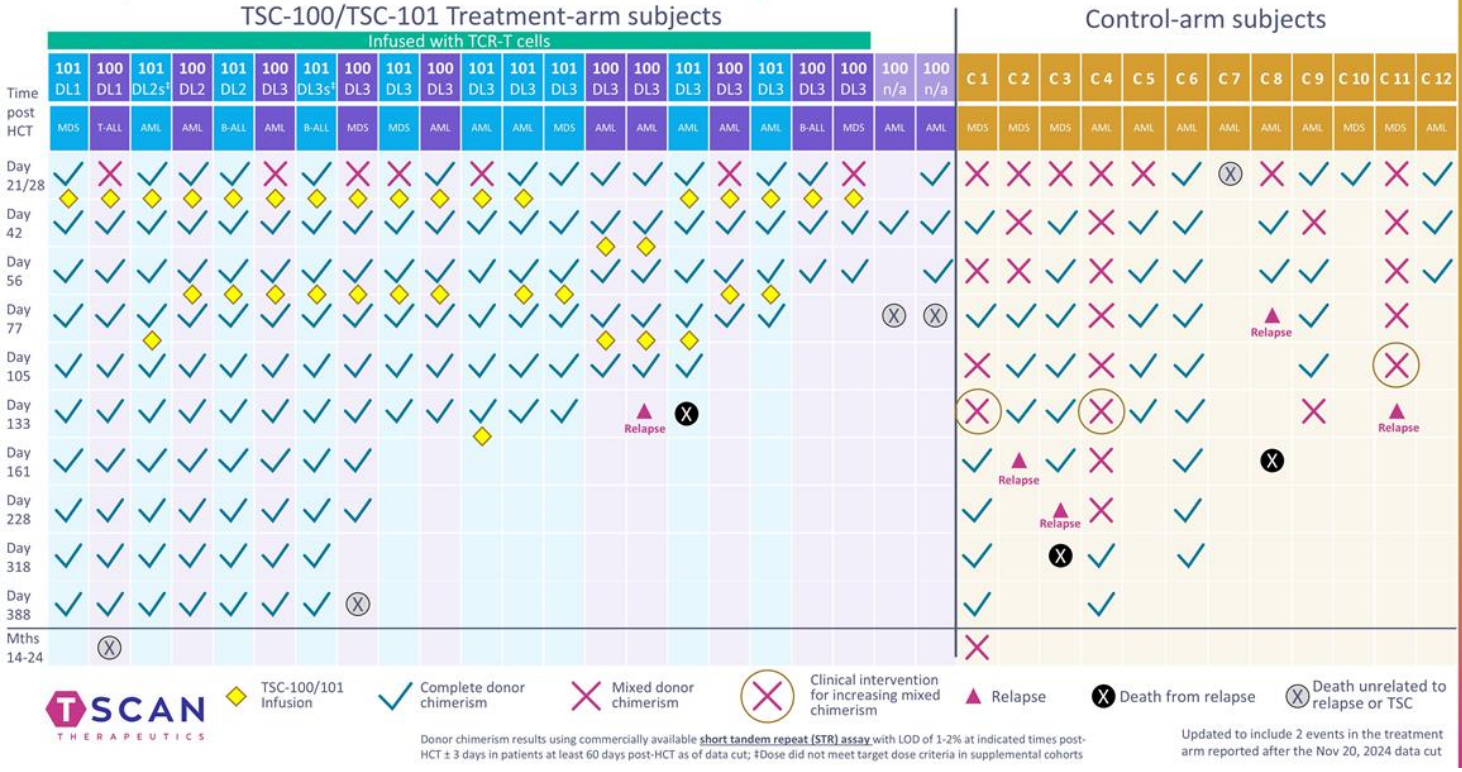
Control arm	0	1	4	6	7	7	7	7	7	7	7
Treatment arm	0	1	2	4	4	4	4	5	6	6	6

TSCAN THERAPEUTICS

Event defined as relapse, clinical intervention for impending relapse (non-TSC), or death
Cox PH Ratio = 0.304, CI = (0.096, 0.966, p = 0.0435); Log-rank p = 0.0321

Updated to include 2 events in the treatment arm reported after the Nov 20, 2024 data cut

Complete donor chimerism achieved in all patients after initial TSC infusion



Donor chimerism results using commercially available **short tandem repeat (STR) assay** with LOD of 1-2% at indicated times post-HCT ± 3 days in patients at least 60 days post-HCT as of data cut; ‡Dose did not meet target dose criteria in supplemental cohorts

Updated to include 2 events in the treatment arm reported after the Nov 20, 2024 data cut

Unusual circumstances for both subjects who relapsed post TCR-T cell infusions

TSC-101 Dose Level 3

- 65 y/o male with AML
- Did not respond to induction chemotherapy (4% blasts)
- *Taken to transplant after reinduction chemotherapy without achieving CR* [1]
- Died Day 129 post transplant with suspected relapse

