# KOL Event

December 10, 2024

# THERAPEUTICS

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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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**SCAN** 

### Agenda

- Ran Reshef, M.D., M.Sc., Director of Translational Research, Blood and Marrow Transplantation Program, Columbia University Irving Medical Center
  - Results from ALLOHA<sup>™</sup> 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



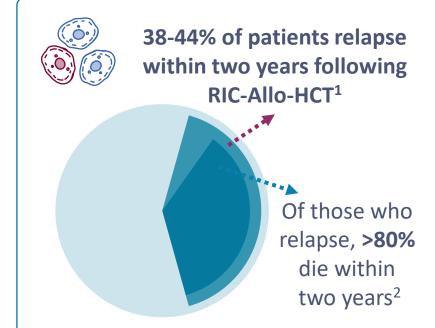
### TSC-100 and TSC-101 Demonstrate the Potential to Reduce Relapse Rates and Increase Relapse-free Survival in Patients with AML, ALL, or MDS Undergoing Allogeneic HCT with Reduced Intensity Conditioning (RIC): Preliminary Results from the Phase 1 ALLOHA Trial

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### Relapse after hematopoietic cell transplant remains an unmet need

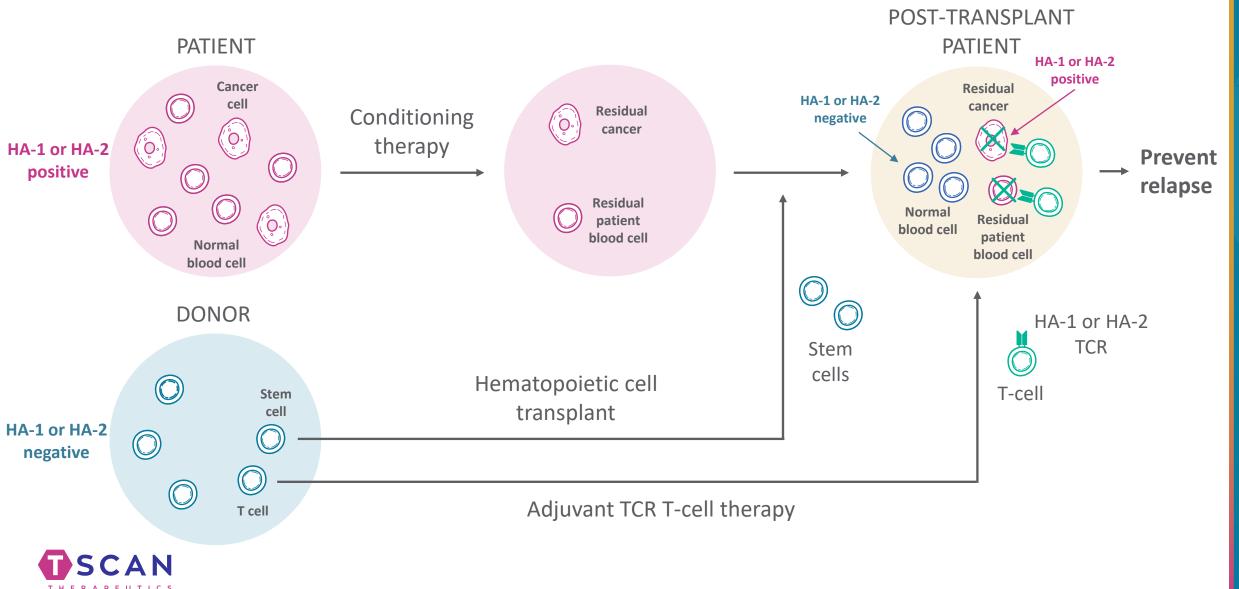
- Allogeneic hematopoietic cell transplantation (HCT) can cure some patients with AML, ALL or MDS
- Advances in reduced intensity conditioning (RIC-HCT) regimens as well as GvHD prophylaxis with post-transplant cyclophosphamide (PTCy) have expanded patient access to HCT by markedly improving treatmentrelated 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



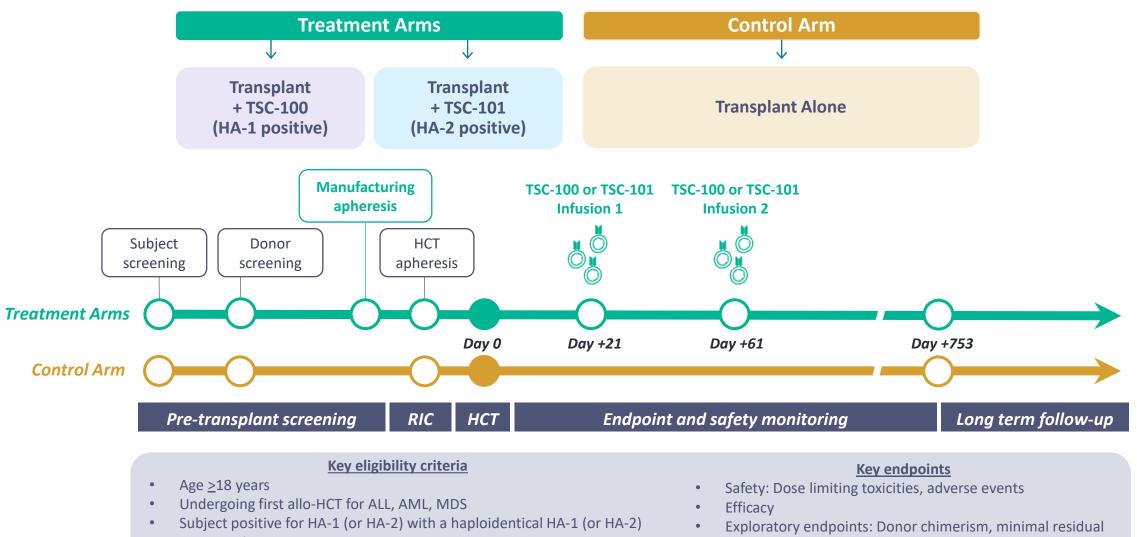


2. Schmid, Blood 2012, Spyridonidis, Leukemia 2012, Schmid, Haematologica 2018

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



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



- negative donor
- Eligible for RIC-HCT followed by PTCy for GvHD prophylaxis

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

disease

### 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 (14%)	2 (17%)	4 (15%)	0 (0%)
	AML	10 (71%)	7 (58%)	17 (65%)	8 (62%)
	MDS	2 (14%)	3 (25%)	5 (19%)	5 (38%)
	TP53 mutated	4 (29%)	2 (17%)	6 (23%)	2 (15%)
Genetics/ cytogenetics	FLT3 mutation	2 (14%)	0 (0%)	2 (8%)	5 (38%)
	Adverse Risk**	11 (79%)	10 (83%)	21 (81%)	8 (62%)
Pre-HCT MRD positive***		8 (57%)	5 (42%)	13 (50%)	7 (54%)
MRD positive or adverse risk genetics		11 (79%)	10 (83%)	21 (81%)	10 (77%)

\*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).

