

**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, 2023

TSCAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40603
(Commission
File Number)

82-5282075
(I.R.S. Employer
Identification No.)

830 Winter Street
Waltham, Massachusetts
(Address of principal executive offices)

02451
(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, 2023, TScan Therapeutics, Inc. (the “Company”) issued a press release announcing a poster presentation highlighting initial results from its ongoing Phase 1 multi-arm clinical trial evaluating TSC-100 and TSC-101 at the 65th American Society of Hematology (“ASH”) Annual Meeting and Exposition. The Company will host a virtual KOL event on Monday, December 11, 2023, at 8:00 a.m. ET to discuss the data presented at ASH. An archived webcast will be available following the call for 30 days on the Events & Presentations section of the Company’s website. A copy of the press release and the presentation materials for the KOL event are attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K. The presentation materials for the KOL event will also be available in 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.

On December 9, 2023, the Company reported initial results from its ongoing Phase 1 multi-arm clinical trial evaluating TSC-100 and TSC-101.

The Phase 1 trial is a multi-arm dose escalation study evaluating TSC-100, TSC-101, or hematopoietic cell transplantation (“HCT”) alone in patients with acute myeloid leukemia (“AML”), acute lymphocytic leukemia (“ALL”) or myelodysplastic syndromes (“MDS”) undergoing haploidentical allogeneic HCT with reduced intensity conditioning. Patients enrolled in Dose Level 1 receive a single dose of either TSC-100 or TSC-101 approximately 21 days post-transplant. Patients enrolled in Dose Level 2 receive the same dose of TSC-100 or TSC-101 approximately 21 days post-transplant, followed by a second dose administered 40 days after the initial dose. For patients in Dose Level 3, the second dose is escalated four-fold. Primary endpoints include safety and dose-finding, and secondary and exploratory endpoints include relapse rates versus standard-of-care as well as qualitative biological readouts, including minimal residual disease (“MRD”) and donor chimerism. MRD specifically measures malignant cells to identify any residual disease present in a patient, and donor chimerism measures a combination of malignant, pre-malignant and normal cells, measuring any remaining patient-derived hematopoietic cells.

Higher sensitivity assays used to detect the activity of T cells:

- Donor chimerism detected by high-sensitivity next-generation sequencing assay (AlloHeme) with limit of detection 0.13%.
- MRD detected by next-generation sequencing with limit of detection of 0.05-0.1%.

Key Highlights from the Initial Results:

TSC-100 treatment arm (N=3 T-ALL, AML, AML)

- 3/3 evaluable patients treated with TSC-100 achieved complete donor chimerism and MRD negativity.

TSC-101 treatment arm (N=3 TP53-mutated MDS, AML, B-ALL)

- 3/3 evaluable patients treated with TSC-101 achieved complete donor chimerism and MRD negativity, including a TP53-mutated MDS patient who remained with no detectable disease for over seven months post-HCT.
- One patient with AML was MRD-positive following HCT and converted to MRD-negative following treatment with TSC-101.

Control arm (N=4, MDS, MDS, TP53-mutated MDS, AML) have been enrolled and received standard of care HCT alone:

- One TP53-mutated MDS control-arm patient evolved with MRD positivity and worsening mixed chimerism, finally experiencing disease relapse approximately six months after transplantation.

- Two MDS control-arm patients developed worsening mixed chimerism that prompted early withdrawal of immunosuppression, which was complicated by grade 1 or grade 3 skin graft-vs-host disease.
- 0/4 patients achieved and maintained complete donor chimerism.

The type and severity of adverse events observed to date were comparable between TSC-100 and TSC-101 treatment arm patients and control arm patients.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
99.1	TScan Therapeutics, Inc. Press Release dated December 9, 2023.
99.2	TScan Therapeutics, Inc. Presentation Materials.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

TScan Therapeutics, Inc.

Date: December 11, 2023

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



TScan Therapeutics Presents Initial Phase 1 Clinical Results on TSC-100 and TSC-101 at the 65th American Society of Hematology Annual Meeting and Exposition

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

No patient-derived hematopoietic cells detected in six of six treatment-arm patients, indicating complete elimination of target cells, versus zero of four control-arm patients

AML patient with detectable disease post-transplant converted to no detectable disease following treatment with TSC-101

Patients enrolled up to the third and final dose level in both treatment arms with no dose limiting toxicities

Company to host virtual KOL event on Monday, December 11, at 8:00 a.m. ET to discuss the data presented at the ASH Annual Meeting and Exposition

WALTHAM, Mass., Dec. 9, 2023 — 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 a poster presentation at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition. The poster highlights initial data from the Phase 1 multi-arm clinical trial evaluating TSC-100 and TSC-101, which are designed to treat residual disease and prevent relapse following hematopoietic cell transplantation (HCT) in patients with acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), or acute lymphocytic leukemia (ALL) (NCT05473910).

“We are excited to present initial clinical data in our heme program, with six patients in our treatment arms and four patients in our control arm. Complete donor chimerism and MRD negativity, two favorable indicators of treatment success, were achieved and maintained in all six treated patients, four of whom have been on the study for over six months. In contrast, these indicators were not achieved in any of the four control-arm patients. In addition, one of the control-arm patients relapsed at six months, and two other control-arm patients required clinical intervention due to worsening chimerism, a sign of potential future relapse,” said Debora Barton, M.D., Chief Medical Officer. “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. After 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. There are currently 10 active clinical sites, and additional sites are in the process of being activated to participate in these expansion cohorts.”

“Hematopoietic cell transplantation is currently the best treatment option for many patients suffering from AML, MDS, and ALL, as approximately 60% of patients are cured by this procedure,” said Gavin MacBeath, Ph.D., Chief Executive Officer. “Unfortunately, for patients who relapse following transplantation, the prognosis is very poor. We have designed TSC-100 and TSC-101 to address this unmet need and increase the success rate of transplantation. We are very encouraged by these early data as they indicate that our therapies are working as designed. The translational data show that our cell therapies are eliminating all residual patient-derived malignant, pre-malignant, and benign cells, which are the cells that drive relapse. We are grateful to all the patients and their families who are participating in this trial and look forward to sharing more data in 2024 as the study continues to enroll.”

