

**Ambition: Curing Blood Cancers  
through cell and genome engineering**

December 2024



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# Vor Bio Clinical Strategy

## Thesis: Trem-cel as a Therapeutic Platform

Enabling multiple targeted therapy modalities



ADCs



CAR-Ts

### Early Clinical Strategy

### Current Clinical Findings



**Trem-cel**

+



**Mylotarg**



**VCAR33<sup>ALLO</sup>**

- Demonstrate clinical proof-of-principle with Mylotarg as approved agent
  - Engraftment of gene engineered graft
  - Shielding the blood system
- Most rapid path to Treatment System

- Testing as monotherapy in post-transplant relapse

Encouraging data with commercial promise

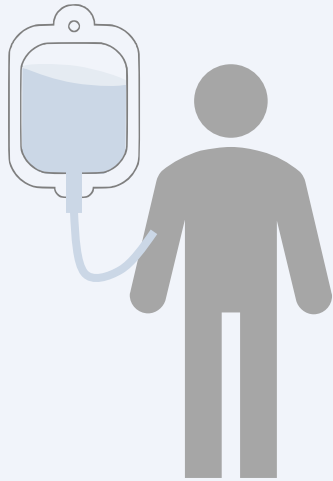
- 100% engraftment
- Robust shielding of the blood system
- Broadened therapeutic index for Mylotarg
- Early evidence of patient benefit (RFS)

- Encouraging biomarker data at lowest dose



# Even After Transplant, High-Risk AML Has Poor Outcomes

## Transplant



A mainstay treatment

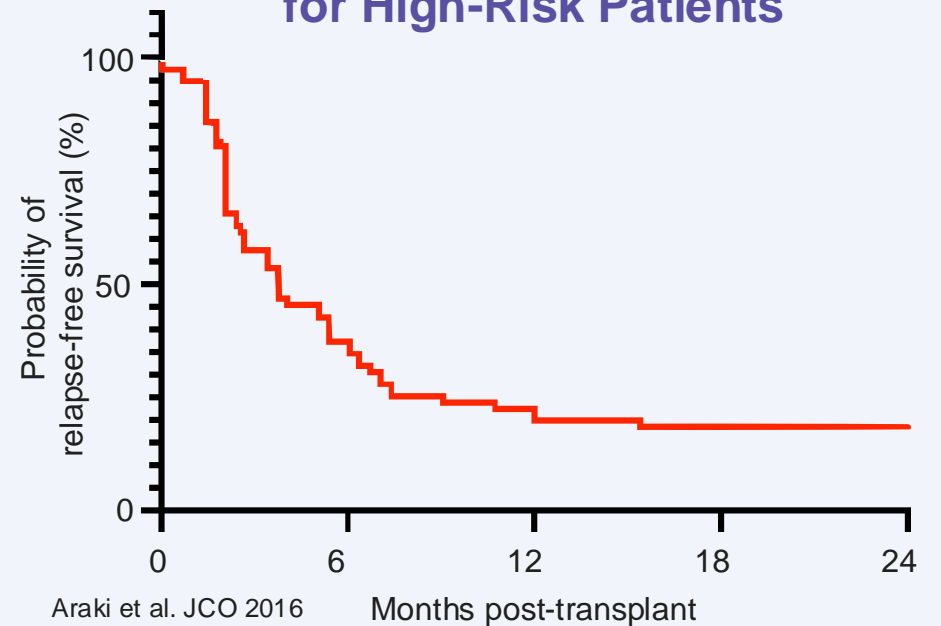
## After Transplant



Maintenance therapy  
unfeasible due to  
drug toxicity

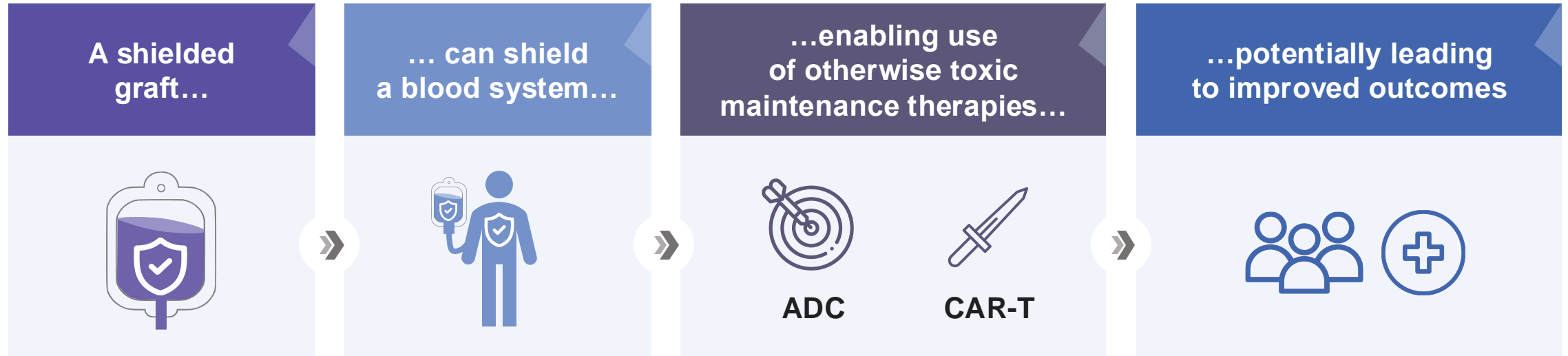
Frequent leukemia relapses and death, poor outcomes

### Watchful Waiting Outcomes for High-Risk Patients





# What If Shielding Could Lead to Improved Outcomes?

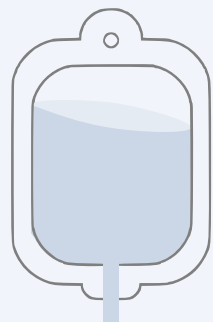


## Required Shielded Graft Attributes

- ✓ **Engraftment**  
Reliably reconstitute the blood system
- ✓ **Shielding**  
Protect against otherwise toxic therapies
- ✓ **Therapeutic Index**  
Optimize efficacy and safety of maintenance therapies
- ✓ **Patient Benefit**  
Prolong relapse-free survival

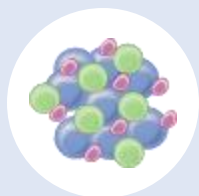
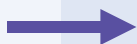


# What is Trem-Cel?



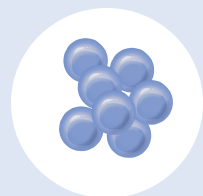
## Starting Material

Apheresis Product from Healthy Matched Donor



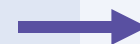
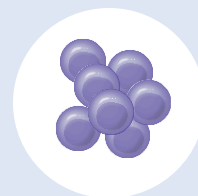
## Stem cell selection

- Removes T cells to reduce graft-vs-host disease
- Allows for large CD34+ dose to accelerate engraftment



## CRISPR/Cas9 gene engineering

- High-efficiency editing of CD33 protein
- Results in blood system that is shielded from CD33-targeted therapy