[1] Not observed in any other patient

[2] Occurred twice

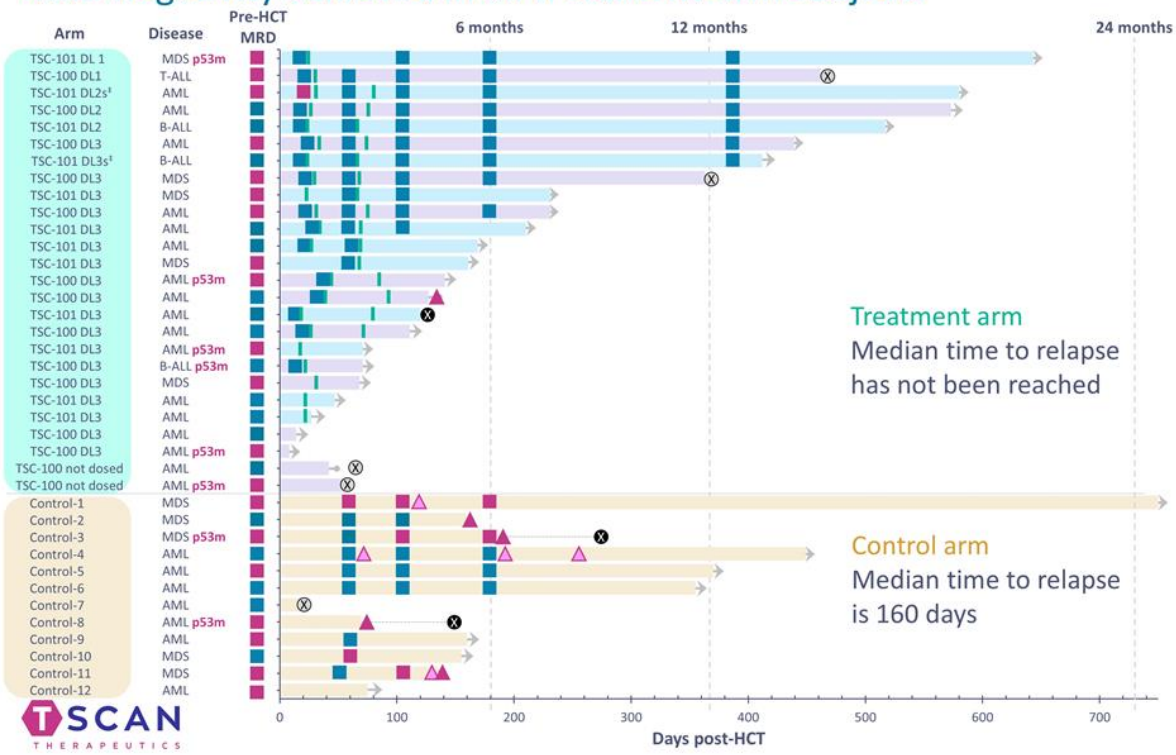
TSC-100 Dose Level 3

- 59 y/o male with AML
- *Donor apheresis for manufacturing occurred after G-CSF mobilization* [2]
- Manufacturing was challenging due to high neutrophils; repeat manufacturing required
- Both infusions were delayed (Day 41 and Day 97)
- Relapse observed in CNS at Day 139 post-transplant with no systemic relapse

TSCAN THERAPEUTICS

Neither circumstance would be permitted in pivotal trial

MRD negativity achieved in all treatment-arm subjects



TSC-100/TSC-101 infusion
Clinical intervention for concern for relapse
Relapse
Death from relapse
Death unrelated to relapse or TSC
Ongoing follow-up
End of study
MRD-positive
MRD-negative
MRD pending

‡Dose did not meet target dose criteria in supplemental cohorts

MRD measured by flow cytometry (lower limit of detection 0.1-1%) or NGS (lower limit of detection 0.05-0.1% in myeloid and 0.001-0.01% in lymphoid malignancies).

Updated to include 2 events in the treatment arm reported after the Nov 20, 2024 data cut

TSCAN THERAPEUTICS

Summary

- Infusions with TSC-100 and TSC-101 were well-tolerated with no DLTs and adverse events consistent with HCT
- TSC-100 and TSC-101 TCR-T cells have been detected >1 year post infusion and have a clear dose-persistence relationship
- 2 of 26 (8%) treatment-arm subjects relapsed as compared to 4 of 12 (33%) control-arm subjects
    - Median time to relapse was not evaluable in TCR-T-treated subjects vs 160 days in the control arm
    - Event-free survival strongly favors the treatment arm (HR=0.30)
- These data support the continued evaluation of TSC-100 and TSC-101 as adjuvant TCR-T cells to treat residual disease and prevent relapse in subjects with AML, ALL, or MDS post RIC-HCT

TSCAN THERAPEUTICS

Pivotal trial design and heme development strategy

TSCAN

Highly collaborative RMAT meeting with FDA provided clear feedback on a path to registration

CMC

- Analytical comparability is sufficient to support a commercial-ready process
- Proposed potency assays are sufficient to support a pivotal study

Clinical

- Proposed patient population is acceptable: AML, MDS, and ALL undergoing allo-HCT with haploidentical or MMUD donors
- Relapse-free survival (RFS) is an appropriate primary end-point to support full approval
- Use of an external control arm using data from CIBMTR is acceptable to support full approval

TSCAN THERAPEUTICS

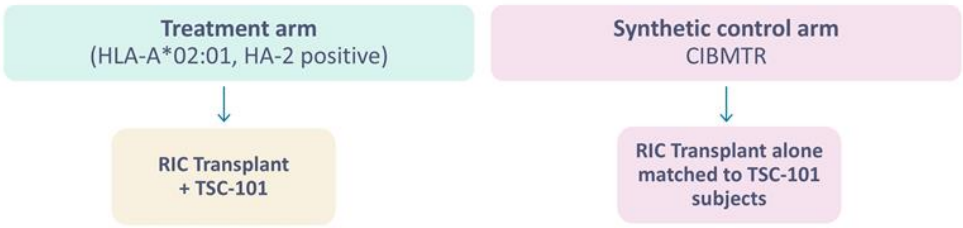
MUD: Matched unrelated donor; MMUD: Mismatched unrelated donor
CIBMTR: Center for International Blood and Marrow Transplant Research

TSC-101 captures ~98% of HLA-A*02:01-positive patients, obviating the need for TSC-100 or a companion diagnostic

Sources: Wang, AACR 2022; Spierings, PLoS Genetics 2007; CIBMTR 2023

Pivotal study designed for full approval using an external control arm

Subjects: AML, MDS, ALL undergoing transplant with reduced intensity conditioning (RIC)
Donors: Haploidentical and mismatched unrelated donors
Enrollment: TSC-101 vs matched controls (1:3)
Companion Diagnostic: Not needed



Endpoints

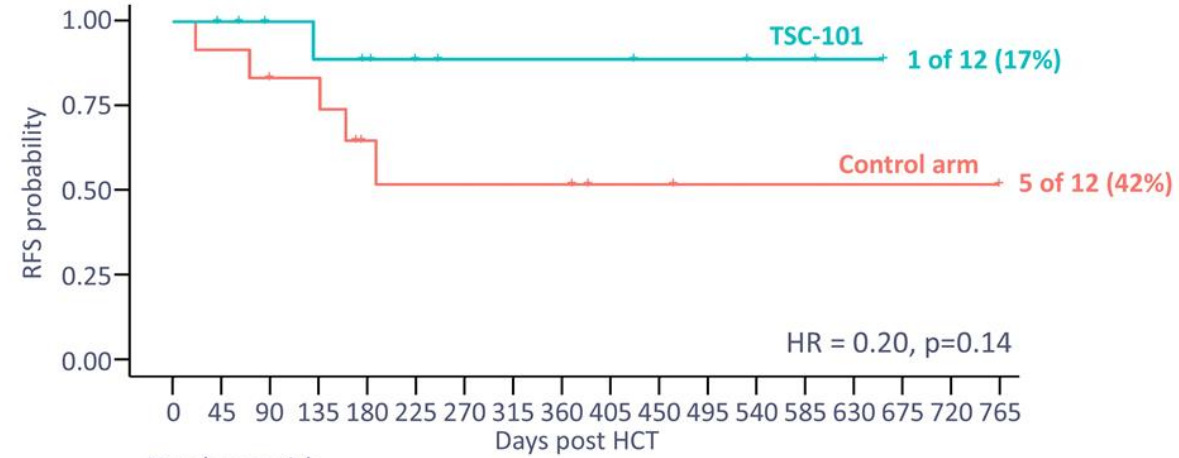
- **Primary**: Relapse-free survival (RFS; Full approval)
- **Key Secondary**: Overall survival, time to relapse, event-free survival
- **Exploratory**: MRD, complete chimerism rates

Readouts

- **Full Approval**: 184 relapse + death events
  - HR 0.60, 85% power
  - N = ~140 treatment arm subjects
- **Study Readout**: 24 months

TSCAN THERAPEUTICS

Target RFS hazard ratio of 0.60 is well supported by data from the ALLOHA Phase 1 study