The Phase 1 trial is a multi-arm dose escalation study evaluating TSC-100, TSC-101, or HCT alone in patients with AML, ALL or MDS undergoing haploidentical allogeneic HCT with reduced intensity conditioning. Patients enrolled in Dose Level 1 receive a single dose of either TSC-100 or TSC-101 approximately 21 days post-transplant. Patients enrolled in Dose Level 2 receive the same dose of TSC-100 or TSC-101 approximately 21 days post-transplant, followed by a second dose administered 40 days after the initial dose. For patients in Dose Level 3, the second dose is escalated four-fold. Primary endpoints include safety and dose-finding, and secondary and exploratory endpoints include relapse rates versus standard-of-care as well as qualitative biological readouts, including MRD and donor chimerism. MRD specifically measures malignant cells, to identify any residual disease present in a patient, and donor chimerism measures a combination of malignant, pre-malignant and normal cells, measuring any remaining patient-derived hematopoietic cells.

Key Poster Highlights:

TSC-100 treatment arm (N=3 T-ALL, AML, AML)

- 3/3 patients treated with TSC-100 achieved complete donor chimerism and MRD negativity.

TSC-101 treatment arm (N=3 TP53 mutated MDS, AML, B-ALL)

- 3/3 patients treated with TSC-101 achieved complete donor chimerism and MRD negativity, including a TP53-mutated MDS patient who remained with no detectable disease for over seven months post-HCT.
- One patient with AML was MRD-positive following HCT and converted to MRD-negative following treatment with TSC-101.

Four control arm patients (MDS, MDS, TP53-mutated MDS, AML) have been enrolled and received standard of care HCT alone:

- One TP53-mutated MDS control-arm patient evolved with MRD positivity and worsening mixed chimerism, finally experiencing disease relapse approximately six months after transplantation.
- Two MDS control-arm patients developed worsening mixed chimerism that prompted early withdrawal of immunosuppression, which was complicated by grade 1 or grade 3 skin graft-vs-host disease.
- 0/4 of the control-arm patients achieved and maintained complete donor chimerism.

Higher sensitivity assays used to detect the activity of T cells:

- Donor chimerism detected by high-sensitivity next-generation sequencing assay (AlloHeme) with limit of detection 0.13%.
- MRD detected by next-generation sequencing with limit of detection of 0.05-0.1%.

A copy of the poster can be accessed on the "Publications" section of the Company's website at www.tscan.com.

Virtual KOL Event

The Company will host a virtual KOL event featuring Monzr M. Al Malki, M.D., on Monday, December 11, 2023, at 8:00 a.m. ET to discuss the data presented at ASH. Dr. Al Malki is an Associate Professor in the Department of Hematology & Hematopoietic Cell Transplantation and Director of the Unrelated Donor Bone Marrow Transplant and Haploidentical Transplant Programs at City of Hope. Details for attending the live event can be found [here](#).

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 hematologic malignancies program; 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.

Contacts

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TScan Therapeutics KOL event: Dec. 11, 2023



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 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 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 and any other filings that TScan has made or may make with the SEC in the future.

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Presenters



Monzr M. Al Malki, M.D.

- Hematologist-Oncologist, City of Hope
- Associate Professor, Division of Leukemia, Department of Hematology & Hematopoietic Cell Transplantation
- Director, Unrelated Donor BMT Program
- Director, Haploidentical Transplant Program

Dr. Al Malki is the lead PI for the current study



Gavin MacBeath, Ph.D.
Chief Executive Officer



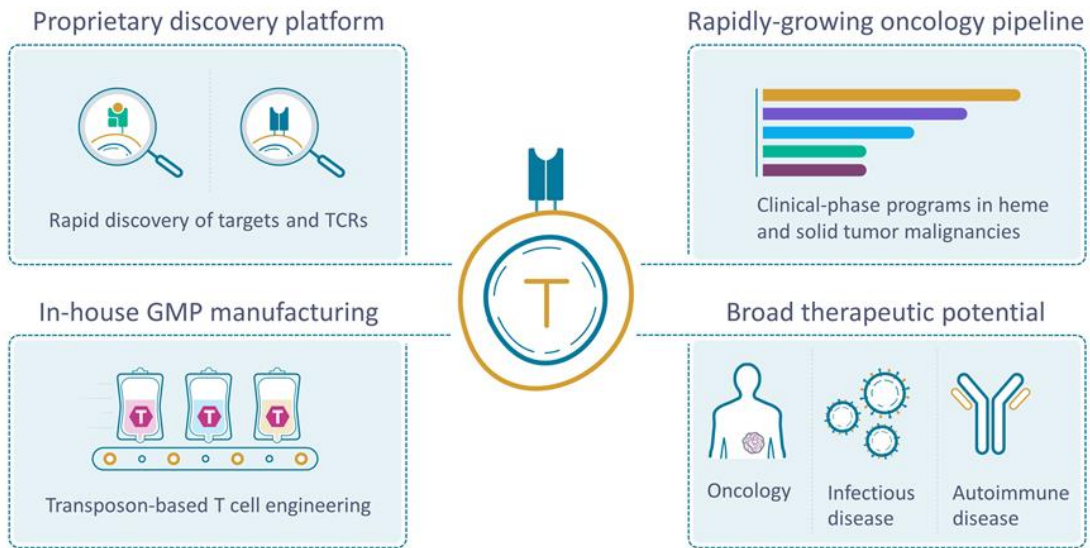
Debora Barton, M.D.
Chief Medical Officer