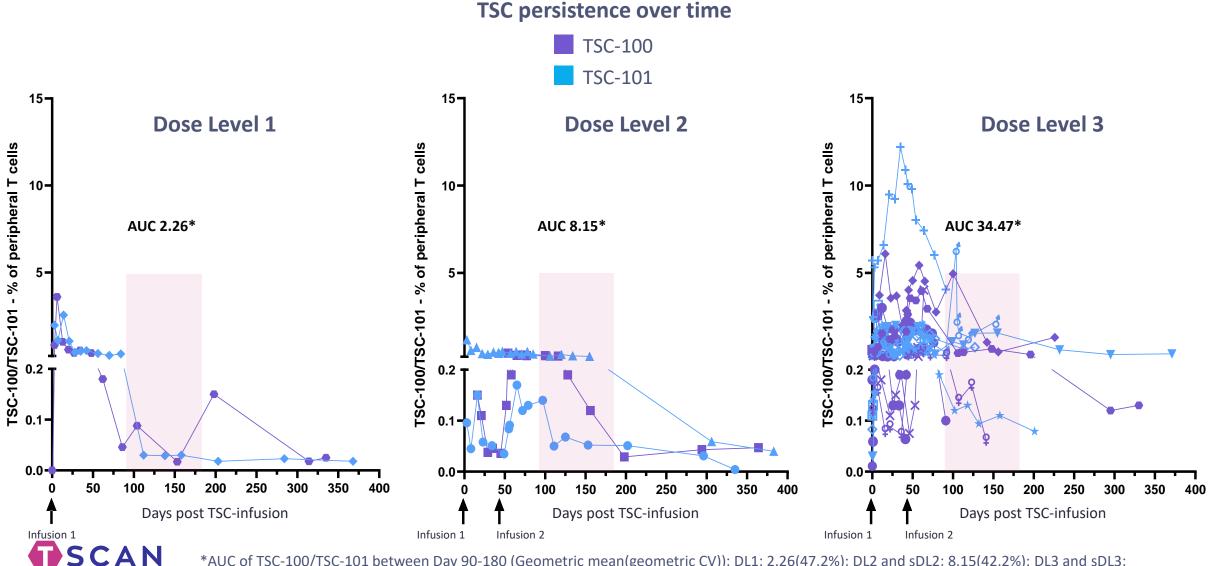


#### Subjects treated at all three dose levels with no dose-limiting toxicities

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



## 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*	<b>TSC-100</b> n=10	<b>TSC-101</b> 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



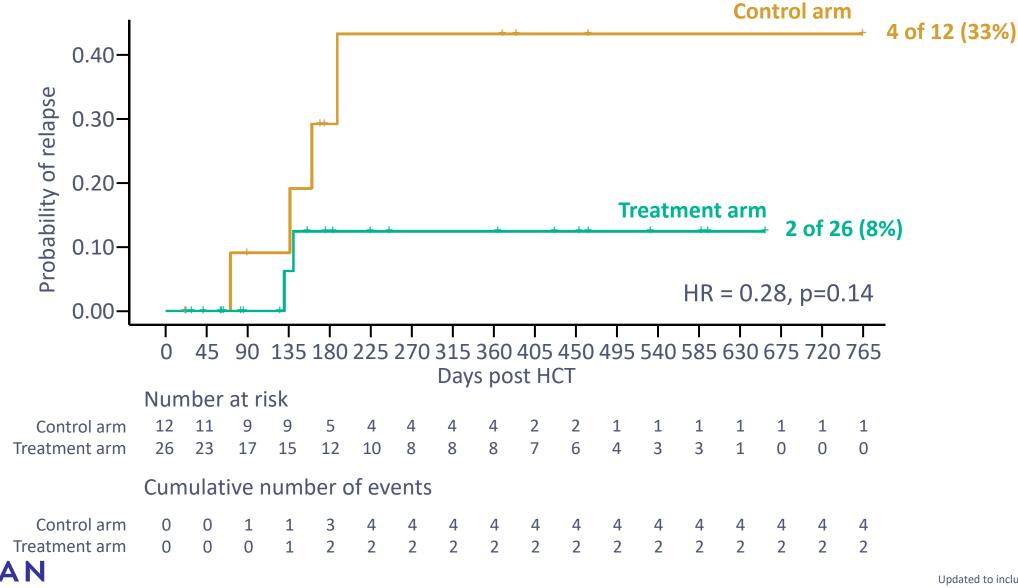
#### Grade <a>3</a> treatment emergent adverse events are consistent with transplantation

Events in >5% of subjects	Any TSC n=22	<b>Control</b> 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)
Нурохіа	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



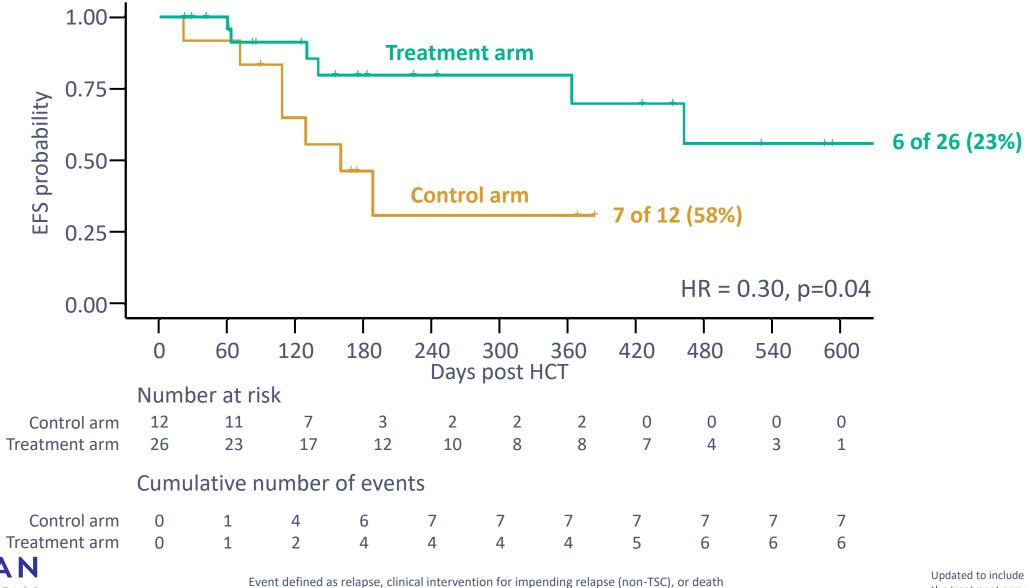
#### TCR-T infusion is associated with fewer relapses