**Trem-cel:**  
Stem Cell Graft  
Shielded from  
CD33-Targeted  
Therapy

~7 day manufacturing process





# VBP101: Trem-cel Phase 1/2a Clinical Trial

## Patient Journey



*Transplant-eligible  
AML and MDS patients  
at high risk of relapse*

Transplant Decision



Consolidation/Salvage

Conditioning

Trem-cel Infusion



Engraftment

Engraftment



Shielding

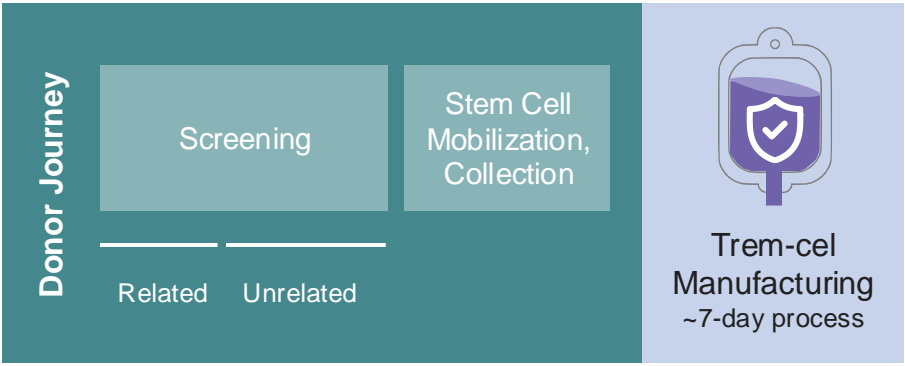
Maintenance Mylotarg

Starting ~day 60 up to 8 cycles  
Dose escalation 0.5-2 mg/m<sup>2</sup>

No delay in typical patient transplant process

Therapeutic Index

Patient Benefit

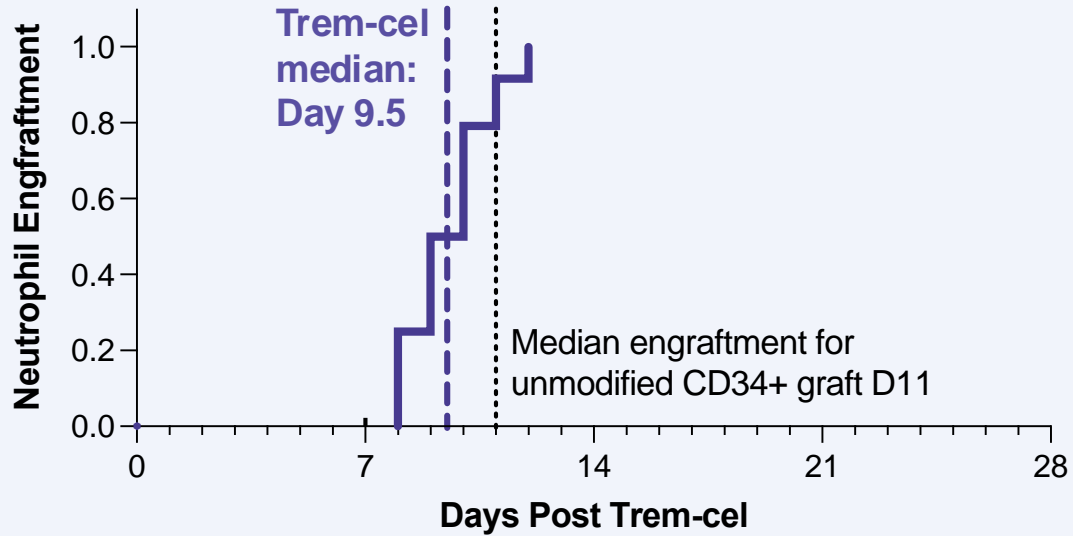


Unedited back-up graft

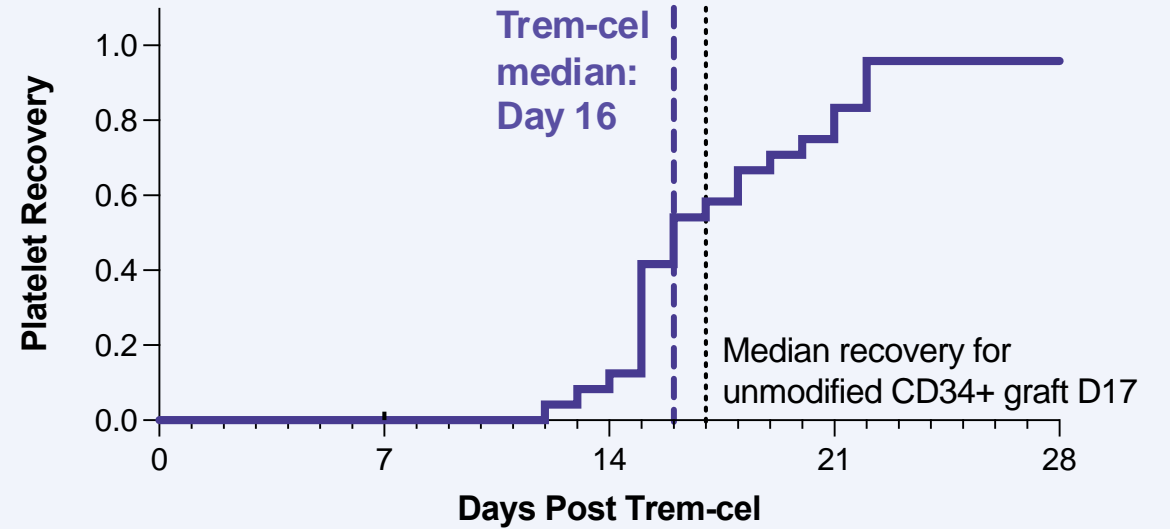


# Trem-cel Achieved Timely Engraftment

## Neutrophil Engraftment (n=25)



## Platelet Engraftment (n=25)



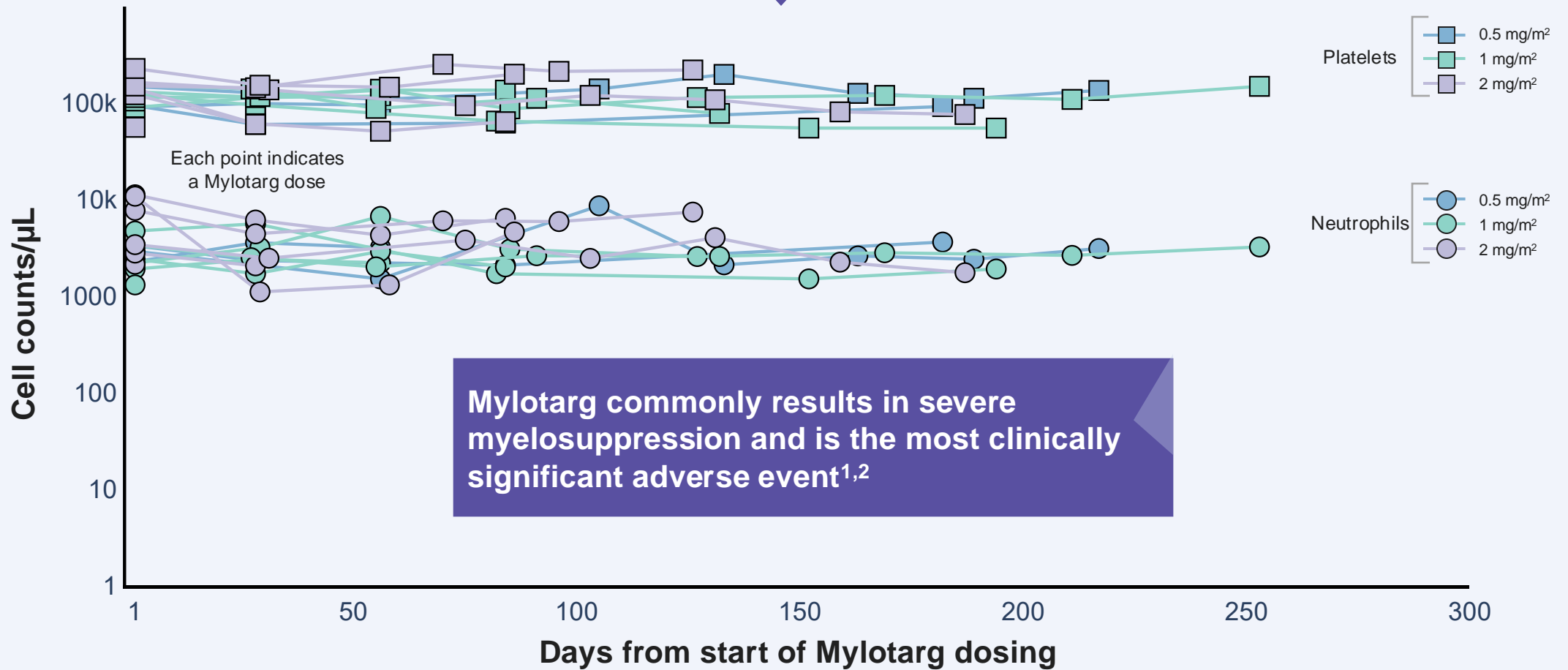
- ✓ High CD33 editing efficiency (median 90%, range 71-94%)
- ✓ 100% neutrophil engraftment
- ✓ 100% achieved full myeloid chimerism at D28

Data cut-off: 1-NOV-2024



# Trem-cel Demonstrated Shielding Across Mylotarg Doses

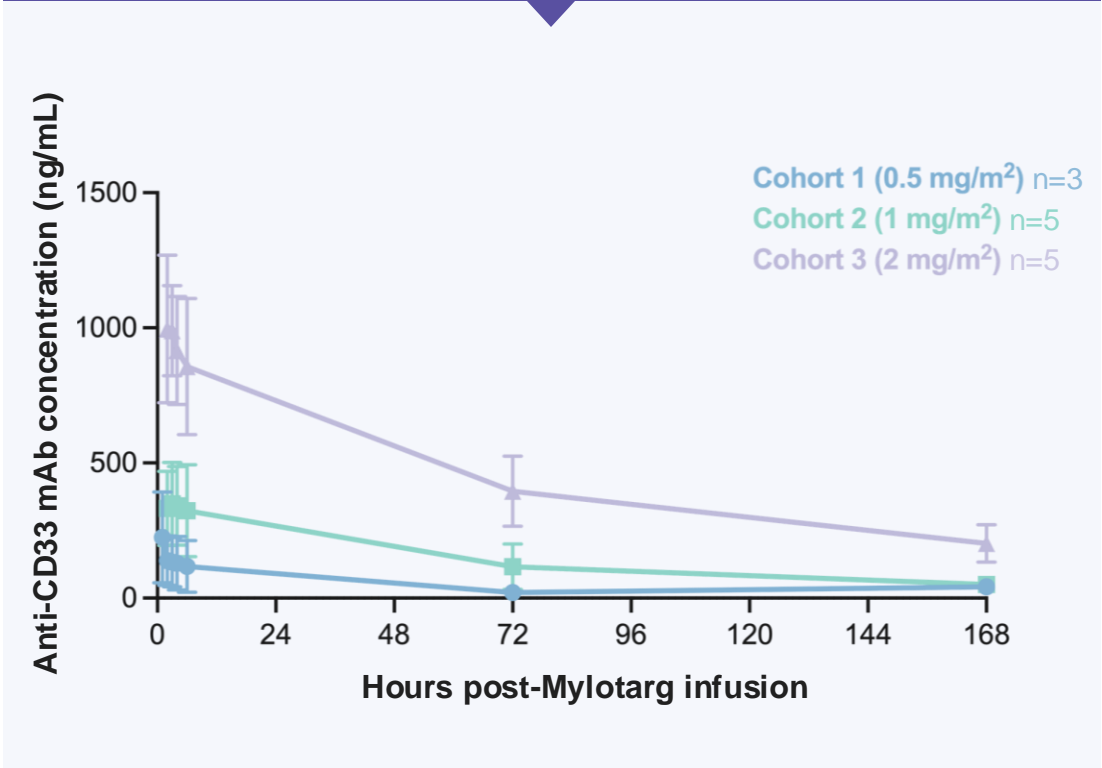
## Neutrophil and Platelet Peripheral Blood Counts with Mylotarg Doses



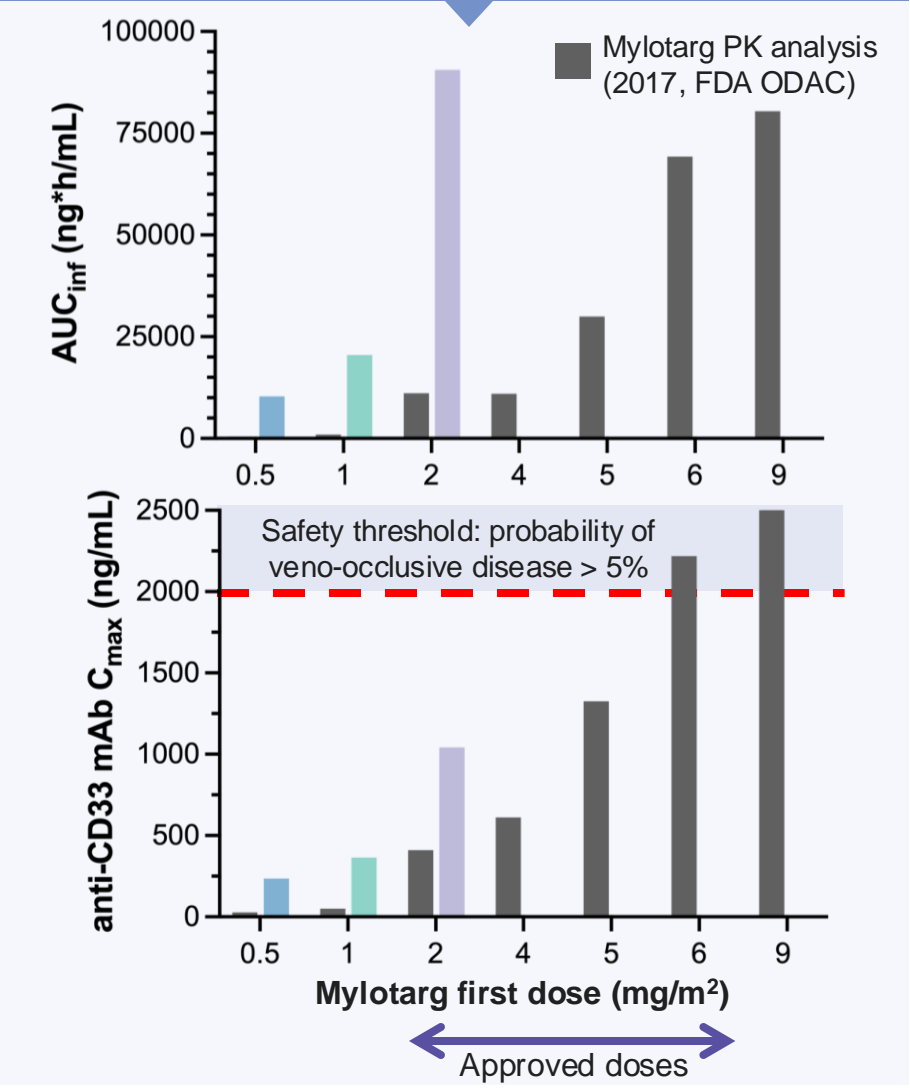
9 1. Sievers et al. Blood 1999 2. Mylotarg prescribing information  
Data cut-off: 1-NOV-2024