Shrikanta Chattopadhyay, M.D.
SVP, Head of Translational Medicine



TScan: A fully integrated, next-generation TCR-T cell company



Platform delivers broad proprietary pipeline



Primary solid tumor IND, T-Plex, supports simultaneous use of multiple TCRs



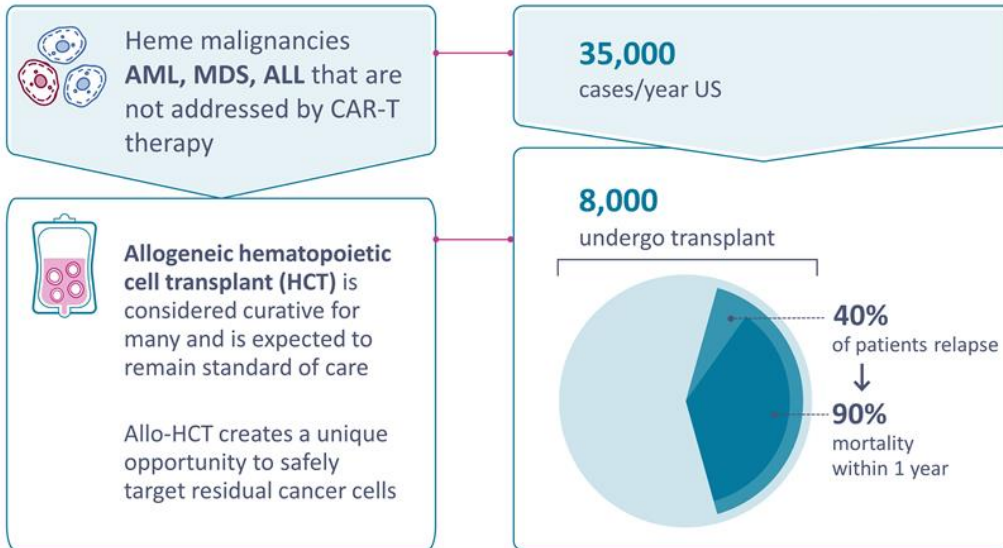
Heme malignancies:
TCR-T candidates designed to treat
residual disease and prevent relapse
in patients undergoing allogeneic HCT



Highlights of ASH presentation

- All six patients treated with TSC-100 or TSC-101 showed no evidence of relapse, with four patients on study for >6 months
 - All six patients showed complete donor chimerism and no evidence of residual disease at every reading starting 3 weeks after their first dose
- One of four control-arm patients relapsed at day 180, and two others required clinical intervention due to worsening biomarkers
 - All four control-arm patients showed mixed donor chimerism
- One AML patient was MRD+ following transplant and became MRD- after receiving TSC-101
- TSC-100 and TSC-101 were generally well-tolerated, with no DLTs and no significant differences in safety between treatment and control arms observed to date (as of Dec. 4, 2023)
- Both TSC-100 and TSC-101 reached dose level 3 and we are continuing to enroll at what we anticipate to be the recommended phase 2 dose

TCR-T has unique potential to address myeloid leukemias

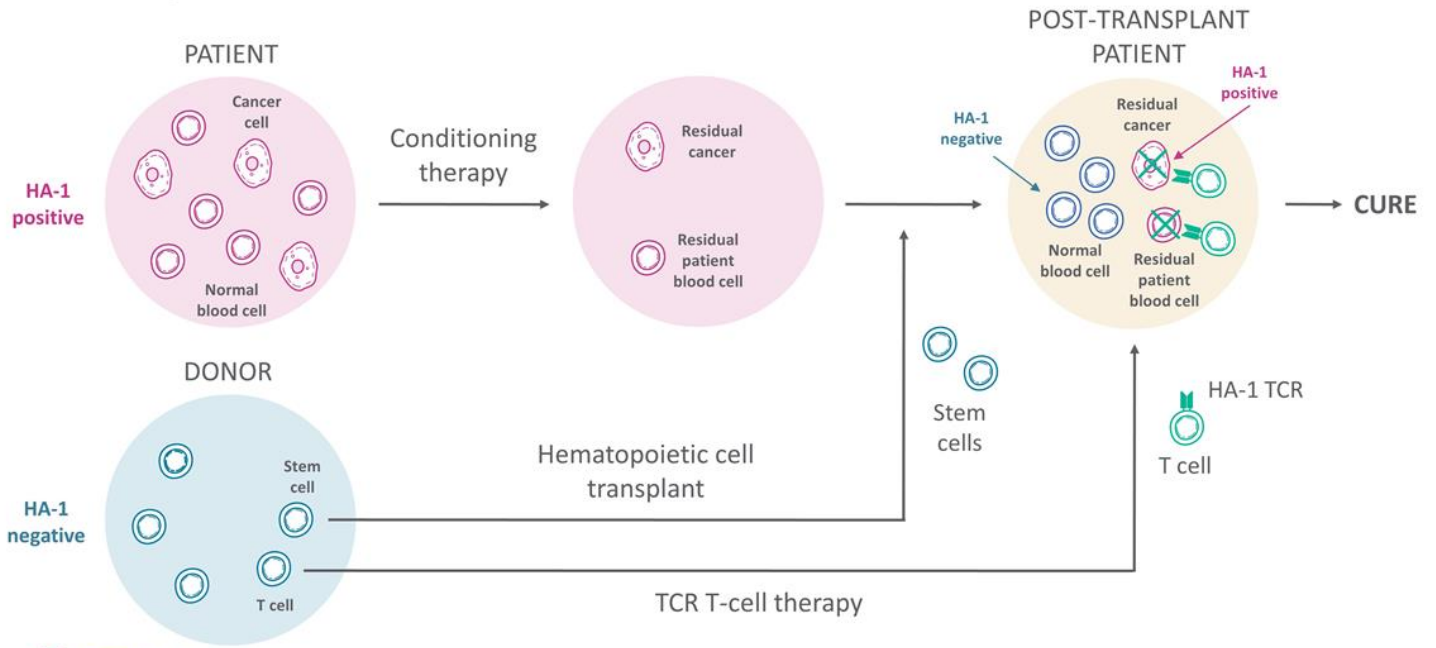


TScan program is designed to treat residual disease to prevent relapse in patients undergoing allogeneic HCT