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

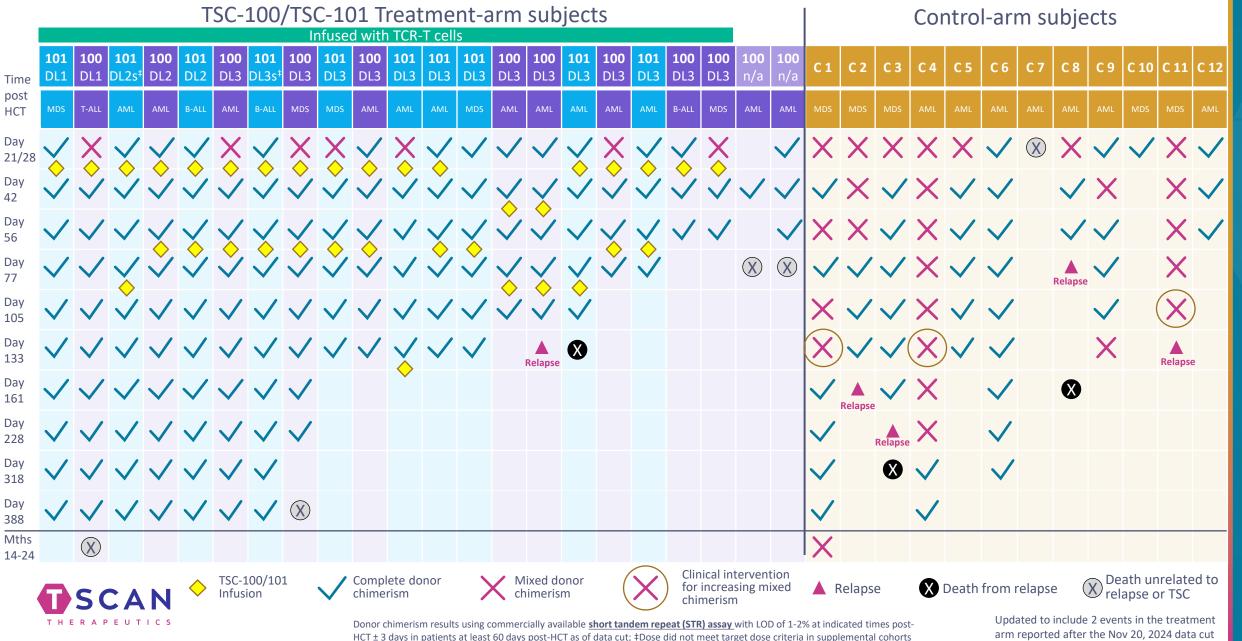
#### Event-free survival (EFS) favors the treatment arm



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



### 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<sup>1</sup>
- Died Day 129 post transplant with suspected relapse

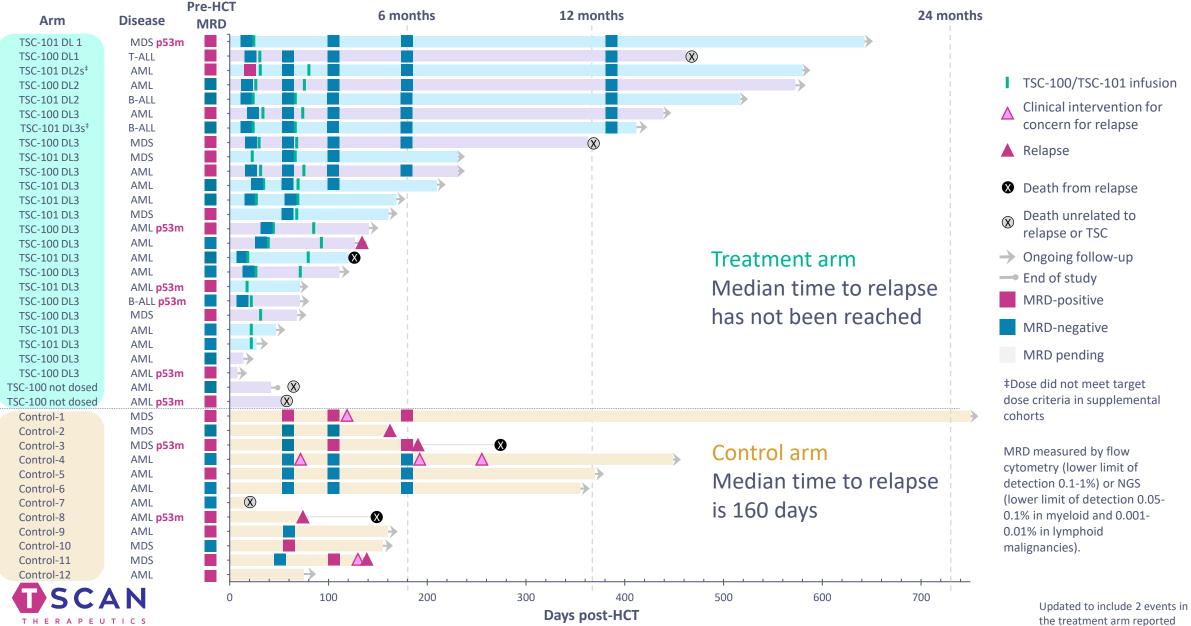
#### TSC-100 Dose Level 3

- 59 y/o male with AML
- Donor apheresis for manufacturing occurred <u>after</u> G-CSF mobilization<sup>2</sup>
- 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

Neither circumstance would be permitted in pivotal trial

<sup>1</sup> Not observed in any other patient <sup>2</sup> Occurred twice

#### MRD negativity achieved in all treatment-arm subjects



the treatment arm reported after the Nov 20, 2024 data cut

#### 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 dosepersistence 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