Number at risk

Control arm	12	11	9	9	5	4	4	4	4	2	2	1	1	1	1	1	1
Treatment arm	12	11	9	8	7	5	4	4	4	4	3	3	2	2	1	0	0	0

Cumulative number of events

Control arm	0	1	2	2	4	5	5	5	5	5	5	5	5	5	5	5	5
Treatment arm	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1

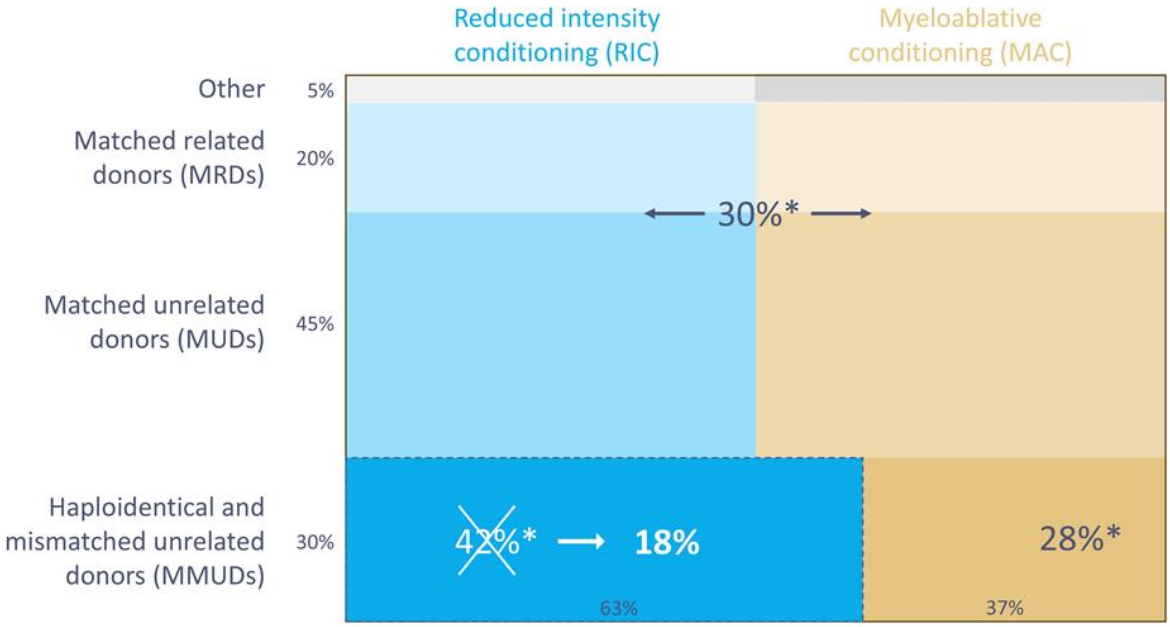
TSCAN THERAPEUTICS

Event defined as relapse, or death
CoxPH Ratio = 0.2, CI = (0.023, 1.718), p = 0.1425; Log−rank p = 0.1034

Updated to include event in the treatment arm reported after the Nov 20, 2024 data cut

Market opportunity

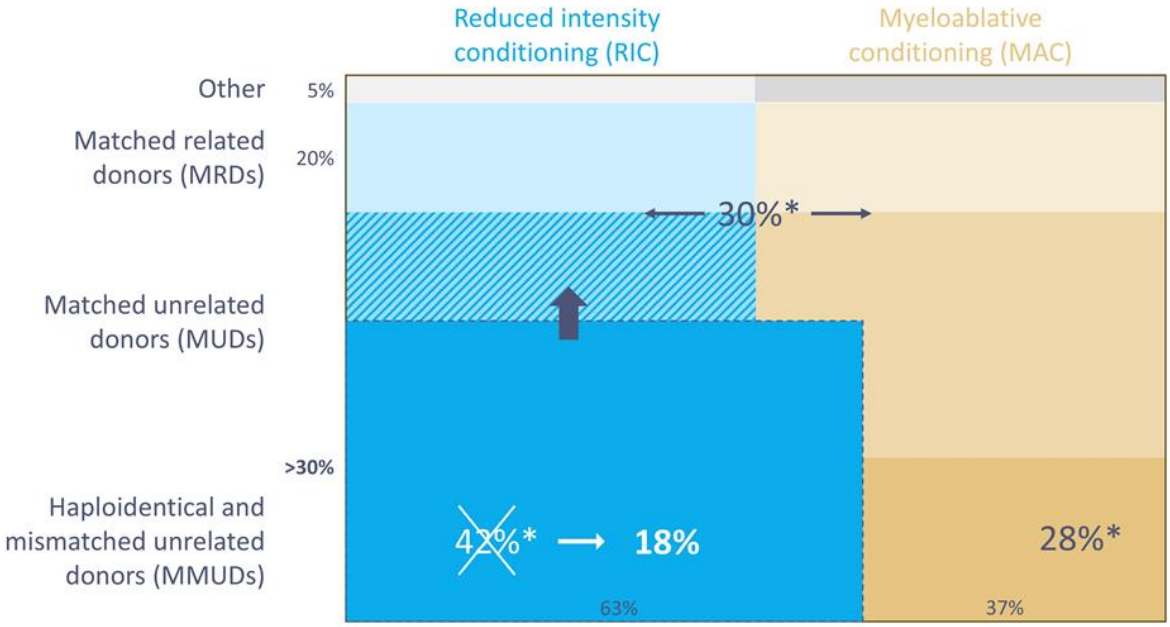
Positive data should accelerate changes in clinical practice and increase the total addressable market



- RFS HR of 0.60 equates to 57% relapse reduction or 18% RR at 2 years
- Current early data show 72.5% relapse reduction

CIBMTR analysis of AML, ALL, MDS allogeneic transplants with reduced intensity conditioning (RIC) between 2017-2019 with 2-year follow-up

Positive data should accelerate changes in clinical practice and increase the total addressable market



* 2-year relapse rates

- RFS HR of 0.60 equates to 57% relapse reduction or 18% RR at 2 years
- Current early data show 72.5% relapse reduction