# Trem-cel Enabled Broadened Therapeutic Index for Mylotarg

## Mylotarg Pharmacokinetic Profile



## C<sub>max</sub> and AUC Across Mylotarg Doses





# Baseline Risk Factor Demographics for AML Patients: VBP101 vs. Comparators

Disease Characteristic	VBP101 AML ITT (n=24)	VBP101 AML Treated with Mylotarg (n=15)	Araki MRD+ Cohort (2016) (n=76)	Jentzsch Adverse Risk Cohort (2022) (n=271)
<b>Cytogenetics Risk ELN 2022</b>				
Favorable	8%	13%	3%	N/A
Intermediate	33%	27%	58%	N/A
Adverse	58%	60%	39%**	100%*
<b>Other AML Risk Factors</b>				
TP53 mutation	33%	40%	NR	NR
Secondary AML <sup>a</sup>	42%	33%	42%	49%
<b>Disease Burden Status</b>				
Remission (MRDneg)	75%	73%	N/A	20%
MRD+ (>0.1-<5% blasts by flow)	13%	20%	100%*	13%
Active disease (≥5% blasts)	13%	7%	N/A	32%***
<b>AML Disease Status</b>				
CR1	63%	60%	67%	61%
CR2	25%	33%	33%	7%
Relapsed or refractory	13%	7%	0	32%***
<b>Adverse Risk Features (Adverse ELN/molecular/cytogenetic, Secondary AML, MRD or active disease, CR2 or Relapsed/Refractory), n (%)</b>				
1	11 (46%)	6 (40%)		
2 or more	13 (54%)	9 (60%)		

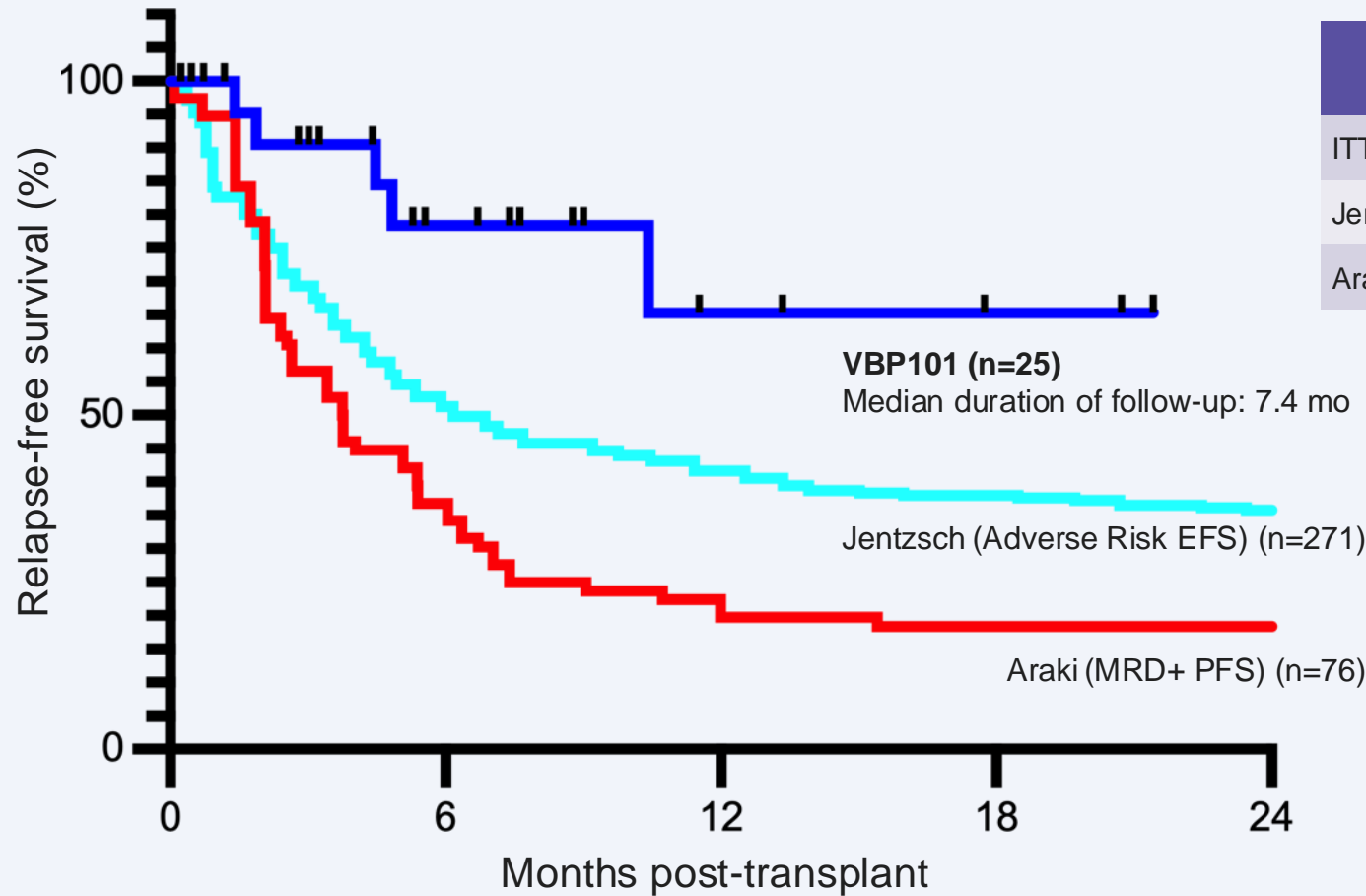
\*Selected comparison cohort (n) from published studies. \*\*Adverse cytogenetics. \*\*\*Includes partial remission, relapsed, refractory. Jentzsch values for disease burden status do not total 100% due to data not reported.

<sup>a</sup>Defined as AML with myelodysplasia-related change and therapy-related AML, NR=not reported, N/A=not applicable

Data cut-off: 01-NOV-2024

# Trem-cel+Mylotarg RFS Appears Favorable vs Published High-Risk AML Comparators

## Relapse-Free Survival of VBP101 (intention-to-treat) vs Araki and Jentzsch (historical controls)



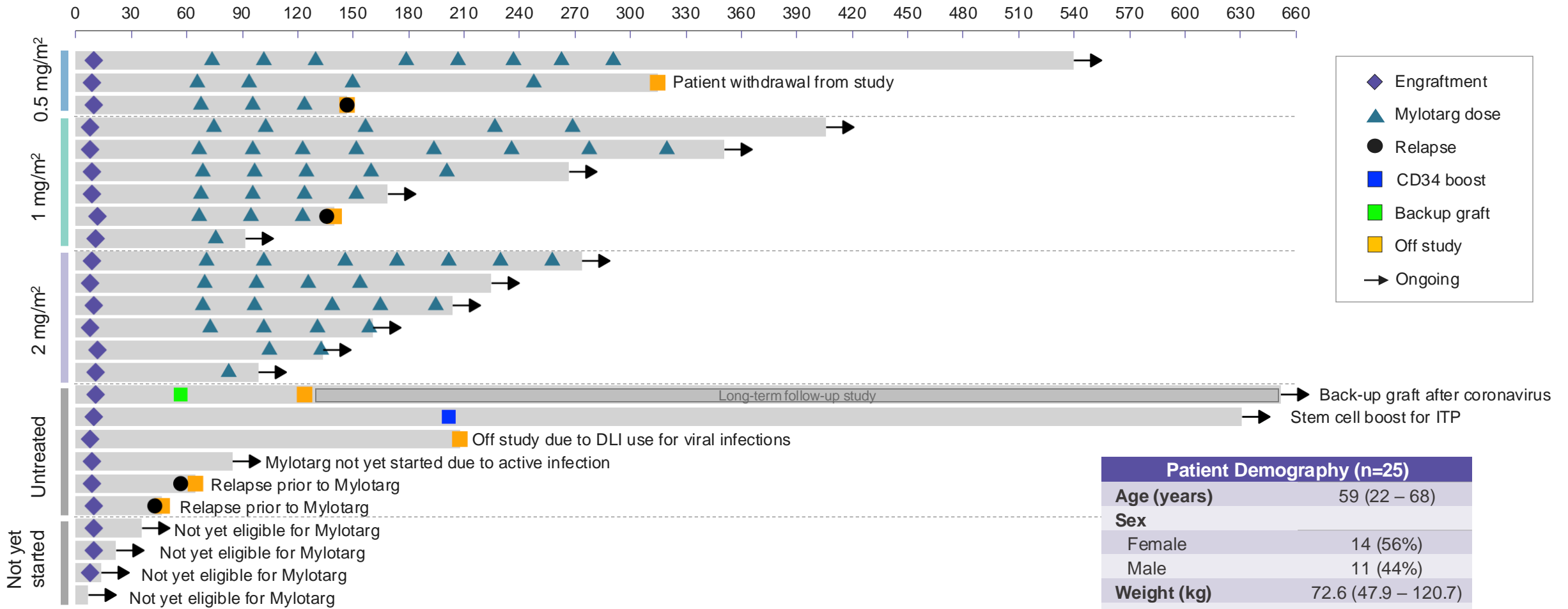
	Median RFS (mo)	P value vs VBP101*	Hazard Ratio* (HR)	HR 95% CI*
ITT	Not reached			
Jentzsch	6.2	0.02	0.36	0.21-0.64
Araki	3.8	0.0004	0.23	0.14-0.40

- Four relapses observed: (all CD33 positive at relapse)
  - 2/4 relapsed prior to Mylotarg treatment
  - 3/4 transplanted with active disease; 1/4 with MRD
  - 4/4 adverse risk cytogenetics
- One patient died off-study due to complications of viral infection

VBP101 data cut-off: 1-NOV-2024. Adapted from Fig 2B MRD+ PFS line from Araki et al. JCO 2016; Adapted from Fig 1C, ELN 2022 Adverse risk EFS line from Jentzsch et al. Blood Cancer Journal 2022. \* = individual comparison to VBP101 using log-rank Mantel-Cox test. Data not from head-to-head trial.