### Pivotal trial design and heme development strategy



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

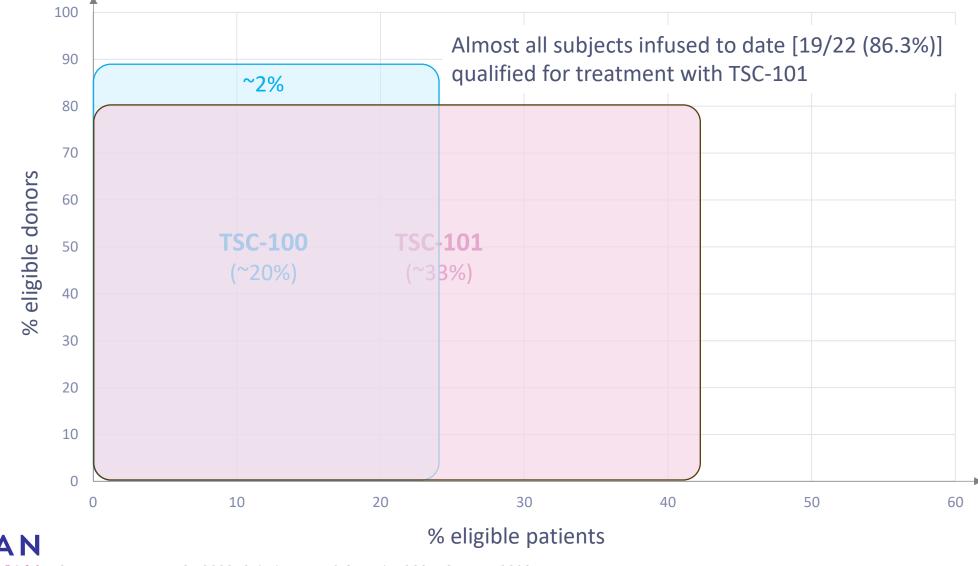
#### CMC

- 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

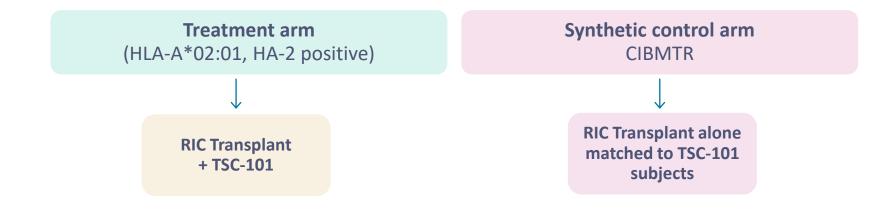
TSC-101 captures ~98% of HLA-A\*02:01-positive patients, obviating the need for TSC-100 or a companion diagnostic



<sup>U</sup>TICS 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

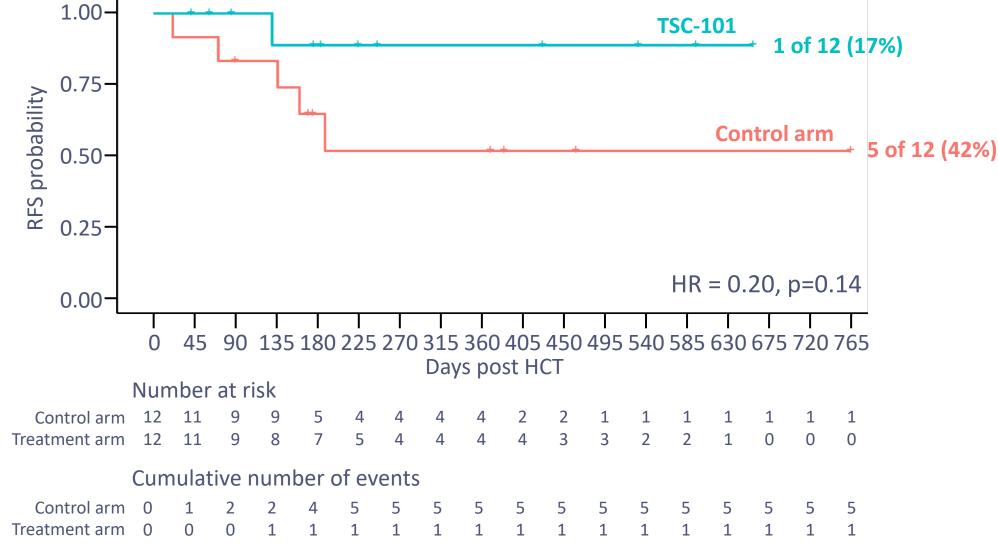
- **Primary**: Relapse-free survival (RFS; Full approval)
- Key Secondary: Overall survival, time to relapse, event-free survival
- **Exploratory**: MRD, complete chimerism rates

#### Readouts

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



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





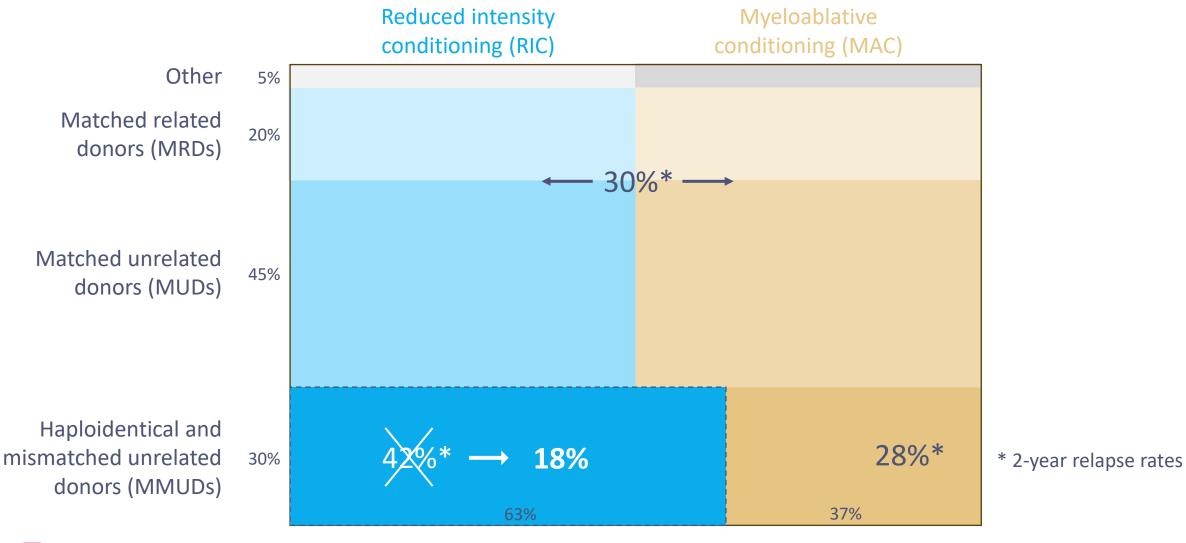
Event defined as relapse, or death CoxPH Ratio = 0.2, CI = (0.023, 1.718), p = 0.1425; Log-rank p = 0.1034