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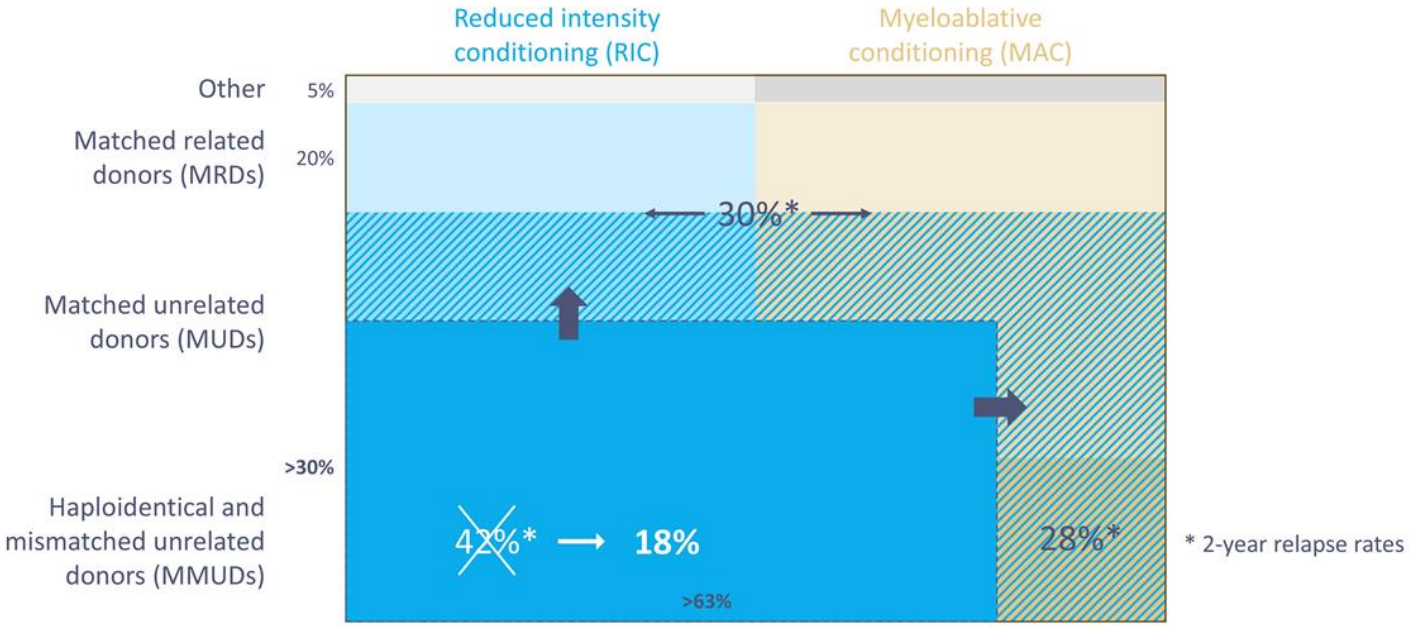

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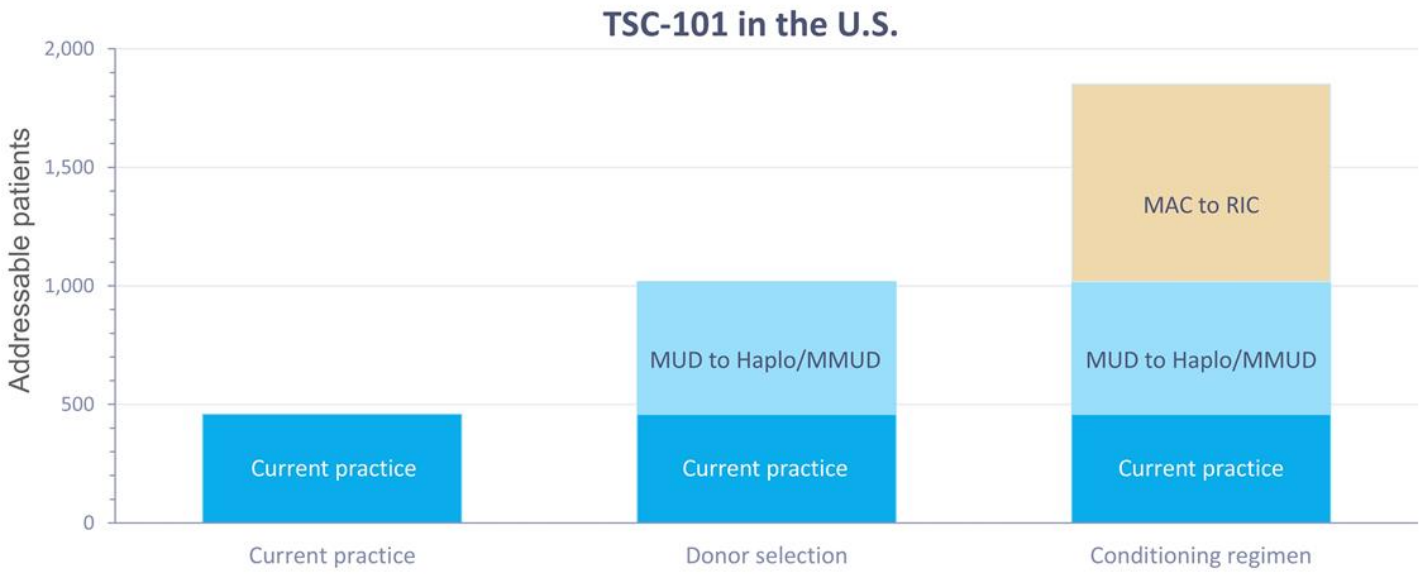
- Current early data show 72.5% relapse reduction

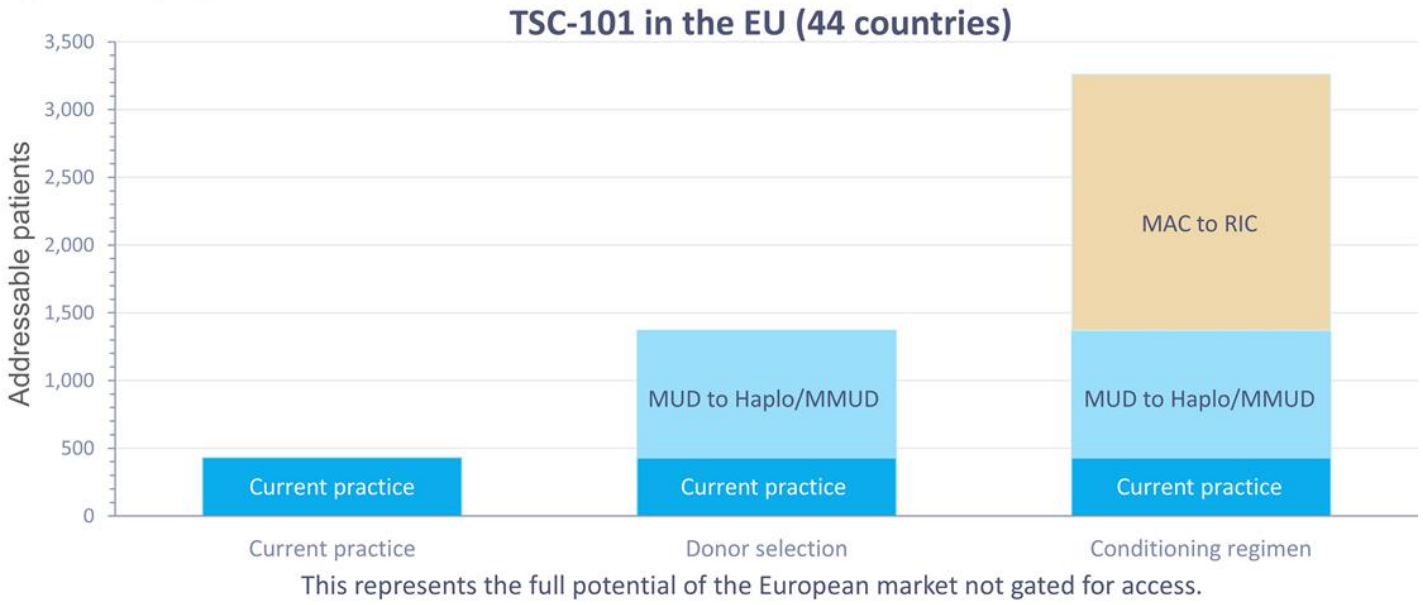
CIBMTR analysis of AML, ALL, MDS allogeneic transplants with reduced intensity conditioning (RIC) between 2017-2019 with 2-year follow-up