# Low Rate of Relapse (2/15) Among Patients Receiving Mylotarg



Patient Demography (n=25)	
Age (years)	59 (22 – 68)
<b>Sex</b>	
Female	14 (56%)
Male	11 (44%)
Weight (kg)	72.6 (47.9 – 120.7)
<b>Primary Disease Diagnosis</b>	
AML	24 (96%)
MDS	1 (4%)

ITP: idiopathic thrombocytopenic purpura or similar immune-mediated thrombocytopenia  
 Data cut-off: 1-NOV-2024





# Any Grade Treatment Adverse Events After Receiving Mylotarg (n=15)

Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4
<b>Hematologic</b>				
Anemia	-	1/15 (7%)	3/15 (20%)	-
Autoimmune hemolytic anemia	-	-	1/15 (7%)	-
Leukopenia	-	-	1/15 (7%)	-
Lymphocyte count decreased	1/15 (7%)	-	-	-
Lymphopenia	-	-	1/15 (7%)	-
Neutropenia	-	2/15 (13%)	3/15 (20%)	-
Platelet count decreased	-	-	2/15 (13%)	-
Thrombocytopenia	-	1/15 (7%)	1/15 (7%)	1/15 (7%) <sup>a</sup>
<b>Hepatobiliary</b>				
ALT increased	2/15 (13%)	1/15 (7%) <sup>b</sup>	-	-
AST increased	1/15 (7%)	-	1/15 (7%) <sup>b</sup>	-
Biliary colic	1/15 (7%)	-	-	-
Alk Phos increased	3/15 (20%)	-	-	-
Blood bilirubin increased	1/15 (7%)	-	-	-
LDH increased	2/15 (13%)	-	-	-
Cholecystitis	-	2/15 (13%)	-	-
Veno-occlusive disease	1/15 (7%) <sup>c</sup>	-	-	-

<sup>a</sup>Following adverse event, patient continued to receive multiple cycles of Mylotarg

<sup>b</sup>ALT/AST elevation attributed to fluconazole toxicity and resolved after discontinuation

<sup>c</sup>Mild grade late-onset veno-occlusive disease occurred 97 days after 0.5 mg/m<sup>2</sup> Mylotarg dose. Predisposing factors included azole toxicity, concurrent norovirus infection and gram-negative bacteremia.

ALT = Alanine aminotransferase; AST = Aspartate aminotransferase; Alk Phos = blood alkaline phosphatase; LDH = blood lactate dehydrogenase

Data cut-off: 1-NOV-2024



## Clinical Update Summary

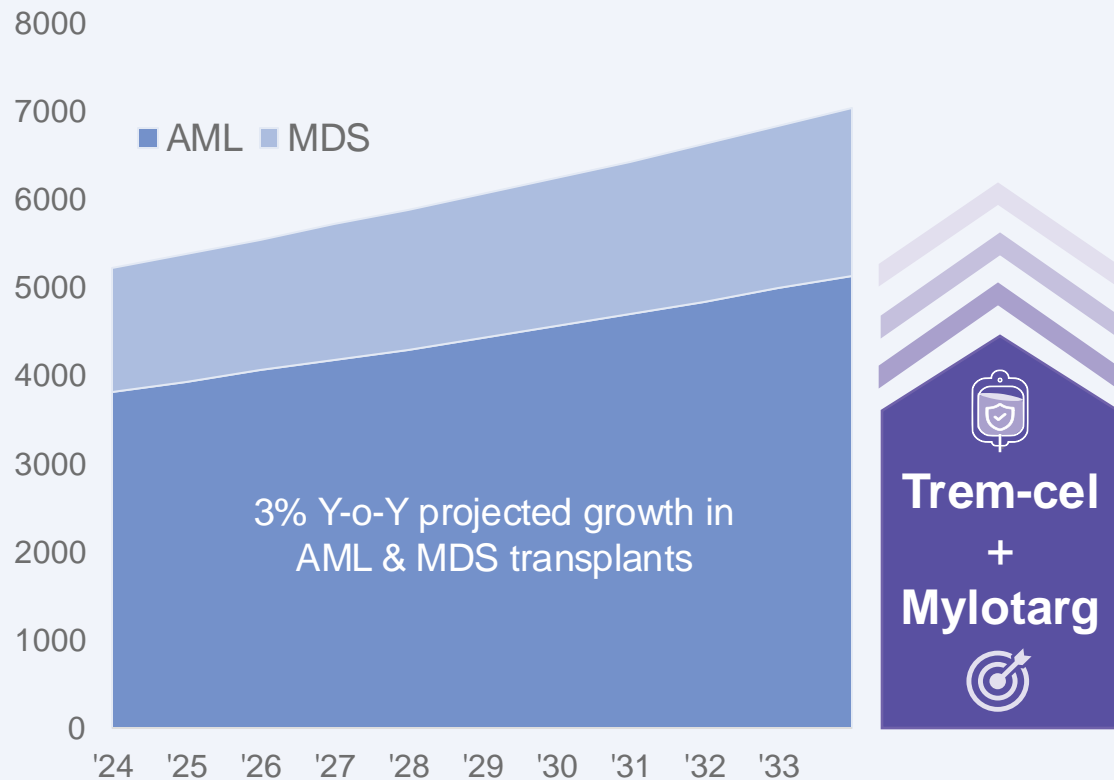
- Robust neutrophil engraftment, platelet recovery and full donor myeloid chimerism
- Consistent shielding from Mylotarg-related cytopenias during repeated 0.5, 1, and 2 mg/m<sup>2</sup> doses
- Immune reconstitution, multilineage chimerism, and safety profile similar to unedited CD34-selected grafts
- Broadened Mylotarg therapeutic index following trem-cel
- Preliminary data suggesting improved RFS compared to published groups of AML patients at high risk of relapse post-HCT





# Trem-cel Platform with Potential >\$1B Commercial Opportunity

## Opportunity to Replace Standard of Care Transplant



## Transformative Treatment



- Shielded transplants to prevent on-target toxicity
- Targeted treatments to improve relapse free survival

## Concentrated Market Opportunity



- ~80% of transplants in 65 US centers
- ~5,000 AML & MDS transplants per year

## Reimbursement Pathway



- 100% cost-based reimbursement for eHSCs\*
- Commercial example: Omisirge® at \$338,000



# Physician Feedback on Trem-cel + Mylotarg Value Proposition



## Perceptions of Trem-Cel

- Streamlined manufacturing with **consistent engraftment**
- Provides **protection of donor cells** from on-target toxicity
- Positive impact on patient outcomes and **reduced GvHD**
- **Enable maintenance therapy** to reduce relapse is compelling

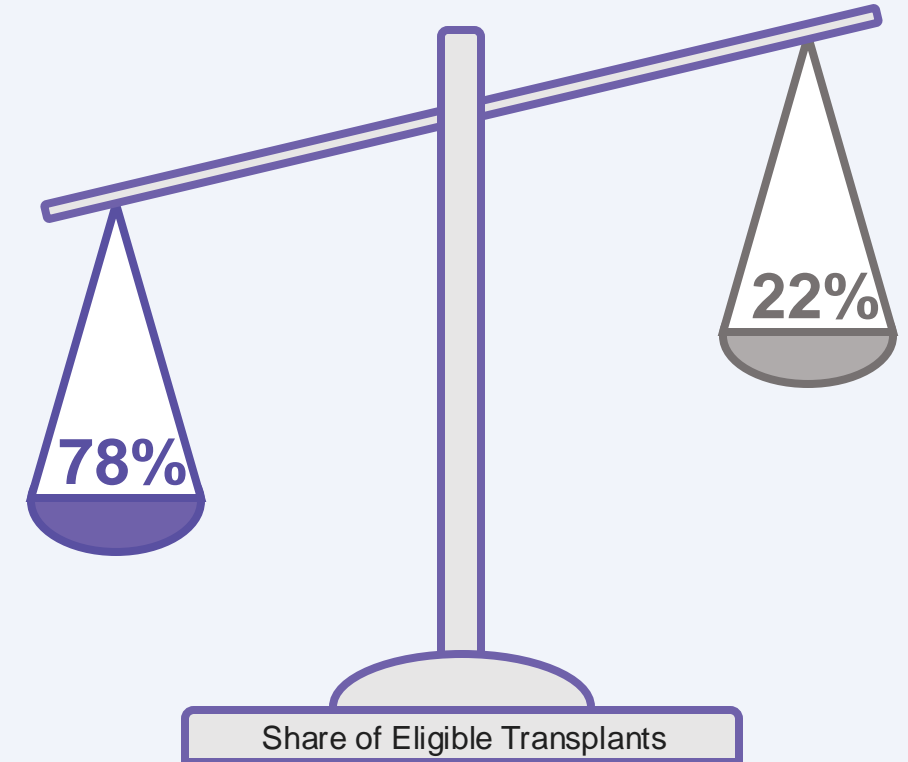


## Perceptions of Mylotarg

- As **monotherapy**, concern for **hepatotoxicity** and neutropenia
- With **trem-cel**, **relative safety concerns are alleviated**
- Benefit of protection with **improved RFS vs. traditional HSCT**

## Trem-Cel + Mylotarg

## SoC Transplant

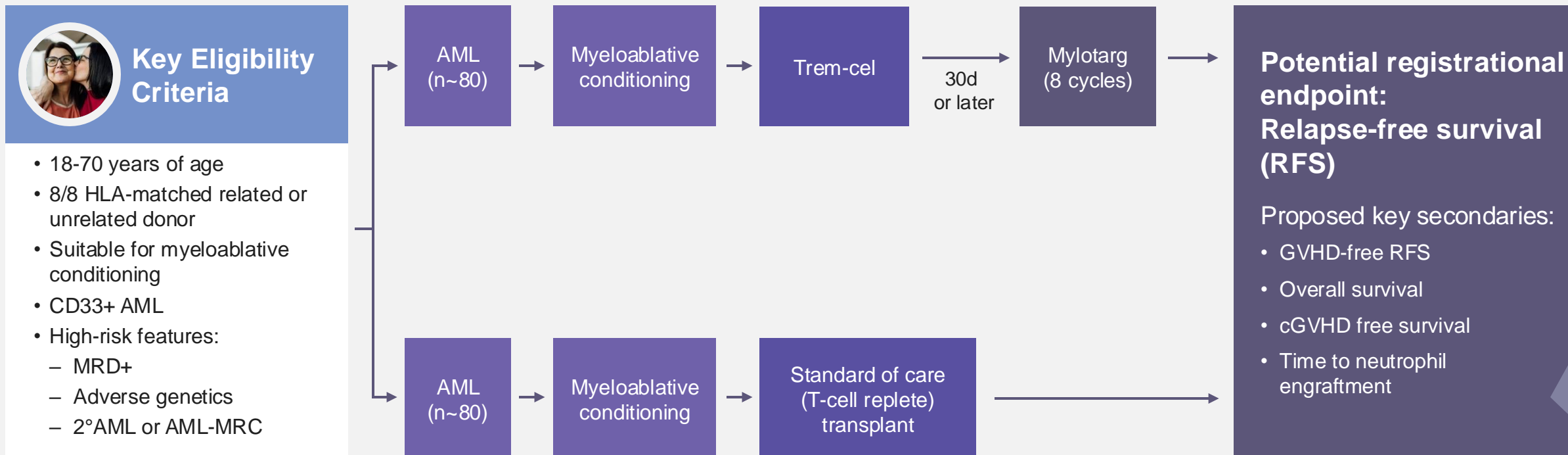


*"I think using that [Trem-Cel + Mylotarg] would aid in the optimization of transplant outcomes and reduce relapse, which is one of the major causes for post transplant mortality." Hematologist-Oncologist*