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



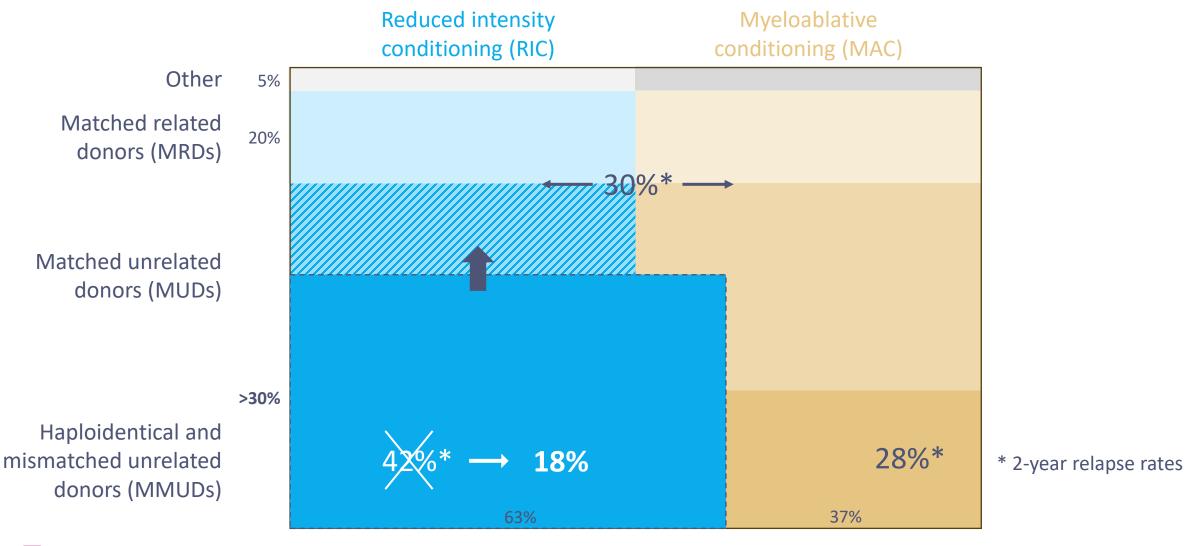
**SCAN** THERAPEUTICS

• 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

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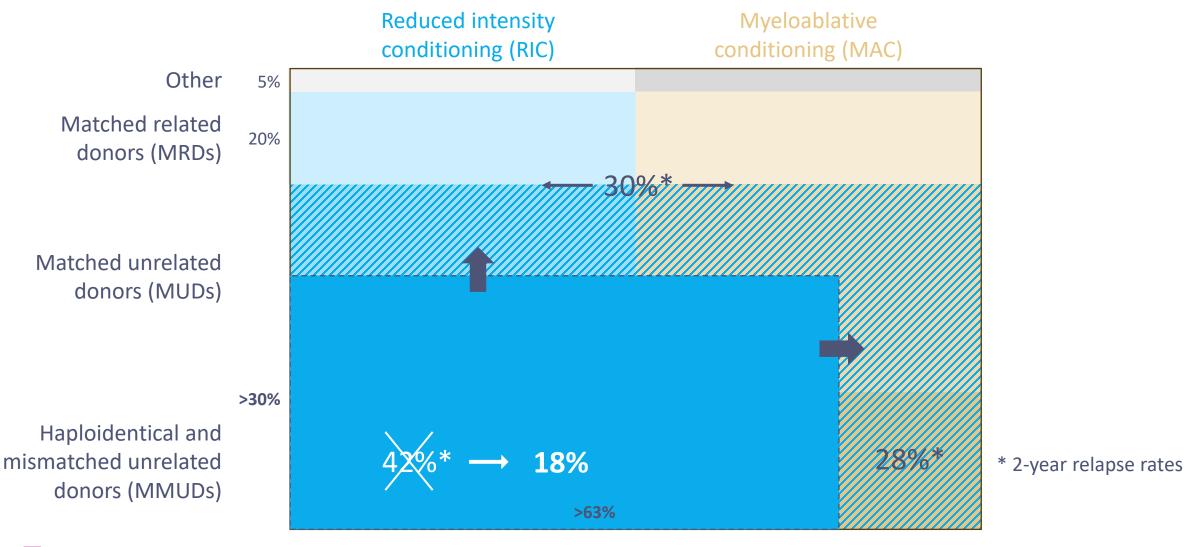




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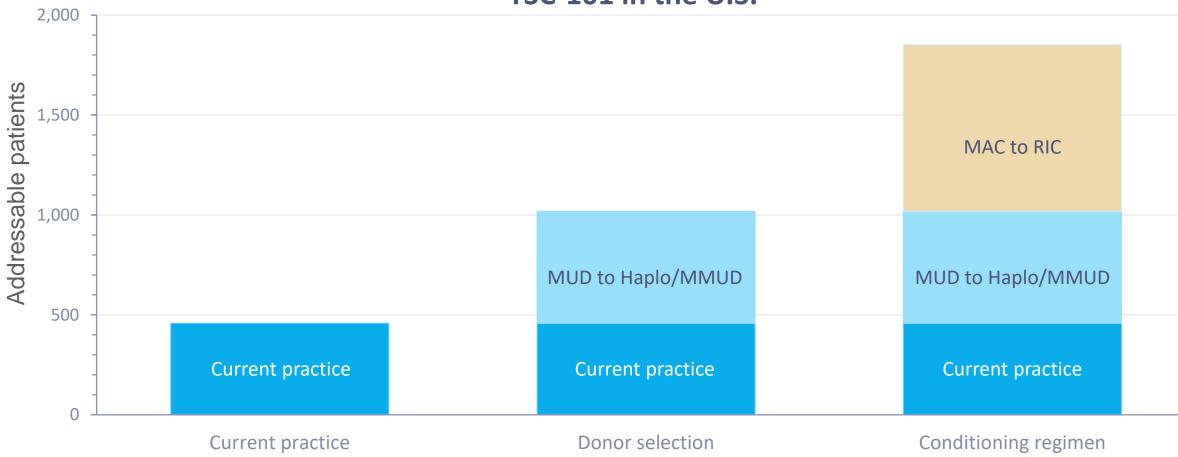
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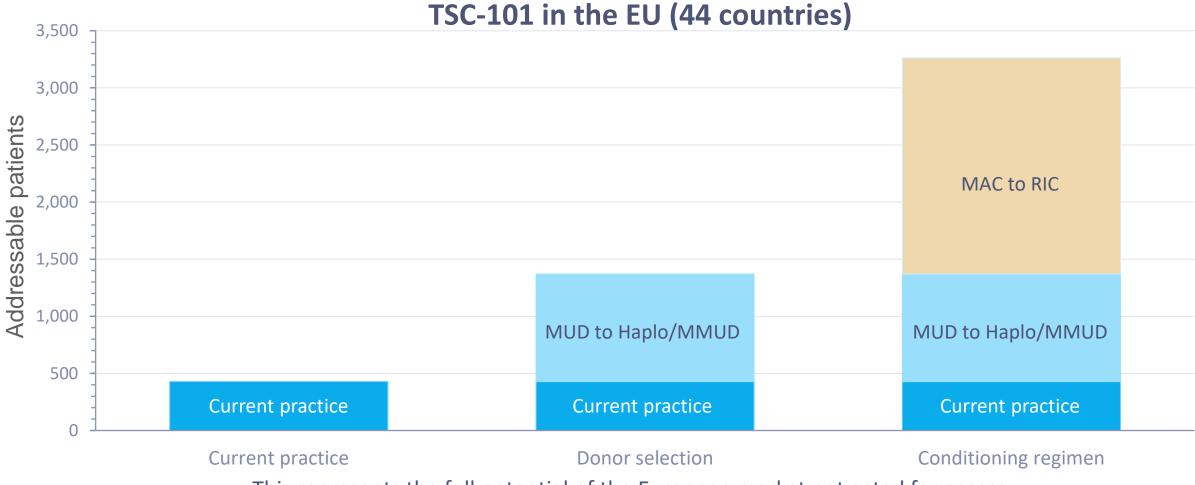
CIBMTR analysis of AML, ALL, MDS allogeneic transplants with reduced intensity conditioning (RIC) between 2017-2019 with 2-year follow-up Increased use of reduced intensity conditioning with haploidentical/MMUD donors has the potential to expand the addressable market dramatically