Increased use of reduced intensity conditioning with haploidentical/MMUD donors has the potential to expand the addressable market dramatically



Sources: CIBMTR 2022 and 2023; Wang, AACR 2022; NMDP analysis; ClearView analysis assumes maximum practice change in each case

Expansion to Europe offers the opportunity to more than double the addressable patient population



This represents the full potential of the European market not gated for access.

Sources: Passweg, Bone Marrow Transplantation 2024 (EBMT Survey Results 2022); Allelefrequencies.net; NMDP analysis; ClearView analysis assumes maximum practice change in each case

New cell therapy approvals benchmark potential TSC-101 pricing approach

CAR-T/Transplant Products

- Strong clinical efficacy across multiple lines of therapy
- Existing reimbursement pathway

~$300-500 K

Recent TIL and TCR-T Approvals

$515 K $727 K

- **Strong clinical efficacy and safety**
- **High unmet need**
- **Defined patient population**

~$500-750 K

One-time Curative Therapies

- Curative potential with durability
- High unmet need
- Ultra rare populations

$1+ M

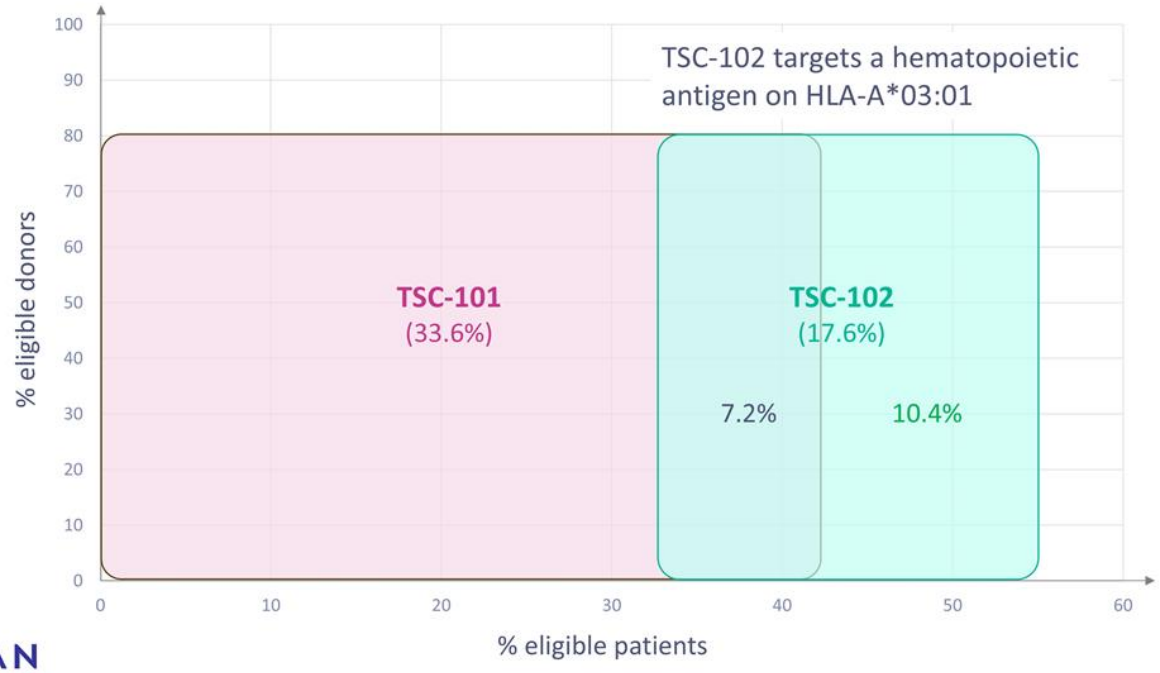
TSC-101

Early engagement with payers and ongoing clinical market research at leading transplant centers confirm value messaging and support practice change based on TSC-101 product characteristics

TSCAN THERAPEUTICS

Expansion opportunities

The addressable market can be expanded with the introduction of additional TCR-Ts that target other HLA types

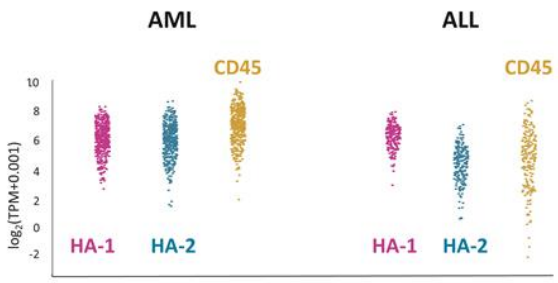


TSCAN THERAPEUTICS

TCRs for additional HLA types will target epitopes on CD45, a universal source of antigens for heme malignancies

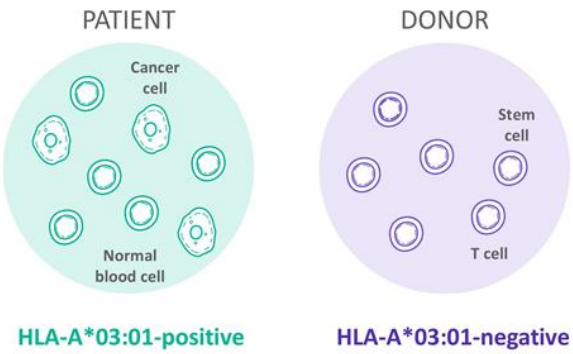
- CD45 is a lineage-specific antigen with expression in all hematopoietic cells, including HSCs
- CD45 is a large protein with many well-known epitopes for high frequency HLAs
- Antigen-negative donors can be selected by mismatching on HLA (using haploidentical and MMUD donors)

CD45 has high and uniform expression in AML and ALL



Source: TCGA

TSC-102 targets an antigen from CD45 presented on HLA-A*03:01



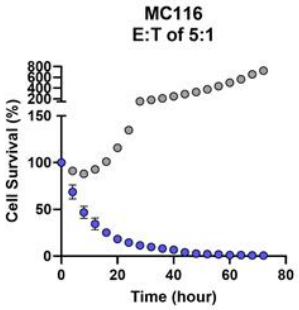
HLA-A*03:01-positive **HLA-A*03:01-negative**