# Potential Registrational Trial Design for Trem-cel/Mylotarg

## Patient Journey





## Summary of FDA Response to Type C Meeting Request

- Agreement that trem-cel engrafts neutrophils and platelets and has a similar safety profile to unedited CD34+ grafts
- Agreement with the trem-cel-Mylotarg registrational clinical trial design with respect to study population, control arm, primary endpoint, stratification factors, and statistical design
- Agreement to provide further updates to FDA from the VBP101 trial alongside submission of the full registrational clinical trial protocol



# VCAR33<sup>ALLO</sup>: CD33-Directed Healthy Donor-Derived CAR-T



Cells harvested from prior transplant donor

**~7-day**  
manufacturing

Rapid process to preserve stemness



Terminally frozen for convenience

T cells exactly matched to patient's immune system

Healthy, stem-like cells more likely to expand and less prone to exhaustion

Clinically validated construct: NIH study using autologous cells showed efficacy at  $1 \times 10^7$  CAR+ cells/kg (2/5 assessable pts)<sup>1</sup>

1. Shah et al. ASH 2023



# VBP301: VCAR33<sup>ALLO</sup> Phase 1/2 Clinical Trial

## Patient Journey

MRD<sup>+</sup> or relapsed AML following standard or trem-cel transplant

Enroll



VCAR33<sup>ALLO</sup> Infusion

Lymphodepletion



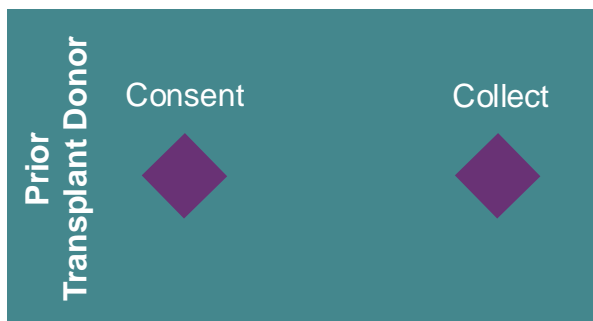
Arm A: Blasts  $\geq$  5%

Arm B: MRD<sup>+</sup>

Day 28 Follow-up



2<sup>nd</sup> transplant if required



3x3 dose escalation starting at  $1 \times 10^6$  CAR<sup>+</sup> cells/kg

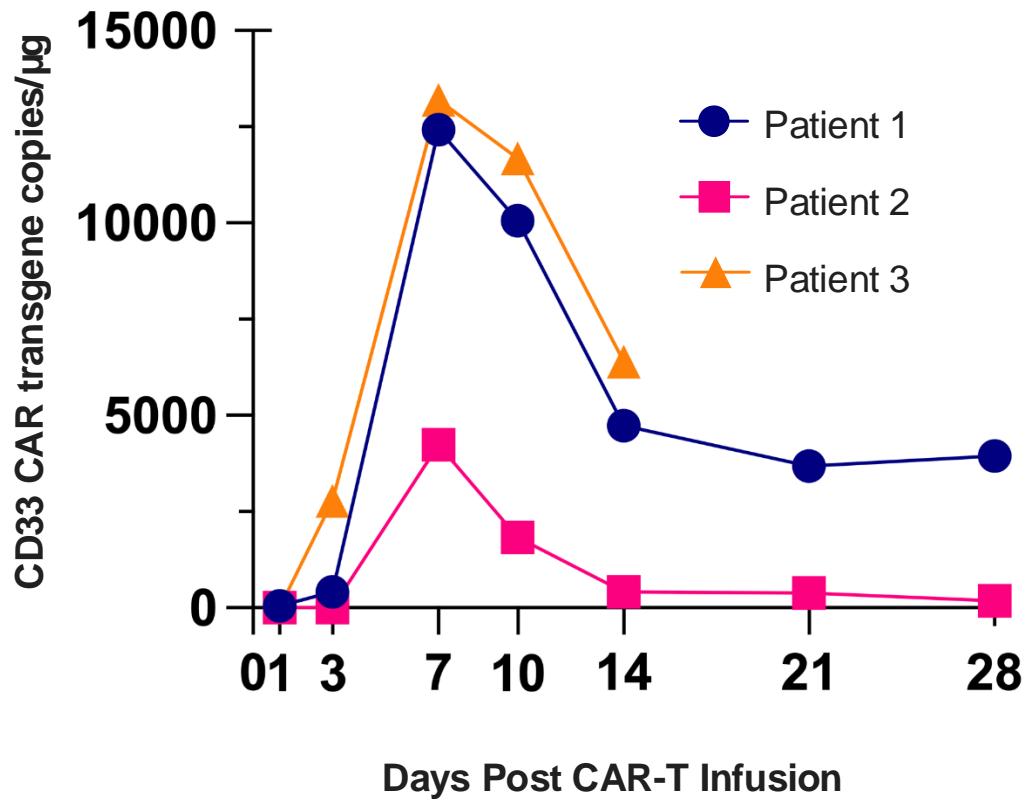
## Key Endpoints

- 01 Safety
- 02 Expansion, persistence
- 03 Disease control/response



# VCAR33<sup>ALLO</sup>: Encouraging Signs of *In Vivo* Expansion

## Peripheral Blood



- Dose escalation schedule:

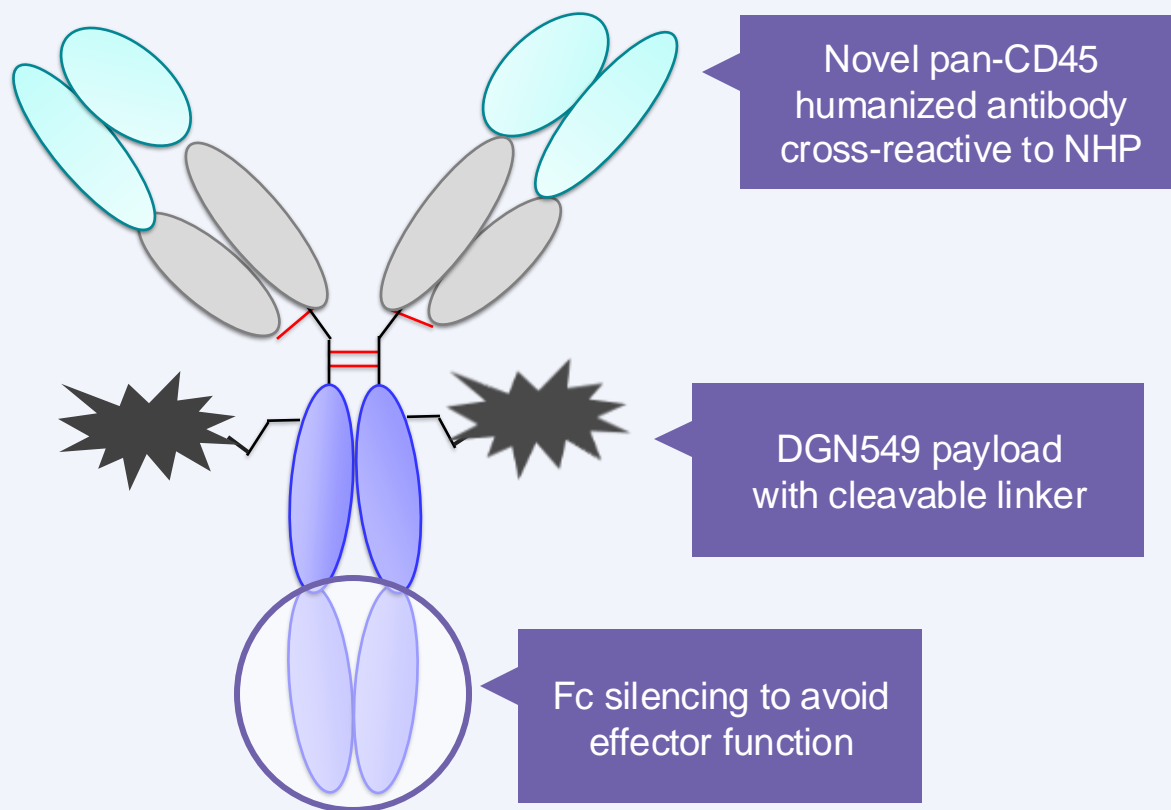
- $1 \times 10^6$  CAR+ cells/kg
- $3 \times 10^6$  CAR+ cells/kg
- $1 \times 10^7$  CAR+ cells/kg

- NCI CD33CART trial (autologous) saw in vivo expansion and 2 responses out of 5 assessable patients at  $1 \times 10^7$  CAR+ cells/kg\*





# VADC45, a Novel CD45-Targeted Antibody Drug Conjugate



CD45 is highly expressed throughout the heme compartment (minus mature RBCs)

Clinically validated linker-payload (Immunogen, alkylating agent)

Robust preclinical data package

IND-enabling studies progressing to completion



# VADC45: Potential Commercial Opportunities



## Treating Relapse - Heme Malignancies

- CD45 is highly expressed in AML and DLBCL
- Target may be oncogenic, driving tissue infiltration, high expression and poor prognosis
- **Opportunity:** R/R AML and MDS



## Non-Chemo Conditioning - Gene Therapies

- Gene therapies such as for sickle cell urgently need non-chemo conditioning agents
- Could avoid oncogenicity and sterility concerns
- **Opportunity:** SCD, TDT alternative conditioning



## Immune Reset - Autoimmune Diseases

- Immune disorders that may require more holistic reset of the entire immune system
- Holistically remove immune cell compartments
- **Opportunity:** Refractory MS, SLE, SSc