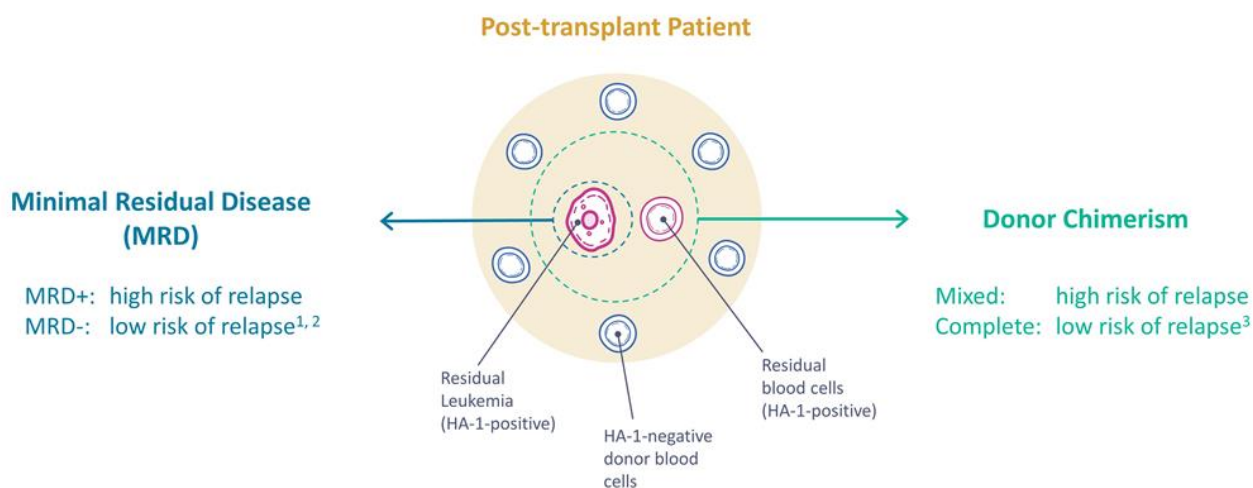


Source: Independent KOL market research conducted June 2020.

TSC-100/101 are designed to eliminate residual cancer cells and prevent relapse following HCT



Key biomarkers for residual leukemia or residual patient-derived blood cells serve as potential early surrogates of efficacy



1. Craddock, J Clin Oncol, 2021
2. Loke, ASH, 2021

3. Lindhal, Bone Marrow Transpl, 2022

Initial Results of a Phase 1 trial of TSC-100 and TSC-101, Engineered T Cell Therapies that Target Minor Histocompatibility Antigens to Prevent Relapse after Allogeneic Hematopoietic Cell Transplantation

Abstract # 2090

Monzr Al Malki¹, Alla Keyzner², Hyung C. Suh³, Aasiya Matin⁴, Erica Buonomo⁵, Yun Wang⁵, Nina Abelowitz⁵, Jim Murray⁵, Gavin MacBeath⁵, Debora Barton⁵, Shrikanta Chattopadhyay⁵, Ran Reshef⁶

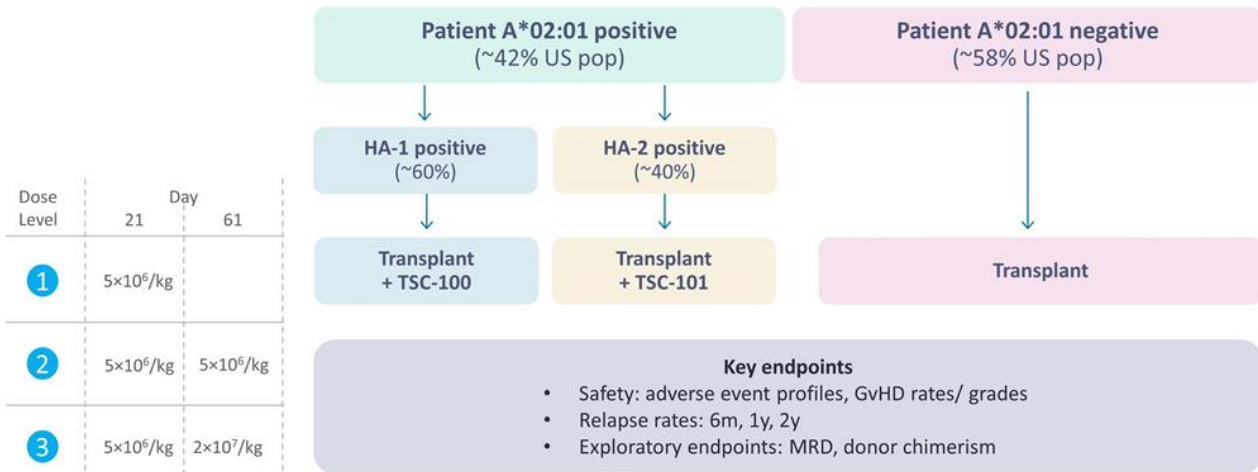
¹City of Hope Medical Center, Duarte CA, ²Mount Sinai Hospital, New York NY, ³Hackensack University Medical Center, ⁴Karmanos Cancer Institute, Detroit MI, ⁵TScan Therapeutics, Waltham MA. ⁶Columbia University Medical Center, New York NY



Confidential

Dose escalation has reached dose level 3 for TSC-100 & TSC-101

AML, MDS, ALL: haploidentical donor transplant with reduced intensity conditioning



Expected relapse rates for HCT alone	
6 months	22%
1 year	33%
2 years	42%

TScan-CIBMTR analysis of RIC-haplo transplants from 2017-2019



Dose Level 3 reached Patient risk factors well-balanced between treatment and control arms