#### TSC-101 in the U.S.

**SCAN** 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

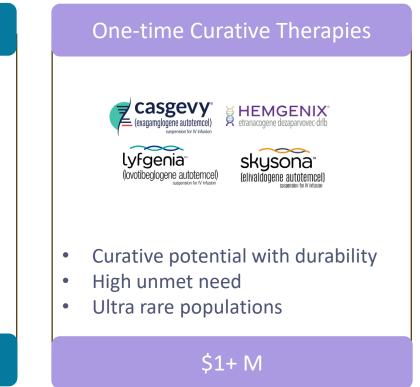
#### ~\$300-500 K

#### Recent TIL and TCR-T Approvals



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

~\$500-750 K



#### **TSC-101**

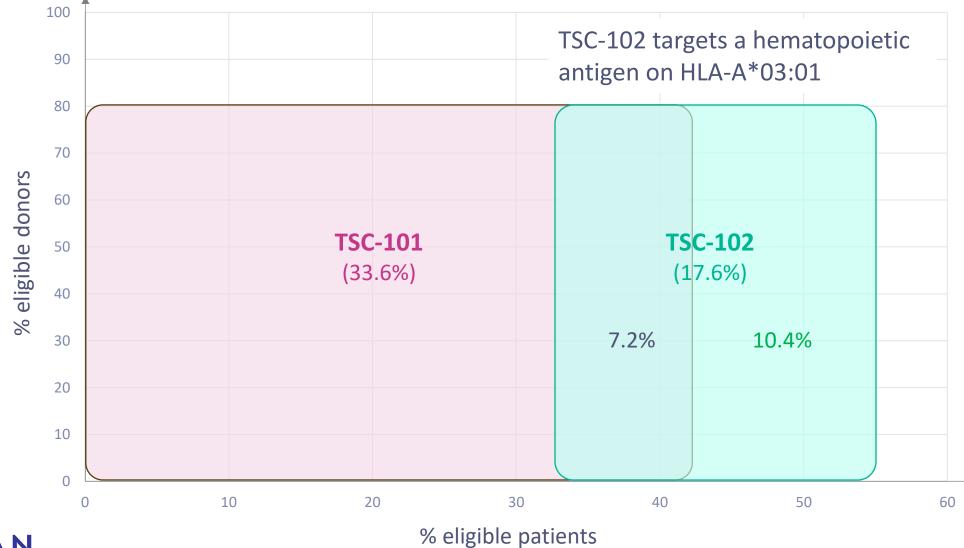
Early engagement with payers and ongoing clinical market research at leading transplant centers confirm value messaging and support practice change based on TSC-101 product characteristics



### Expansion opportunities

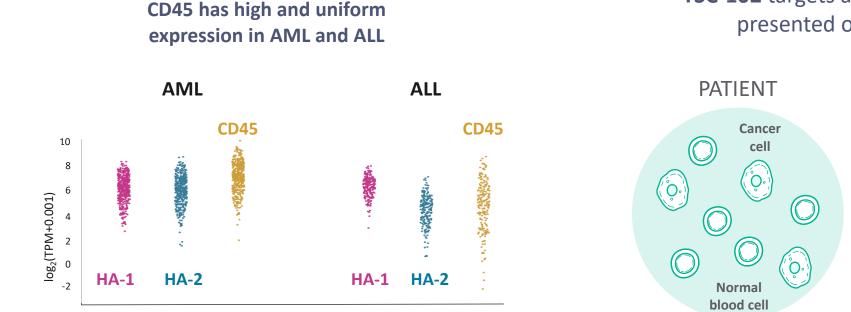


The addressable market can be expanded with the introduction of additional TCR-Ts that target other HLA types



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

- 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)



Stem cell O O O T cell

DONOR

HLA-A\*03:01-positive

HLA-A\*03:01-negative

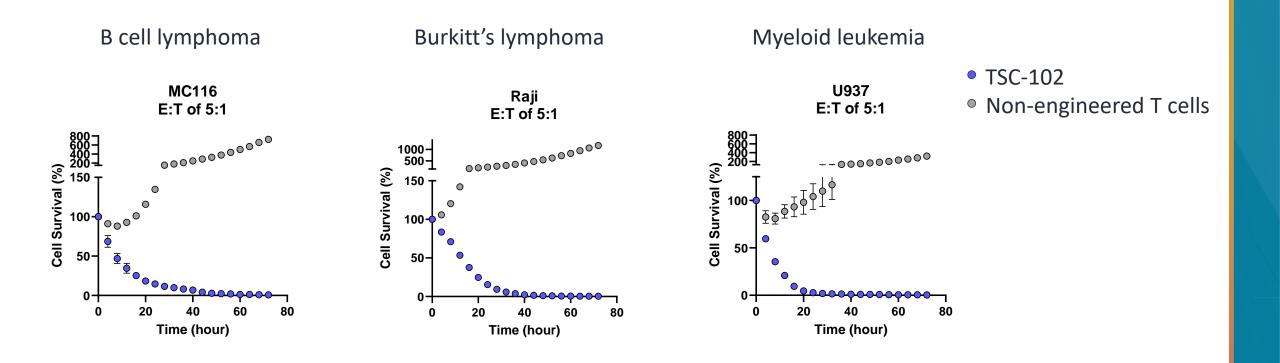


Source: TCGA

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

Lead TCR for TSC-102 selectively kills A\*03:01<sup>+</sup>/CD45<sup>+</sup> cancer cell lines