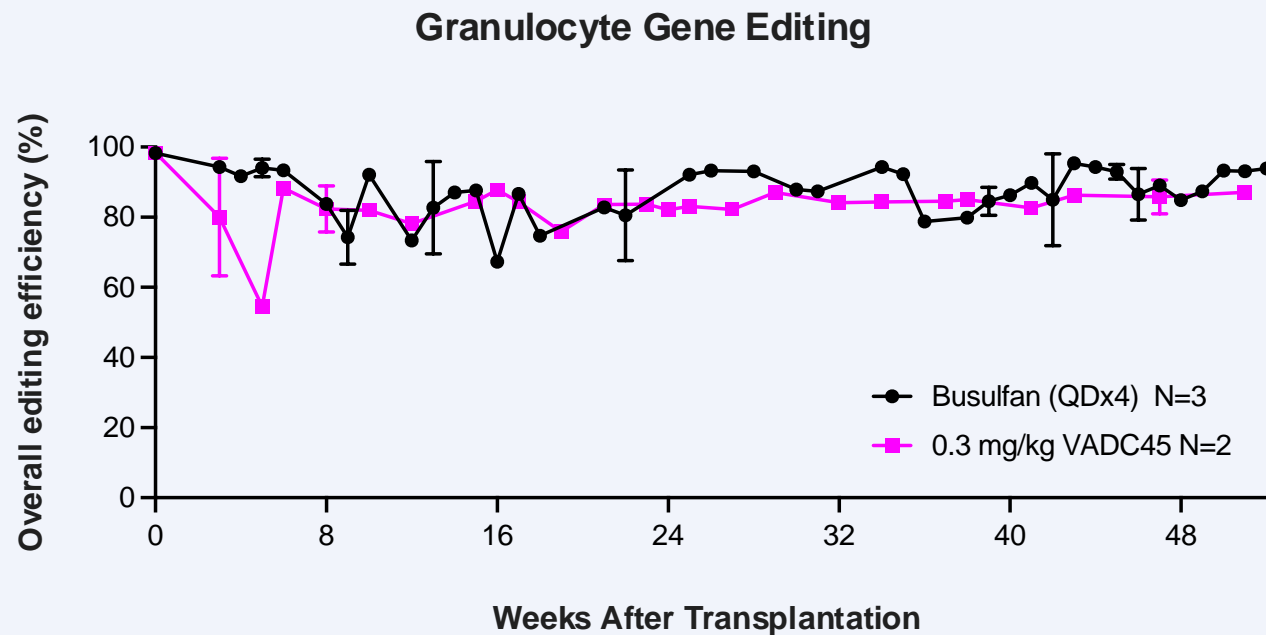
## Epitope Engineering - Shielded Grafts

- Precise epitope for VADC45 has been identified
- Experiments are ongoing for epitope modification which retains protein functionality
- **Opportunity:** Heme malignancies



# Single Dose of VADC45 Enabled Gene-edited HSC Engraftment

## Engraftment and Persistence of Gene-edited Stem Cells



NHPs received autologous transplantation of BCL11A-edited HSCs with conditioning via chemo (busulfan) compared to single dose of VADC45



Very high myeloid chimerism achieved within days of transplant

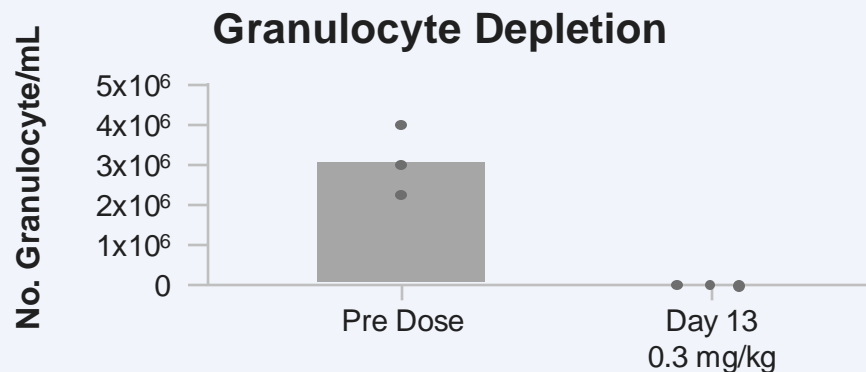
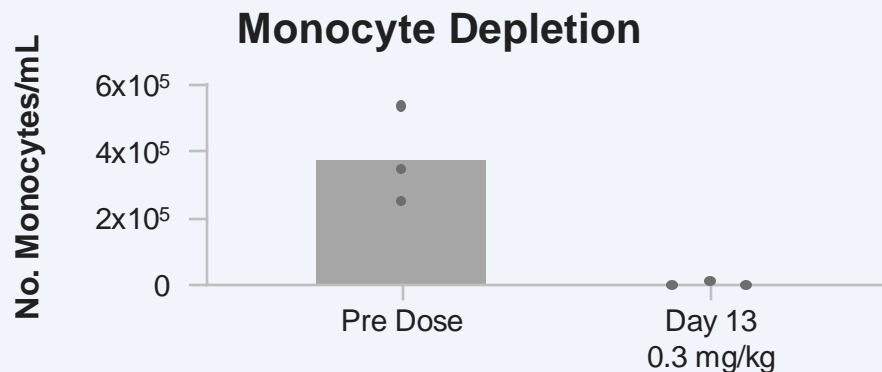
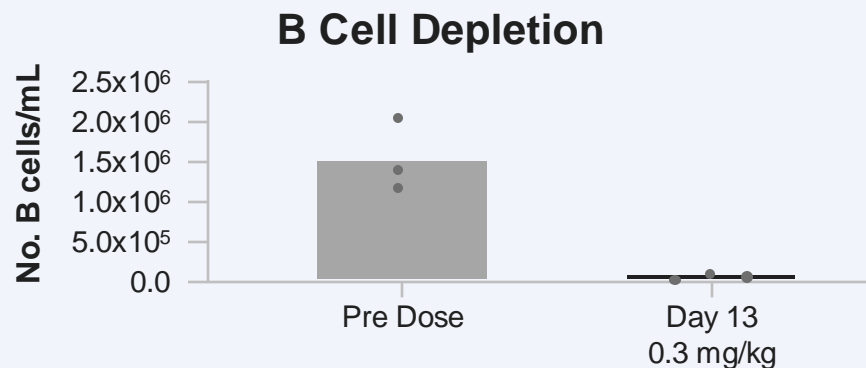
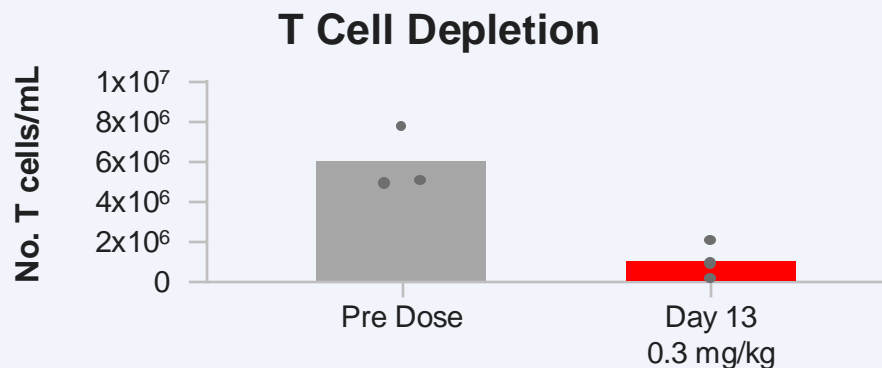


Persistently high edited populations through one year from transplant



# Single Dose of VADC45 Efficiently Depleted Immune Cells

## Immune Cell Depletion from Peripheral Blood (NHP)





# Next-Generation Approaches

**Targets Beyond CD33**



**Expansion into additional indications**

**Multi-targeted CAR-Ts**



**Avoidance of potential tumor escape**

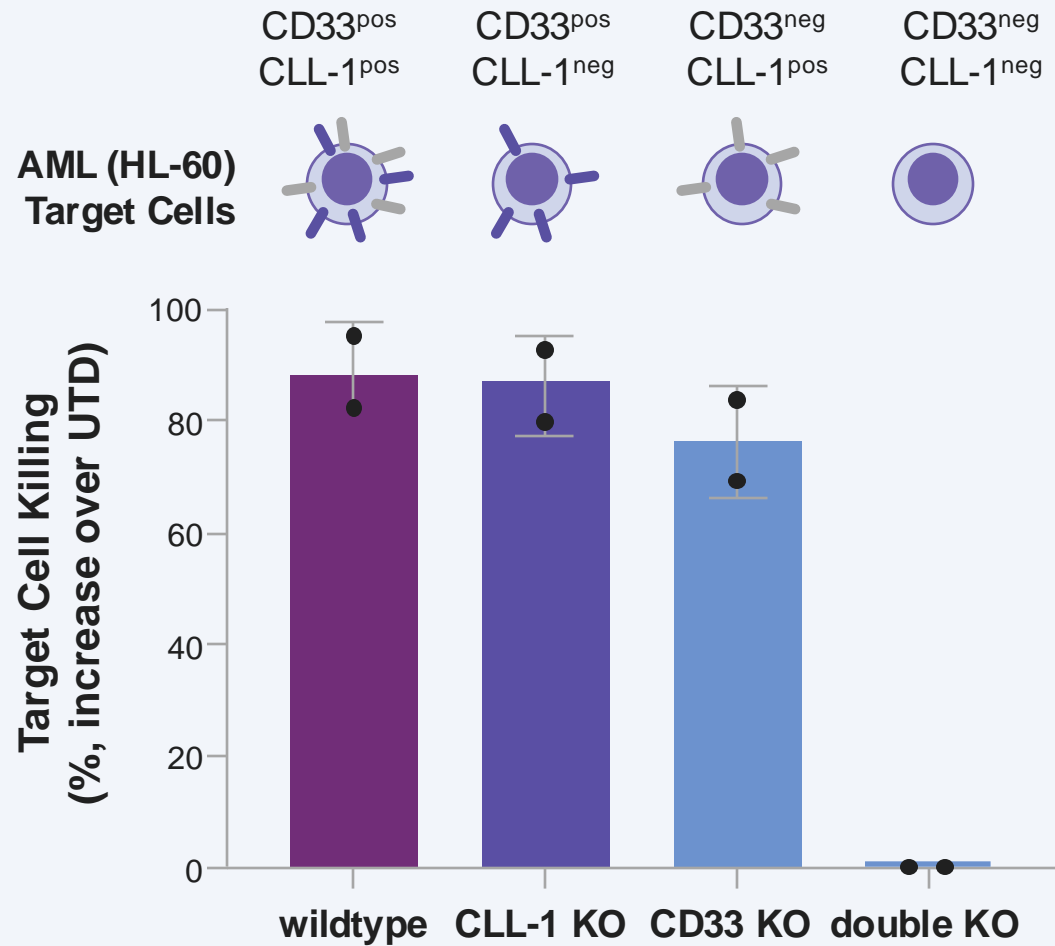
**Multiplex-edited grafts**



**Broader options for treatment**



# In Vitro PoC for Multi-Specific CAR-T: Cell Killing and Shielding



- 2 independent T cell donors
- 48h co-culture of CAR-T cells with HL60 (AML) target cells
- E:T ratio 1:1