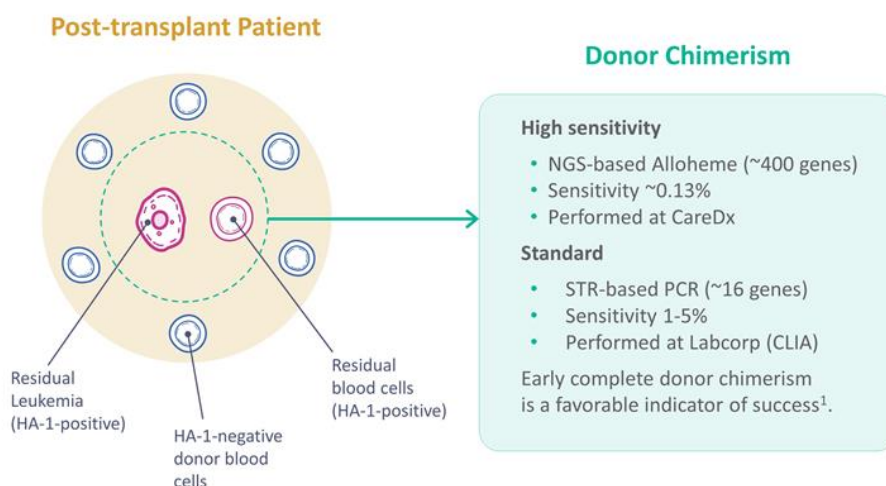
	TSC-100				TSC-101				Control Arm			
Patient ID	P-004-0004	P-007-0002	P-004-0007	P-006-0003	P-004-0001	P-004-0005	P-004-0006	P-004-0008	P-002-0001	P-007-0001	P-006-0001	P-006-0002
Diagnosis	T-ALL	AML	AML	MDS	MDS	AML	B-ALL	B-ALL	MDS	MDS	MDS	AML
Molecular Markers	ATM <2%	FLT3-ITD	Trisomy 8 IDH2, NRAS, ASXL1	SRSF2 ASXL1 STAG2	Del5q, mTP53	IDH2, SRSF2, ASXL1 CUX1	n/a	n/a	Trisomy 8, SRSF2 ASXL1	None	Del5q Mono 7 mTP53	Mono 7, RUNX1, EZH2
Pre-HCT MRD	Positive	Negative	Positive	Positive	Positive	Positive	Negative	Pending	Positive	Negative	Positive	Pending
RIC regimen	Flu/ Cy/ TBI	Thio/ Bu/ Flu	Flu/Mel/ TBI	Flu/Cy/ TBI	Flu/ Mel/ TBI	Flu/Mel/ TBI	Flu/Mel/ TBI	Flu/Mel/ TBI	Flu/ Cy/ TBI	Flu/ Cy/ TBI	Flu/Mel/ Thio	Flu/ Cy/ TBI
HCT date	21 Mar 2023	27 Apr 2023	08 Sep 2023	31 Oct 2023	16 Feb 2023	20 Apr 2023	22 Jun 2023	05 Oct 2023	01 Nov 2022	03 Feb 2023	25 May 2023	29 Aug 2023
Dose Level	DL1	DL2	DL3	DL3	DL1	sDL2 [‡]	DL2	sDL3 [‡]	N/A			
TCR-T treatment day	#1 Day 29	#1 Day 25 #2 Day 76	#1 Day 34 #2 Day 75	#1 Day 27 #2 Day 69*	#1 Day 21	#1 Day 27 #2 Day 82	#1 Day 21 #2 Day 62	#1 Day 27 #2 Day 70*	N/A			

‡ Dose did not meet target dose criteria, * scheduled dosing



Data cutoff Dec. 4, 2023

Key biomarkers for residual leukemia or residual patient-derived blood cells serve as potential early surrogates of efficacy



1. Lindhal, Bone Marrow Transpl, 2022

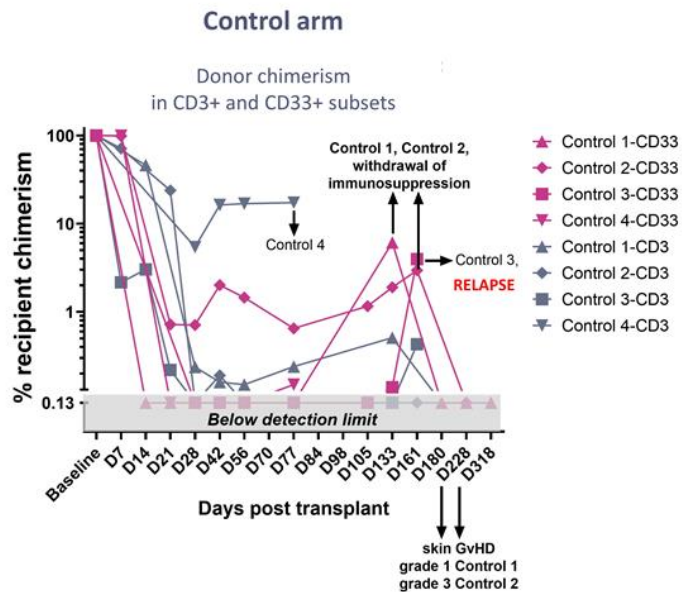
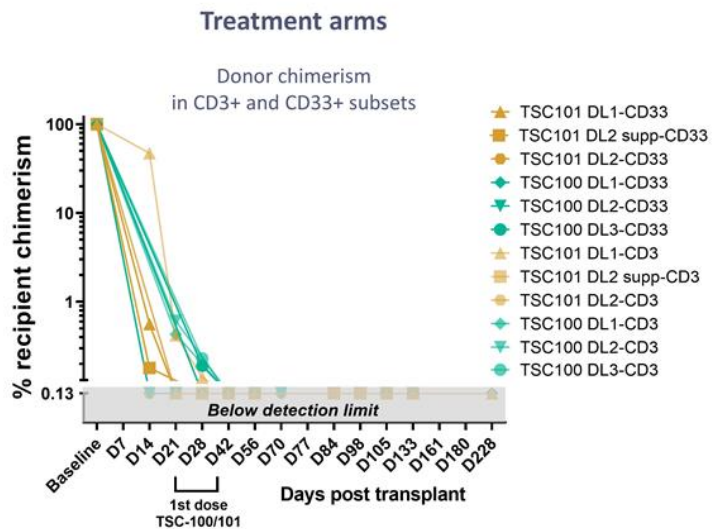
Complete donor chimerism achieved and maintained in 6/6 (100%) treated patients versus 0/4 (0%) control patients

Day post HCT	Treatment arm patients						Control arm patients					
	TSC-100 DL 1	TSC-100 DL 2	TSC-100 DL 3	TSC-101 DL 1	TSC-101 DL 2-supp	TSC-101 DL 2	Control patient #1	Control patient #2	Control patient #3	Control patient #4		
Day 21/28	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	
Day 42	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	◆ TSC-100/101 dosing
Day 56	✓	✓	✓	✓	✓	✓	✗	✗	✓	✗	✗	✗ NGS-mixed donor chimerism
Day 77	✓	✓		✓	✓	✓	✗	✗	✓	✗	✗	✗ NGS and STR-mixed donor chimerism
Day 105	✓	✓		✓	✓	✓	✗	✗	✓			✓ NGS and STR-complete donor chimerism
Day 133	✓	✓		✓	✓	✓	✗	✗	✓			⊗ Clinical intervention for increasing mixed chimerism (STR)
Day 161	✓			✓			✓	✗	✗			
Day 228	✓			✓			✓	✓		Relapse Day 180		

Donor chimerism detected by high-sensitivity next-generation sequencing (NGS) assay (AlloHeme) with limit of detection 0.13% or CLIA-certified short-tandem read (STR) PCR assay with limit of detection 1-5%



Complete chimerism maintained >7 months in treated patients; Worsening chimerism and one relapse observed in control-arm patients



Key biomarkers for residual leukemia or residual patient-derived blood cells serve as potential early surrogates of efficacy