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

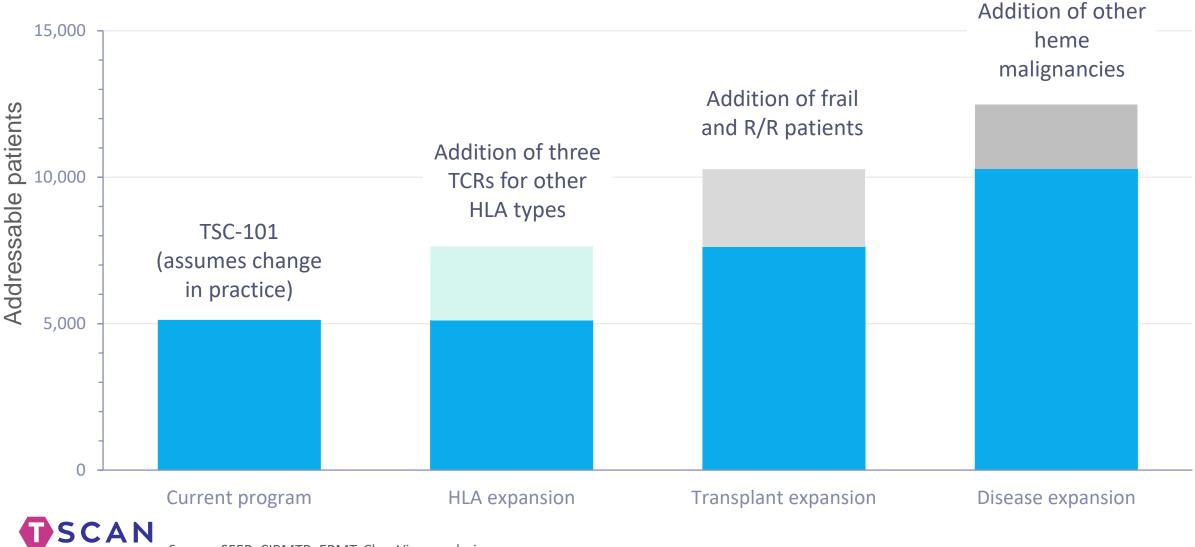




### Eight TCR-T candidates in clinical development, with new TCR-Ts advancing

	Indications	Programs (target)	HLA type	Discovery	Lead optimization	IND-enabling	Phase 1	Phase 2/3
		<b>TSC-100</b> (HA-1)	HLA-A*02:01					
	AML, MDS, ALL	<b>TSC-101</b> (HA-2)	HLA-A*02:01					
		<b>TSC-102</b> (CD45)	HLA-A*03:01			<b>— *</b>		
HPV+ SOLID TUMORS	Head & Neck, Cervical, Anal	(	HLA-A*02:01 HLA-C*07:02					
	NSCLC, Head & Neck, Sarcoma	<b>TSC-201</b> (MAGE-C2)	HLA-B*07:02 HLA-A*02:01 HLA-A*24:02					
SOLID TUMORS		<b>TSC-202</b> (MAGE-A4)	HLA-A*02:01					
(T-PLEX)		<b>TSC-203</b> (PRAME)	HLA-A*02:01 HLA-B*07:02 HLA-A*24:02					
		<b>TSC-204</b> (MAGE-A1)	HLA-A*02:01 HLA-C*07:02 HLA-A*01:01 HLA-A*03:01 HLA-B*07:02					
AUTOIMMUNITY	Crohn's	AMGEN						
	AN							

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



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









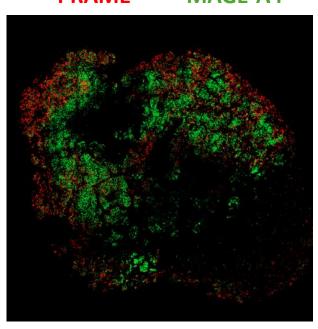
## Solid tumor program update



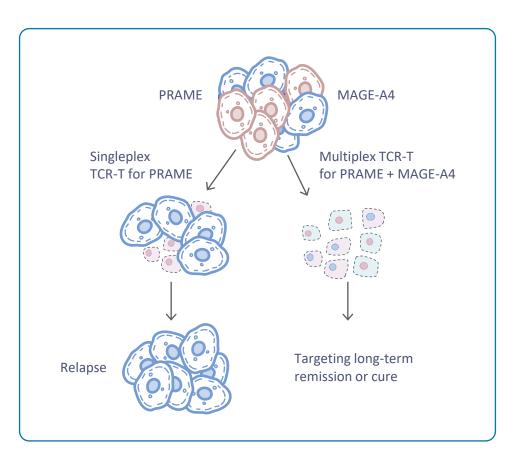
### Multiplex TCR-T therapy is designed to address the heterogeneity of solid tumors

Many immune-rich cancers exhibit target heterogeneity

### Non-small cell lung cancer PRAME MAGE-A4

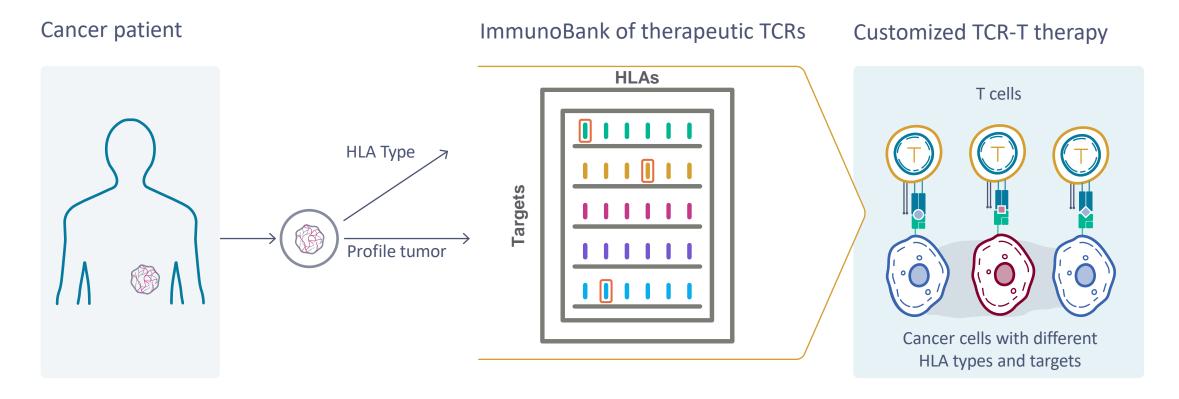


TCR-Ts against multiple targets may be required to improve efficacy and durability





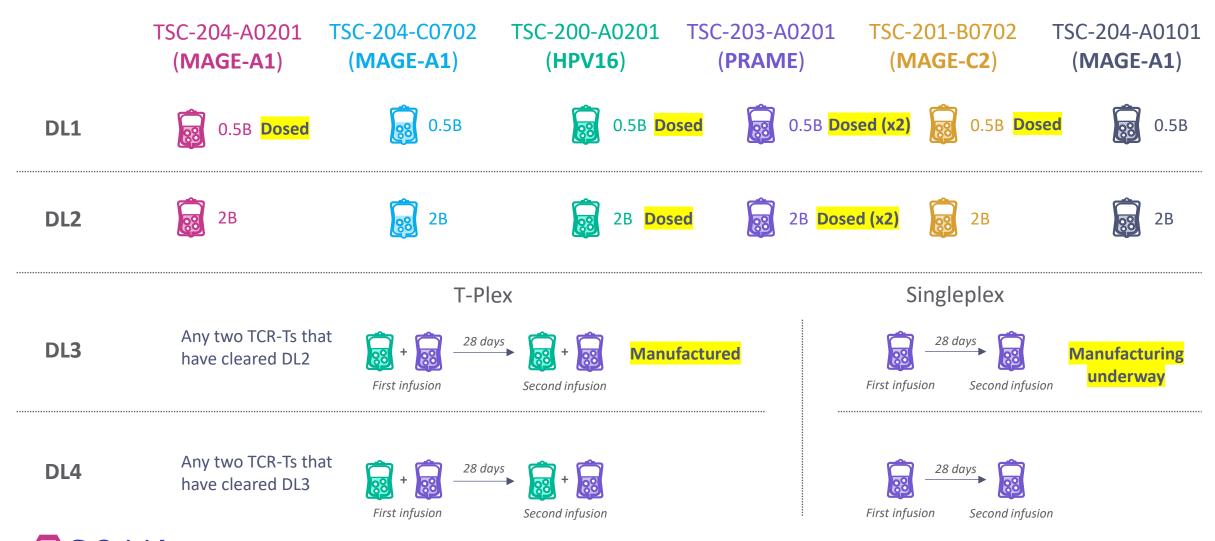
# TScan is building and expanding the ImmunoBank of TCRs to enable enhanced, multiplex TCR-T cell therapy