TSCAN THERAPEUTICS

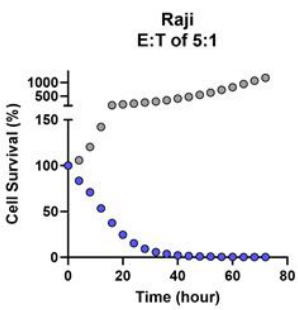
Lead TCR for TSC-102 selectively kills A*03:01^{+}/CD45^{+} cancer cell lines

TCR-T cells effectively kill heme-derived cancer cell lines

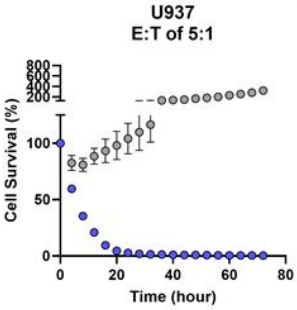
B cell lymphoma



Burkitt's lymphoma



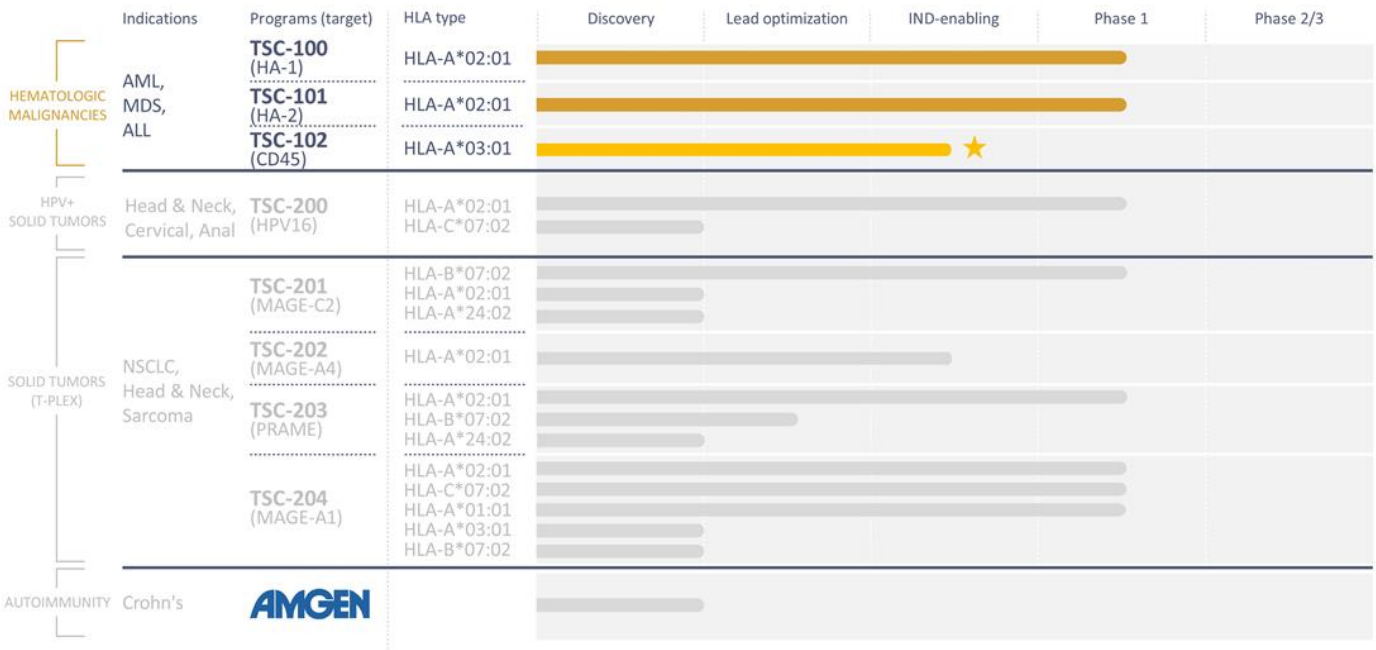
Myeloid leukemia



- TSC-102
- Non-engineered T cells

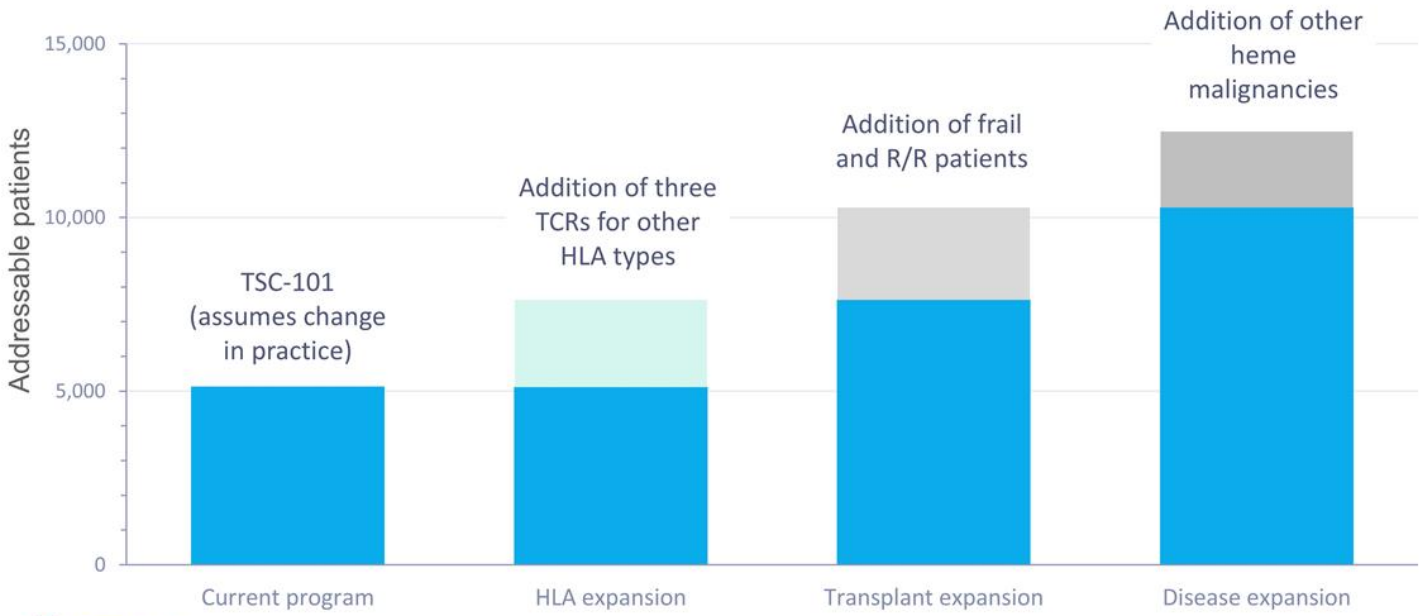
TSCAN THERAPEUTICS

Eight TCR-T candidates in clinical development, with new TCR-Ts advancing



TSCAN THERAPEUTICS

Expansion opportunities for the heme program provide a way to reach over 10,000 patients in the U.S. and Europe