Minimal Residual Disease (MRD)

High sensitivity

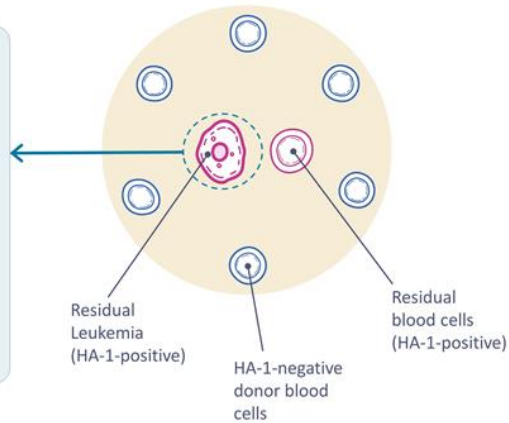
- Next-gen sequencing
- Sensitivity ~0.1%
- Performed at Columbia University

Standard

- Flow cytometry
- Variable sensitivity
- Performed at treating site

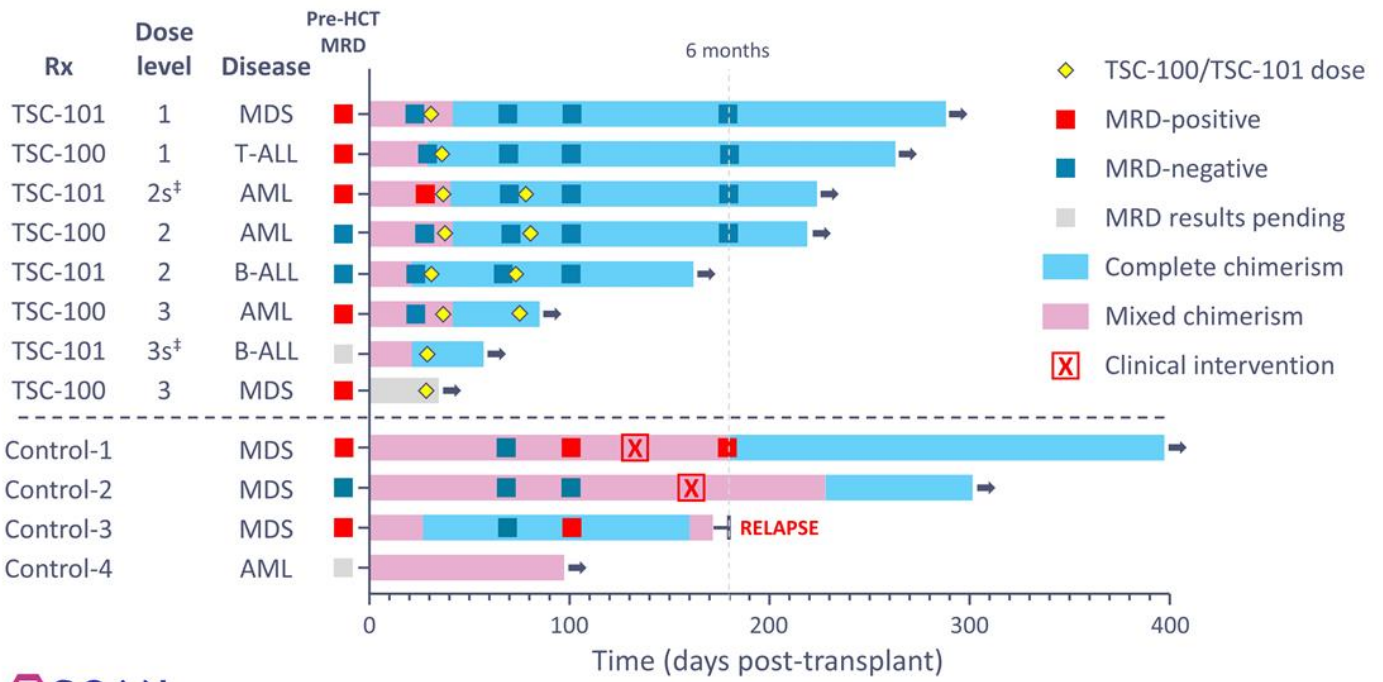
MRD+ patients post-transplant (~30%) have ~90% chance of relapse^{1,2}.

Post-transplant Patient



1. Craddock, J Clin Oncol, 2021
2. Loke, ASH, 2021

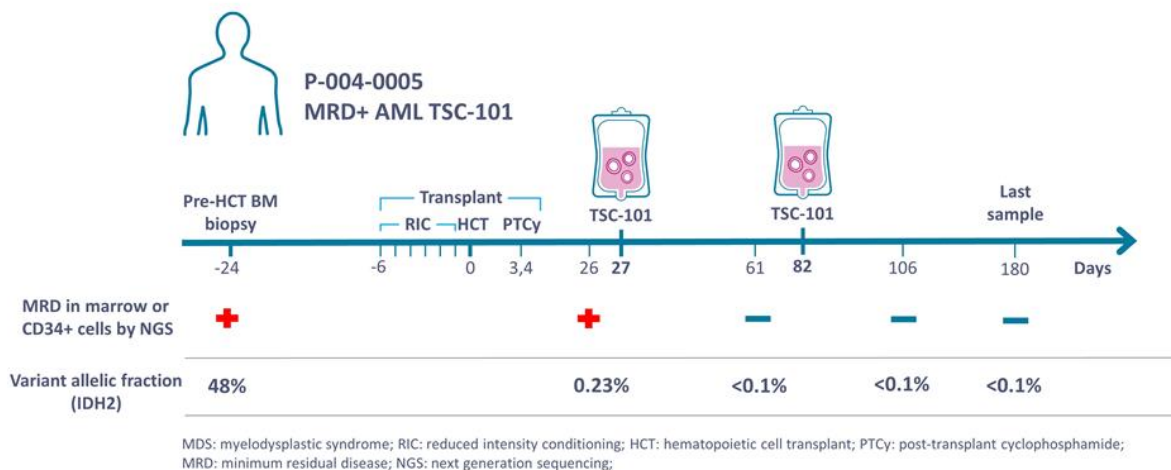
All treated patients achieved MRD negativity & complete donor chimerism*



*MRD and chimerism determined by NGS (lower limits of detection 0.05-0.1% and 0.13%, respectively)