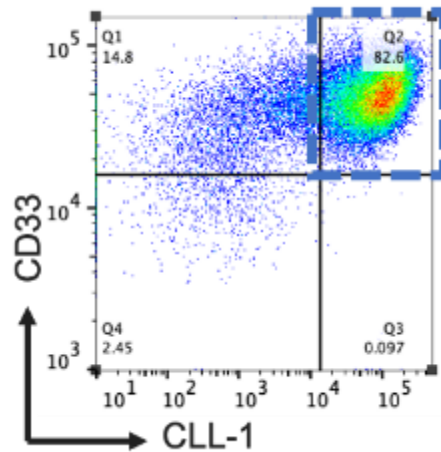
## Multi-Specific CAR-T cell (CD33+CLL-1)

- Highly effective AML target cell killing
- “OR gated” CAR which eliminates target cells expressing both OR one target only
- Highly specific CAR leaving double knock-out target cells intact
- Can be paired with Multiplex (CD33+CLL-1)-edited HSPCs which provide shielding



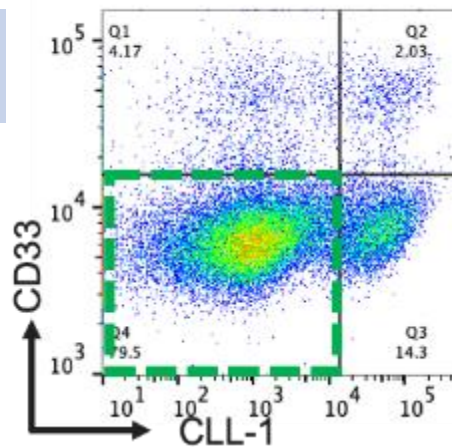
# Multiplex HSC Editing: Minimize Translocations

Mock



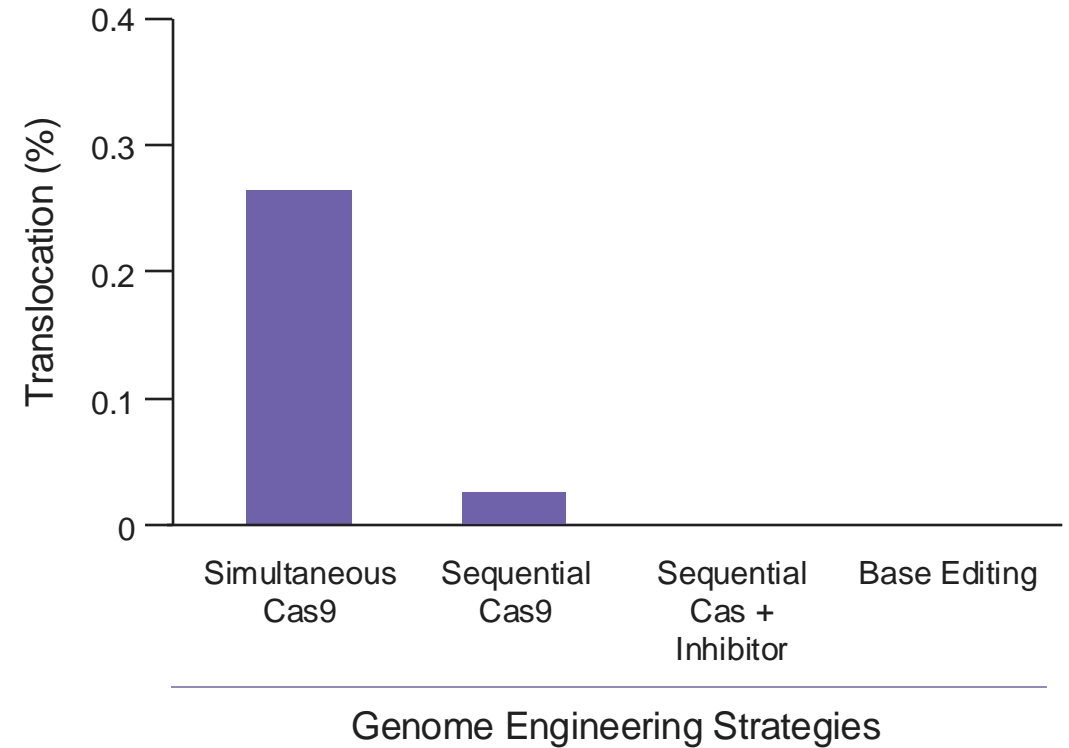
CD33<sup>+</sup>CLL-1<sup>+</sup>  
Double Pos  
**82.6%**

Base Edited



CD33<sup>-</sup>CLL-1<sup>-</sup>  
Double KO  
**79.5%**

Minimized Translocation



Adapted from [Precision Genome Engineering Keystone Symposia – 2022 Poster 3002](#)





# Vor Bio Unique Approach to Potentially Cure Blood Cancers



## **Trem-cel, a first-in-class investigational\* shielded stem cell transplant**

- Reliable engraftment, robust shielding of the blood system
- Platform therapy addressing >\$1B potential market opportunity



## **Trem-cel + Mylotarg combination**

- Broadened Mylotarg therapeutic index
- Early evidence of patient benefit prolonging relapse-free survival
- Supportive feedback from FDA on registrational trial design



## **VCAR33<sup>ALLO</sup>, differentiated transplant donor CAR-T therapy**

- Encouraging signs of in vivo expansion with strong trial enrollment



## **VADC45**

- Four distinct potential commercial opportunities



[www.vorbio.com](http://www.vorbio.com)



# Pipeline to Change the Standard of Care in Blood Cancers

Description			Preclinical		Clinical		Anticipated Milestones
Program / Trial	Modality	Indication	Discovery/ Validation	IND- Enabling	Phase 1/2	Phase 2/3	
<b>Trem-cel + Mylotarg / VBP101</b>	Shielded CD33-deleted transplant + CD33-directed ADC	AML, MDS	▶				Clinical data in 2H 2025
<b>VCAR33<sup>ALLO</sup> (healthy transplant donor CAR-T) / VBP301</b>	CD33-directed transplant donor CAR-T	AML post-transplant	▶				Clinical data in 1H 2025
<b>Trem-cel + VCAR33 Treatment System</b>	Shielded CD33-deleted transplant + CD33-directed transplant donor CAR-T	AML	▶				IND filing following initial trem-cel and VCAR33 <sup>ALLO</sup> data
<b>VADC45 ADC</b>	CD45-directed ADC	AML, conditioning, immune reset	▶				Finalizing IND preparedness
<b>CD33-CLL1 Treatment System</b>	Multi-specific CAR-T	AML	▶				
	Multiplex-edited shielded transplant	AML	▶				



# Experienced Leadership Team



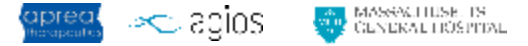
**Robert Ang, MBBS, MBA**  
President and CEO