TSCAN THERAPEUTICS

Source: SEER, CIBMTR, EBMT, ClearView analysis

Next steps and milestones

- Continue to enroll ALLOHA Phase 1 study using commercial manufacturing process at TScan
- Transfer commercial process to external CDMO
- Reach final agreement with FDA on pivotal trial design
- Initiate pivotal trial with manufacturing at external CDMO

TSCAN THERAPEUTICS

Q&A

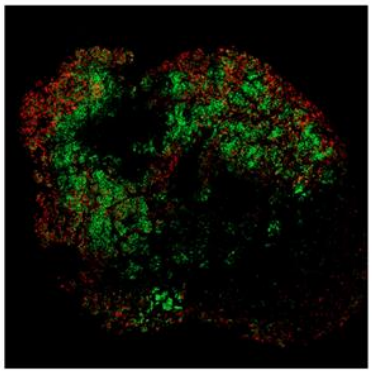
Solid tumor program update

Multiplex TCR-T therapy is designed to address the heterogeneity of solid tumors

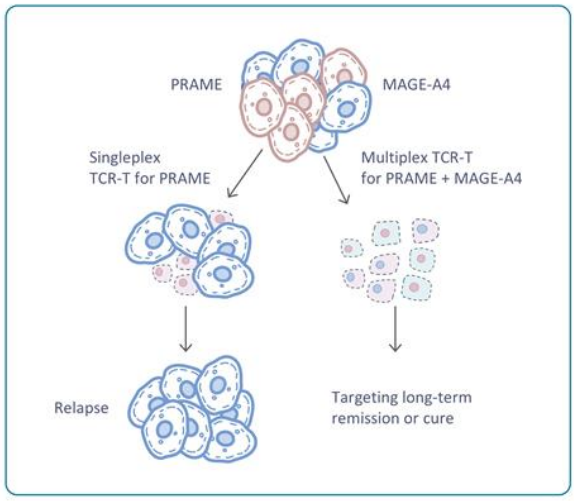
Many immune-rich cancers exhibit target heterogeneity

Non-small cell lung cancer

PRAME **MAGE-A4**

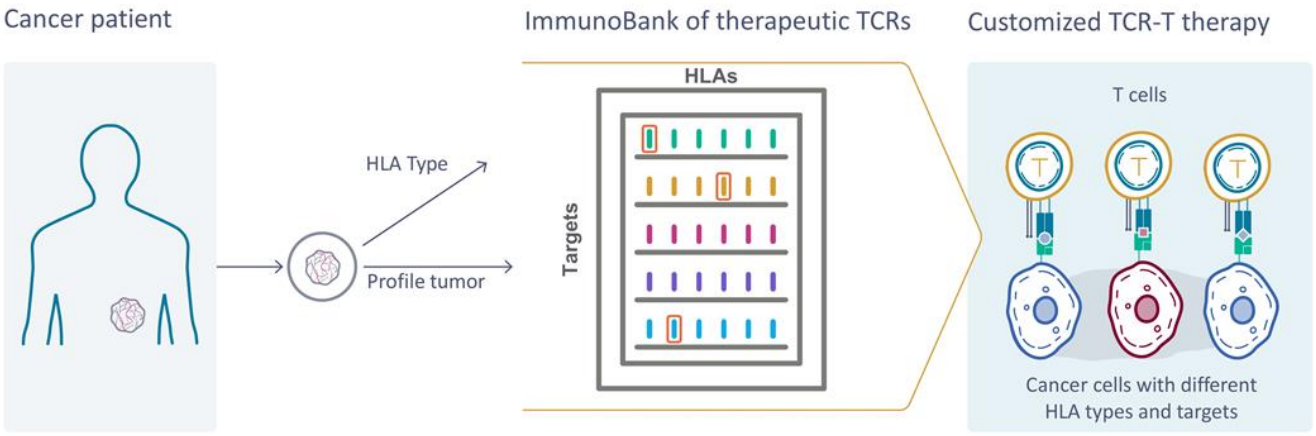


TCR-Ts against multiple targets may be required to improve efficacy and durability



TSCAN THERAPEUTICS

TScan is building and expanding the ImmunoBank of TCRs to enable enhanced, multiplex TCR-T cell therapy



- Determine target and HLA expression in patient tumor
- Manufacture and administer customized, multiplex TCR-T therapy

TSCAN THERAPEUTICS

Dose escalation scheme provides a rapid path to multiplex TCR-T in Phase 1

	TSC-204-A0201 (MAGE-A1)	TSC-204-C0702 (MAGE-A1)	TSC-200-A0201 (HPV16)	TSC-203-A0201 (PRAME)	TSC-201-B0702 (MAGE-C2)	TSC-204-A0101 (MAGE-A1)
DL1	0.5B **Dosed**	0.5B	0.5B **Dosed**	0.5B **Dosed (x2)**	0.5B **Dosed**	0.5B
DL2	2B	2B	2B **Dosed**	2B **Dosed (x2)**	2B	2B

	T-Plex	Singleplex
DL3	Any two TCR-Ts that have cleared DL2 → 28 days → *First infusion* / *Second infusion* → **Manufactured**	28 days → *First infusion* / *Second infusion* → **Manufacturing underway**
DL4	Any two TCR-Ts that have cleared DL3 → 28 days → *First infusion* / *Second infusion*	28 days → *First infusion* / *Second infusion*

TSCAN THERAPEUTICS

As of Dec. 5, 2024

Progressing multiple TCRs through early dose levels sets us up to investigate multiplexed therapy in 2025

- ☑ Enroll study efficiently
- ☑ Manufacture successfully
- ☑ Progress through dose escalation to T-Plex
- ☑ Early signs of anti-tumor activity

TSCAN THERAPEUTICS

Strategy for 2025

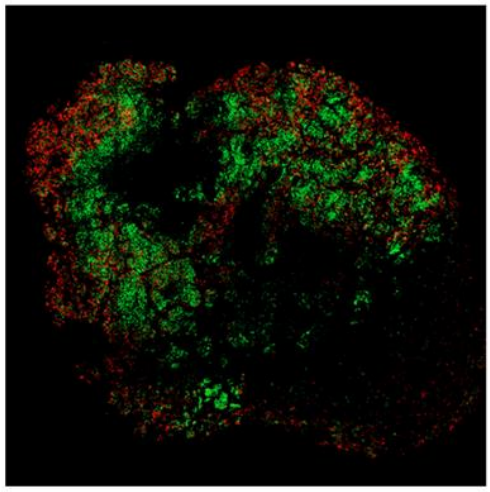
TSCAN

Program will focus on immune-rich cancers with high unmet need

- Initial patients have included all comers
  - Anal, Head & Neck, Melanoma, NSCLC, Ovarian, Sarcoma, Thyroid
- We have now reached dose levels that enable T-Plex
- T-Plex and DL3 singleplex are expected to be the first efficacious dose levels
- Goal is to end 2025 with clearly interpretable data in defined areas
- Focus on immune-rich cancers with high unmet need