‡ Dose did not meet target dose criteria in supplemental cohorts

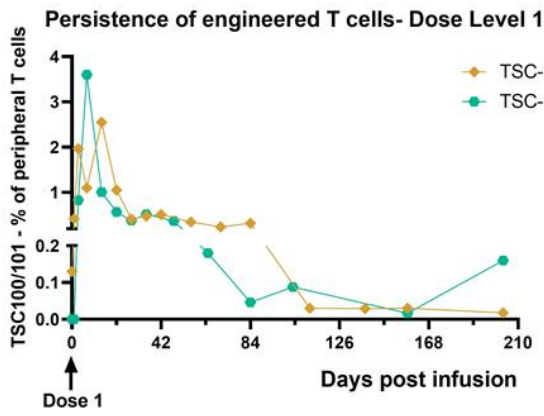
One AML patient converted from MRD-positive post-transplant to MRD-negative following treatment with TSC-101



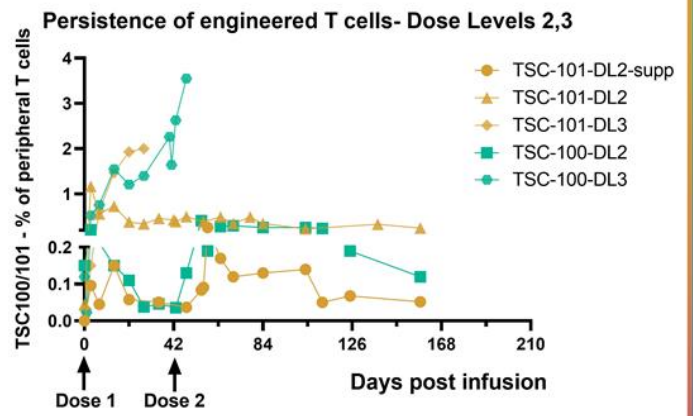
TSC-100 & TSC-101 persisted in peripheral circulation for over 200 days

- All patients had detectable TSC-100 or TSC-101 TCR-T cells at all time points to date
- Repeat dosing resulted in increased levels of circulating TCR-T cells

Single dose cohorts



Repeat dose cohorts



Most frequent \geq grade 2 adverse events* were similar between treatment and control arms

Adverse event \geq Grade 2	TSC-100/ 101 arms Highest Grade# N=8	Control arm Highest Grade# N=4
Anemia	3	4
Abdominal Pain	2	2
Nausea/ vomiting	2	2
Diarrhea	3	2
Fatigue	2	2
Pyrexia	2	3
Pneumonia	2	3
ALT/ AST increased	3	2
Thrombocytopenia	4	4
Neutropenia	3	3
Creatinine increased	2	2

* Events after Day 21 or after TSC-100/TSC-101

Grading by CTCAE v 5.0



TSC-100/TSC-101 arms had median post-HCT follow-up 193 days (34-291 days)
Control arm had median post-HCT follow-up 249 days (97-398 days)

Serious adverse events were similar between treatment and control arms

Arm	Patient ID	Serious Adverse Event	Highest Grade*	Post Transplant Day	TSC Relatedness
TSC-100-DL3	P-004-0007	Sepsis, respiratory failure	4	+9	Not applicable (pre-TSC)
TSC-101-DL2supp	P-004-0005	Pyrexia	1	+21	Not applicable (pre-TSC)
TSC-101-DL1	P-004-0001	Acute graft versus host disease in gastrointestinal tract, acute kidney injury	3	+49	Possible related
TSC-101-DL1	P-004-0001	Adenovirus viremia, Pneumonia, Clostridium difficile infection	2	+71	Not Related
TSC-101-DL1	P-004-0001	Pyrexia	1	+148	Not Related
TSC-101-DL1	P-004-0001	Interstitial pneumonitis	2	+182	Not Related
Control Arm	P-006-0001	Cytokine release syndrome	2	+2	Not Applicable
Control Arm	P-006-0002	Neck pain	3	+53	Not Applicable
Control Arm	P-007-0001	Acute graft versus host disease in skin	3	+49	Not Applicable
Control Arm	P-007-0001	Acute graft versus host disease in gastrointestinal tract	3	+53	Not Applicable
Control Arm	P-007-0001	Pneumonia	3	+56	Not Applicable

*Grading by CTCAE v5.0 or MAGIC consortium grading for GvHD or ASTCT grading for CRS

Adverse events of special interest were similar between treatment and control arms

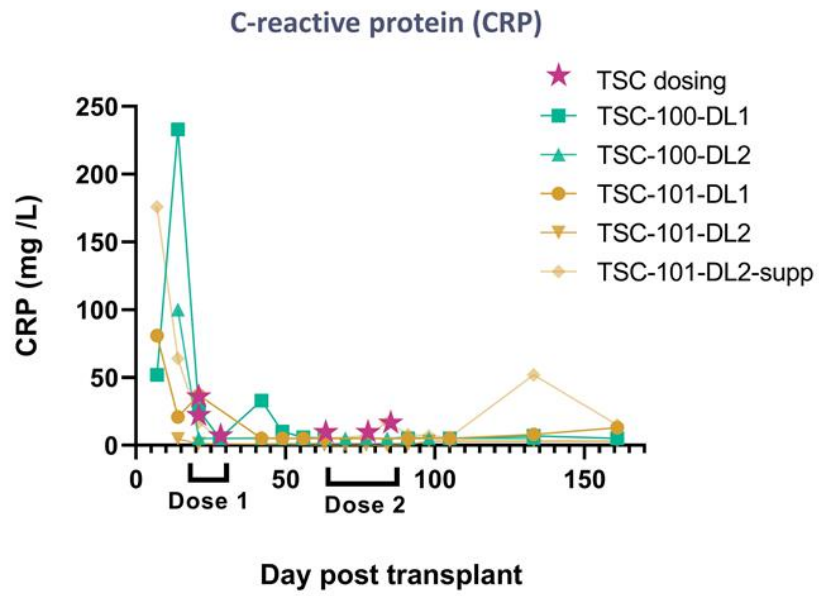
All cytokine release syndrome (CRS) events occurred before TSC-100/ TSC-101 treatment