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



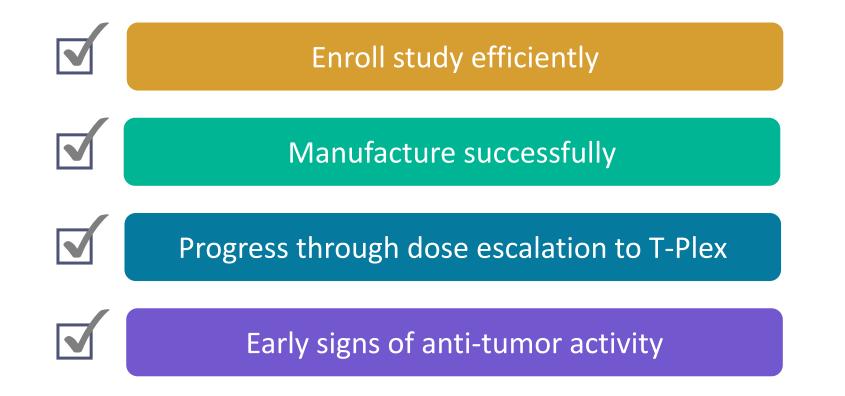
Dose escalation scheme provides a rapid path to multiplex TCR-T in Phase 1





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





## Strategy for 2025



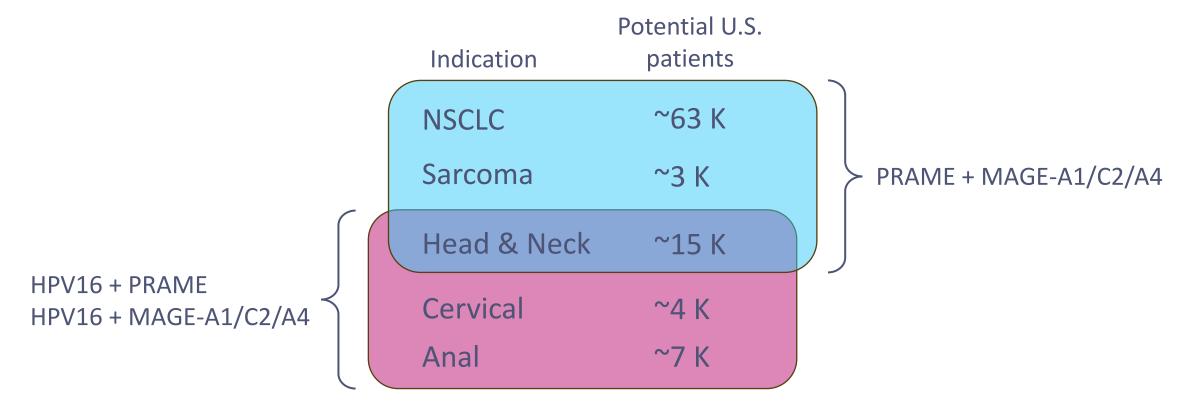
## Program will focus on immune-rich cancers with high unmet need

- Initial patients have included all comers
  - Anal, Head & Neck, Melanoma, NSCLC, Ovarian, Sarcoma, Thyroid
- We have now reached dose levels that enable T-Plex
- <u>T-Plex and DL3 singleplex are expected to be</u> 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

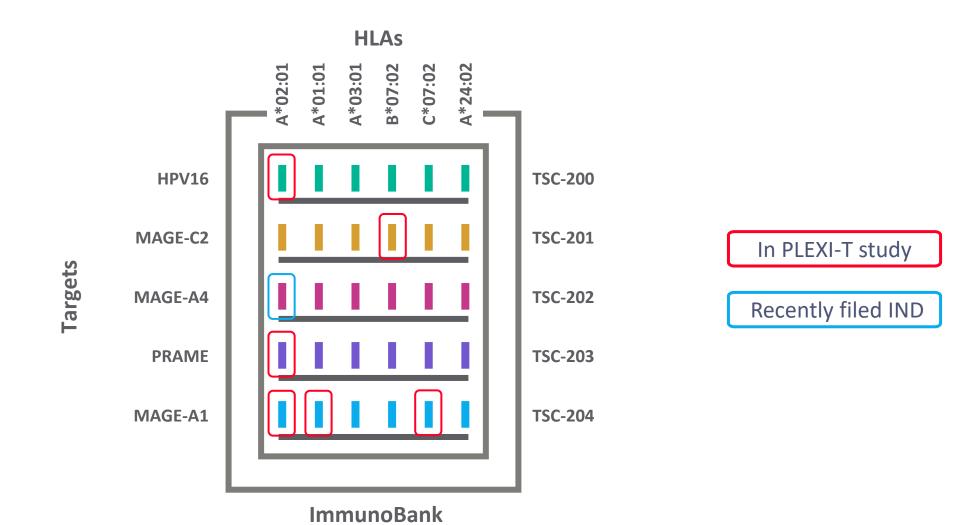


## T-Plex enrollment will focus on four key indications with high unmet need



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

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



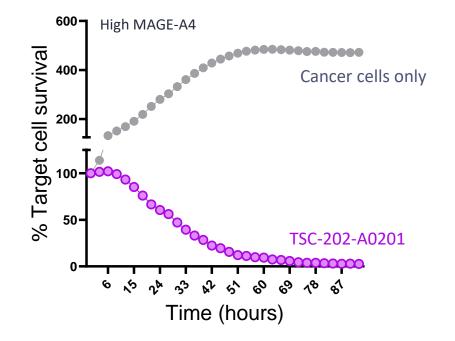


### T-Plex eligibility expected to increase substantially with addition of MAGE-A4

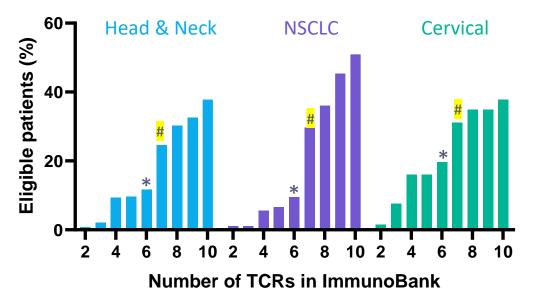
MAGE-A4 A\*02:01 IND submitted

T-Plex eligibility increases as ImmunoBank grows

#### Strong cancer cell killing



Eligible patients are already being identified for MAGE-A4



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



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



### 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