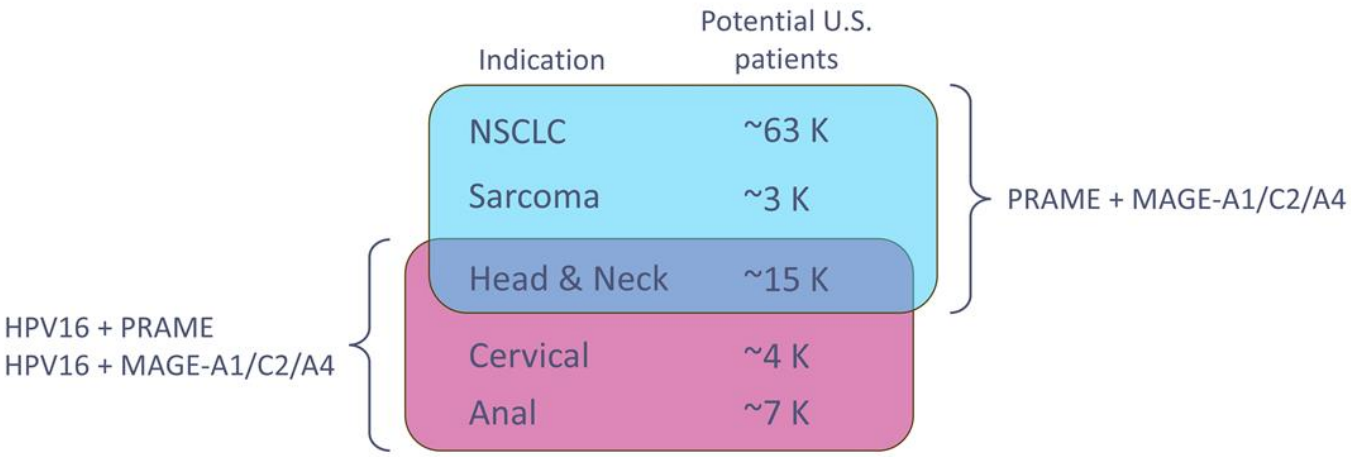
Non-small cell lung cancer

MAGE-A4 PRAME



TSCAN THERAPEUTICS

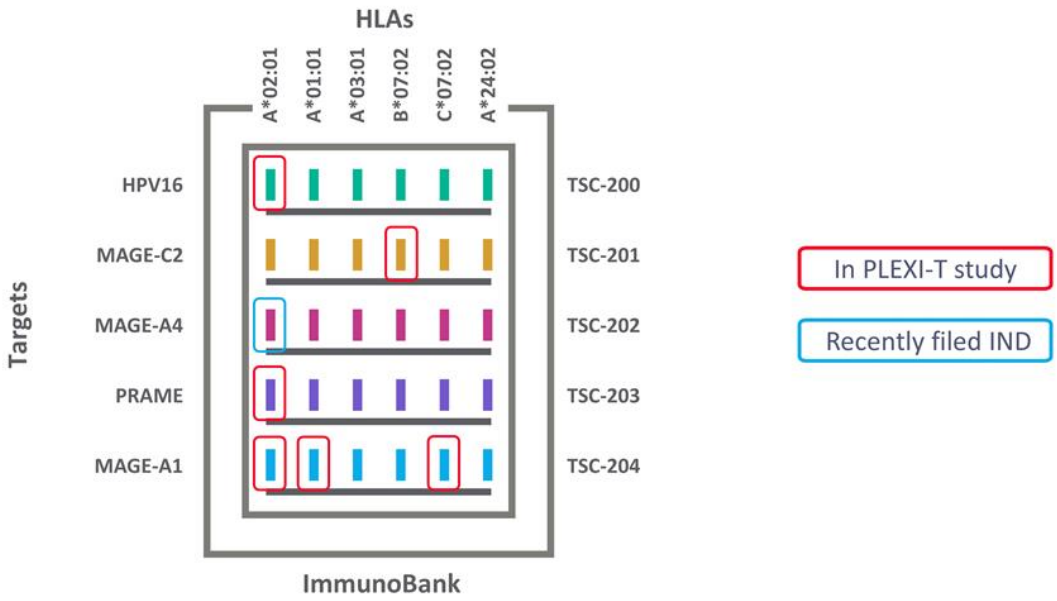
T-Plex enrollment will focus on four key indications with high unmet need



- High unmet need
- Evidence of T cell infiltration
- Clinical signal in early TCR-T trials
- Significant addressable patient population in second- and third-line treatment

TSCAN THERAPEUTICS

TScan is strategically building the ImmunoBank to enable multiplex TCR-T therapy in immune-rich solid tumors

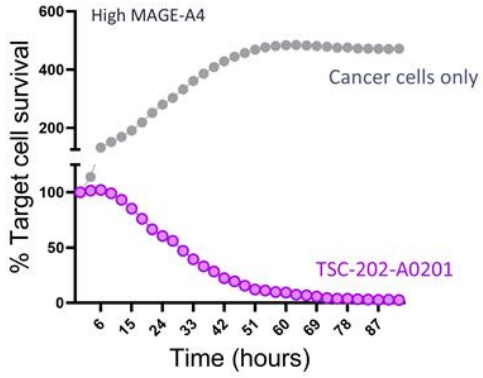


TSCAN THERAPEUTICS

T-Plex eligibility expected to increase substantially with addition of MAGE-A4

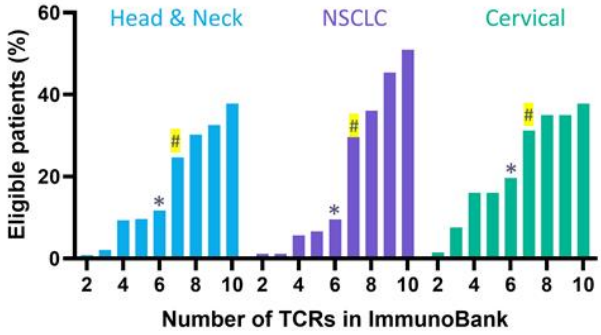
MAGE-A4 A*02:01 IND submitted

Strong cancer cell killing



Eligible patients are already being identified for MAGE-A4

T-Plex eligibility increases as ImmunoBank grows



Eligible patients include patients who are positive for at least two TCR-Ts in the ImmunoBank

*Current number of TCR-Ts in ImmunoBank

Addition of MAGE-A4 A*02:01 to ImmunoBank

TSCAN THERAPEUTICS

Eight TCR-T candidates in clinical development, with new TCR-Ts advancing

TSCAN THERAPEUTICS

Summary

- Eight patients dosed with singleplex TCR-T
- Two TCRs advanced through DL2 and now eligible for T-Plex (HPV16 A*02:01 and PRAME A*02:01)
- First T-Plex product successfully manufactured
- Early evidence of dose-dependent T cell activation and expansion *in vivo*
- IND filed for MAGE-A4 A*02:01

Dose first multiplex patient

Safety and response data for multiplex therapy

TSCAN THERAPEUTICS

Q&A

TSCAN