Arm-Dose Level	Patient ID	Grade*	Adverse Event	Transplant Day of Onset	Duration	TSC relatedness
TSC-100-DL2	P-007-0002	Grade 1	CRS	+3	2 days	Not applicable (pre-TSC)
TSC-101- DL2supp	P-004-0005	Grade 2	CRS	+1	3 days	Not applicable (pre-TSC)
TSC-101-DL2	P-004-0006	Grade 1	CRS	+1	5 days	Not applicable (pre-TSC)
Control	P-002-0001	Grade 1	CRS	+2	3 days	Not applicable
Control	P-007-0001	Grade 1	CRS	+3	2 days	Not applicable
Control	P-006-0001	Grade 2	CRS	+2	2 days	Not applicable
TSC-100-DL1	P-004-0004	Grade 1	Skin GvHD	+48	8 days	Possibly related
TSC-101-DL1	P-004-0001	Grade 3	GI GvHD	+49	8 days	Possibly related
TSC-101-DL2supp	P-004-0005	Grade 1	Skin GvHD	+43	3 days	Possibly related
TSC-101-DL2	P-004-0006	Grade 1	Skin GvHD	+127	7 days	Possibly related
Control	P-007-0001	Grade 3	GI GvHD	+53	18 days	Not applicable
Control	P-007-0001	Grade 3	Skin GvHD	+49	12 days	Not applicable
Control	P-002-0001	Grade 1	Skin GvHD	+180	pending	Not applicable

*MAGIC consortium grading for graft-versus host disease (GvHD); ASTCT grading for cytokine release syndrome (CRS)

Lab markers of CRS changed minimally after TSC-100 or TSC-101 administration

No clinical CRS or neurotoxicity reported after TSC-100 or TSC-101 dosing



Summary and next steps

- Initial data look promising, with no relapses in treatment arms (median follow-up >6 months)
- TSC-100 and TSC-101 eliminated all detectable patient-derived malignant, pre-malignant, and benign cells in every patient treated to date
- TSC-100 and TSC-101 were generally well-tolerated, and the third and final dose level has been reached
- 10 clinical sites are currently enrolling patients
 - We plan to open expansion cohorts at the recommended Phase 2 dose
 - We anticipate expanding to 15 sites by mid-2024

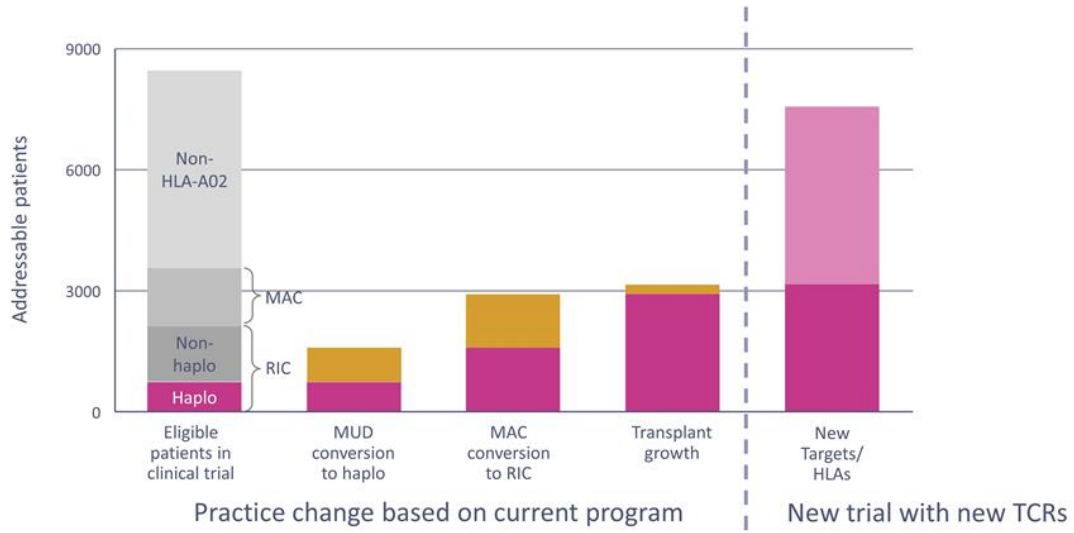


Questions and Answers



Potential near-term opportunity to address the unmet need for thousands of patients

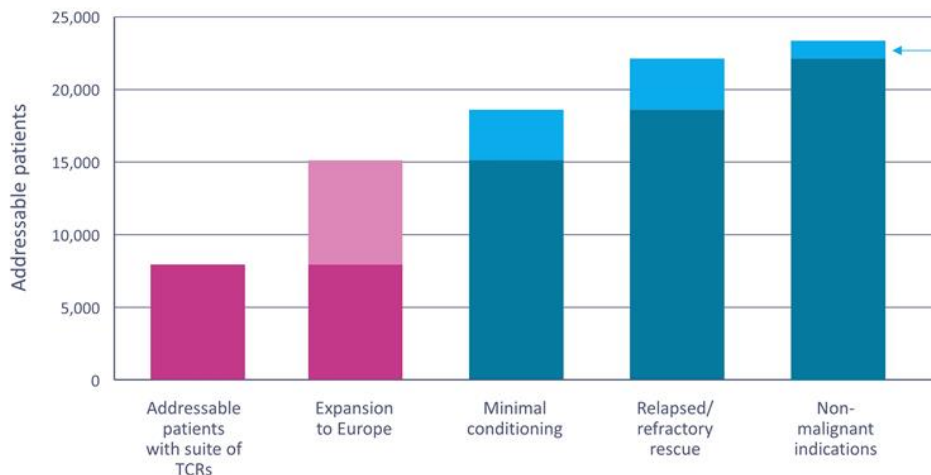
US addressable market could triple with changes in transplant practice and double with additional HLAs and targets



HCT: Hematopoietic Cell Transplant. MAC: Myeloablative Conditioning; MRD: Matched Related Donor; MUD: Matched Unrelated Donor, RIC: Reduced Intensity Conditioning
 Source: SEER, CIBMTR, ClearView Analysis

Long-term opportunities to address tens of thousands of patients globally in multiple indications

Several global expansion and lifecycle management opportunities to address additional patient populations with significant unmet needs



Non-malignant diseases that receive haplo transplants:

- Sickle cell disease
- Inherited erythrocyte differentiation/function abnormalities
- SCID and other immune disorders
- Histiocytic disorders
- Inherited platelet disorders
- Inherited metabolism disorders
- Autoimmune diseases



Source: SEER, CIBMTR, ClearView Analysis