**Han Choi, M.D., LL.M**  
Chief Financial Officer



**Eyal Attar, MD**  
Chief Medical Officer



**Tirtha Chakraborty, PhD**  
Chief Scientific Officer



**Tania Philipp**  
Chief People Officer



**John King, MBA**  
Chief Commercial Officer & Head of Business Development



**David Phillips, MBA**  
Senior Vice President, Head of Quality



**Samir Vattompadam, MS**  
Senior Vice President, Portfolio Strategy and Program Management

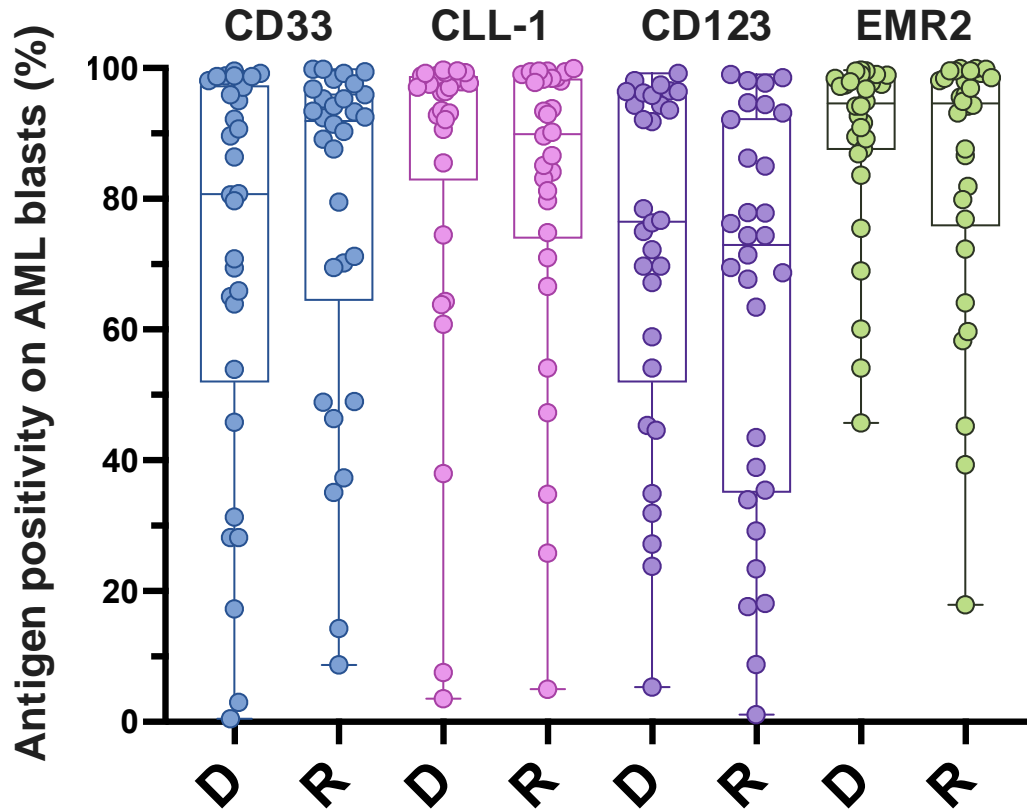


## Deep Cell & Gene Therapy Expertise

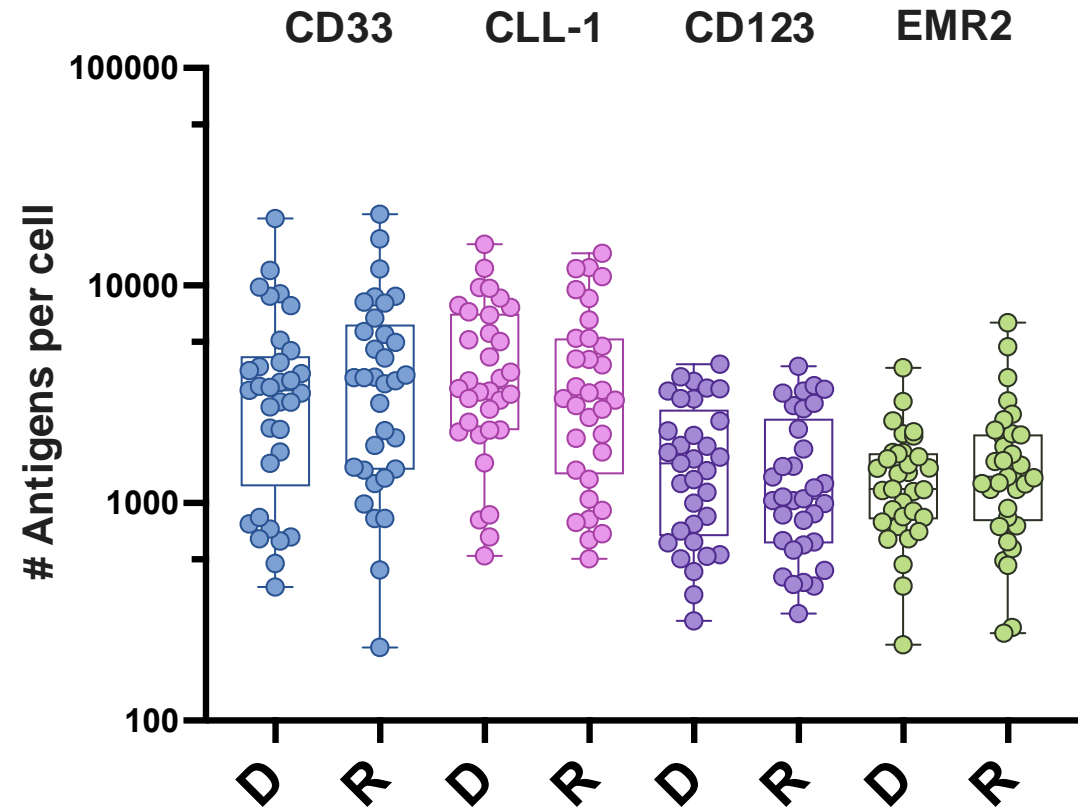


# CD33 is Amongst Highest Quality Targets in AML

Ubiquity of Antigen Expression (Flow Cytometry)



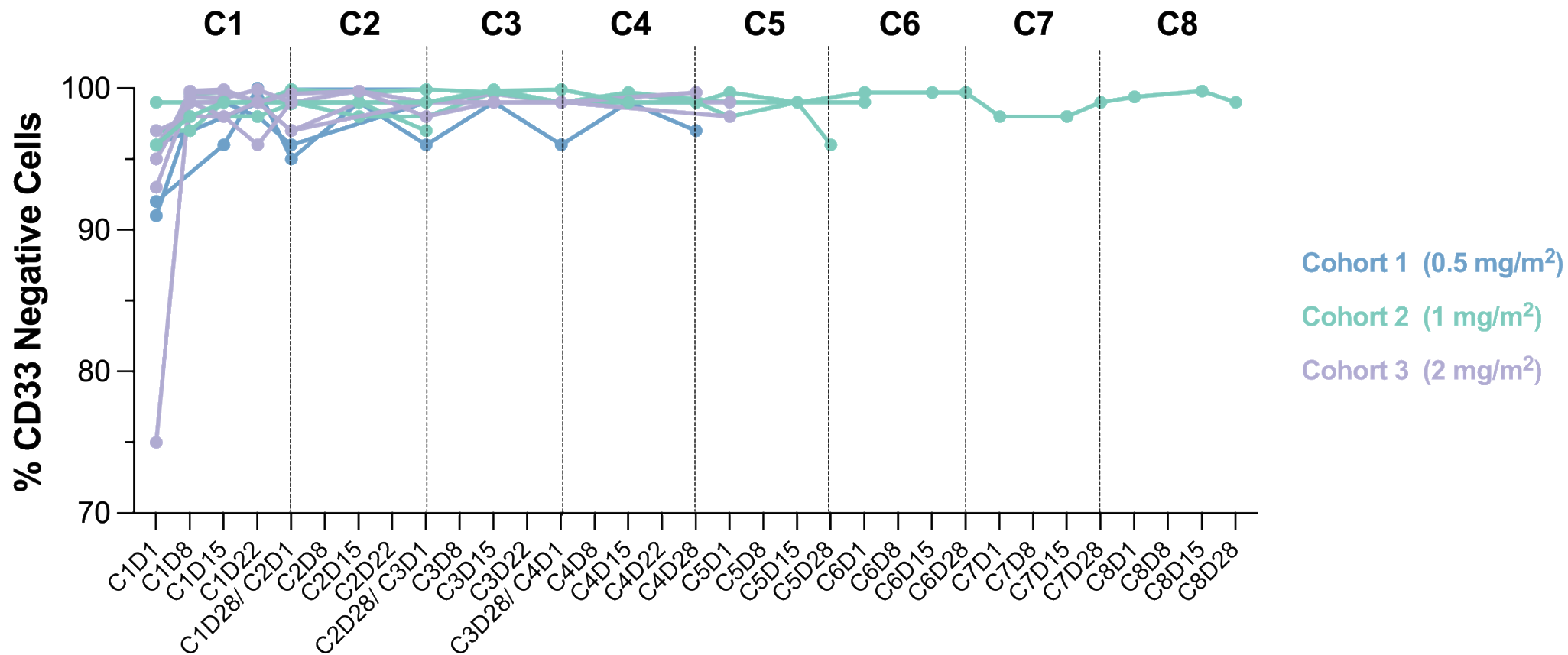
Density of Antigen Expression (QuantiBRITE)





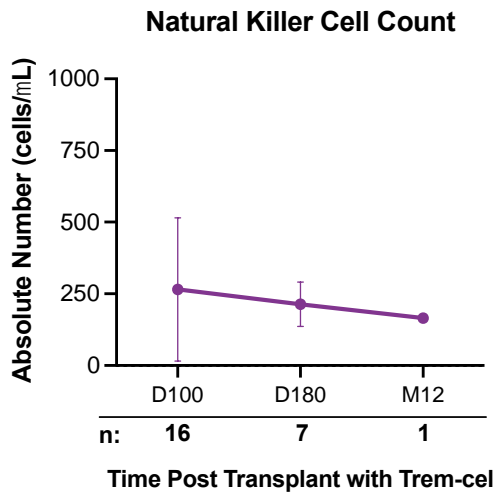
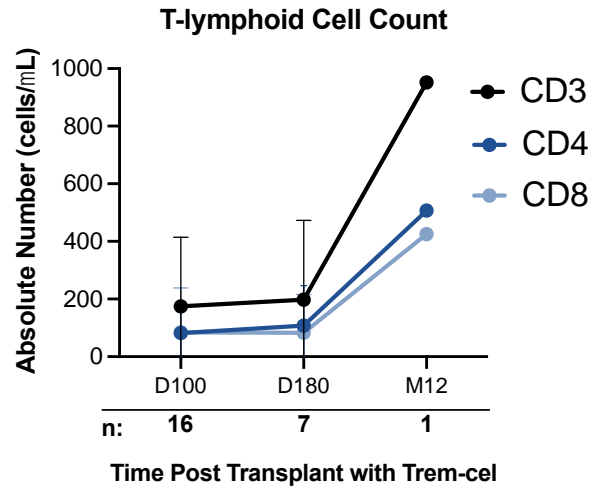
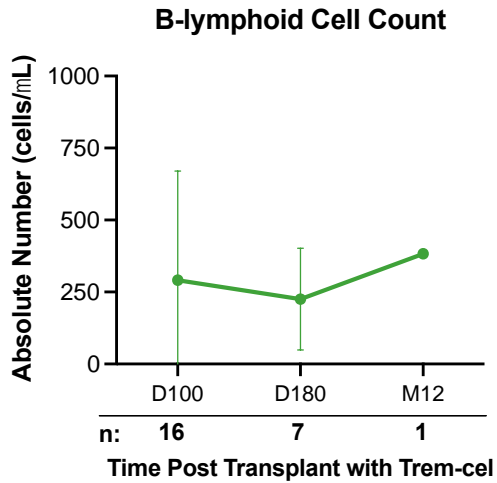
# CD33 Negative Cells Enriched with Mylotarg Doses

## Loss of CD33 Expression on Myeloid Cells (Peripheral Blood, n=20)

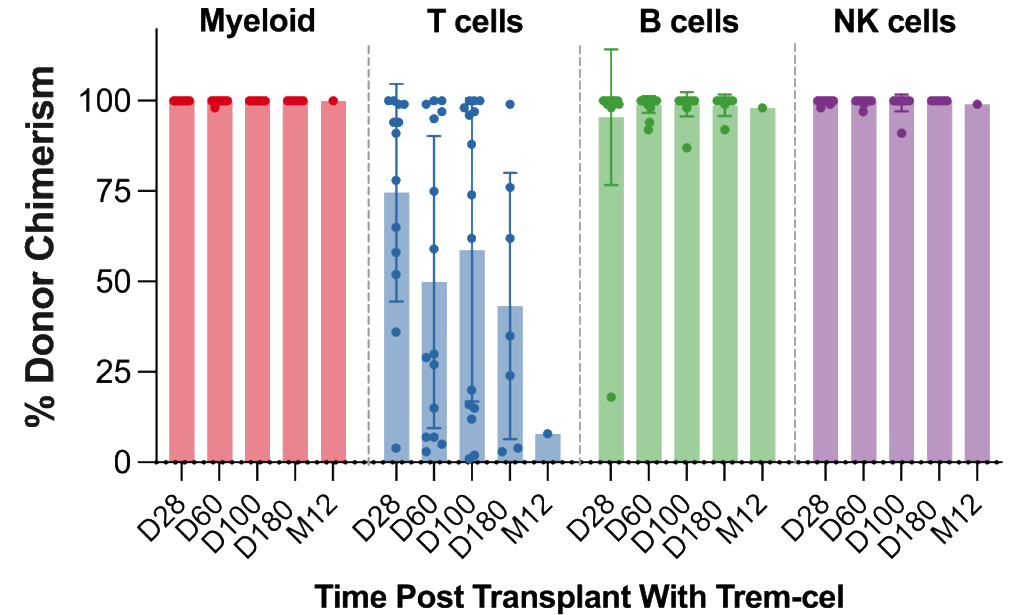




# Immune Reconstitution, Full and Sustained Myeloid Chimerism, and CD33-negative Myeloid Cells Are Observed



## Lineage-Specific Donor Chimerism (Peripheral Blood)



% CD33-Negative Analysis	Drug Product*	D28*	D60*
NGS Gene Editing	90 (78-94) n=18	94 (85-98) n=19	94 (86-97) n=16
Flow Cytometry	N/E	93 (74-98) n=22	94 (78-99) n=19

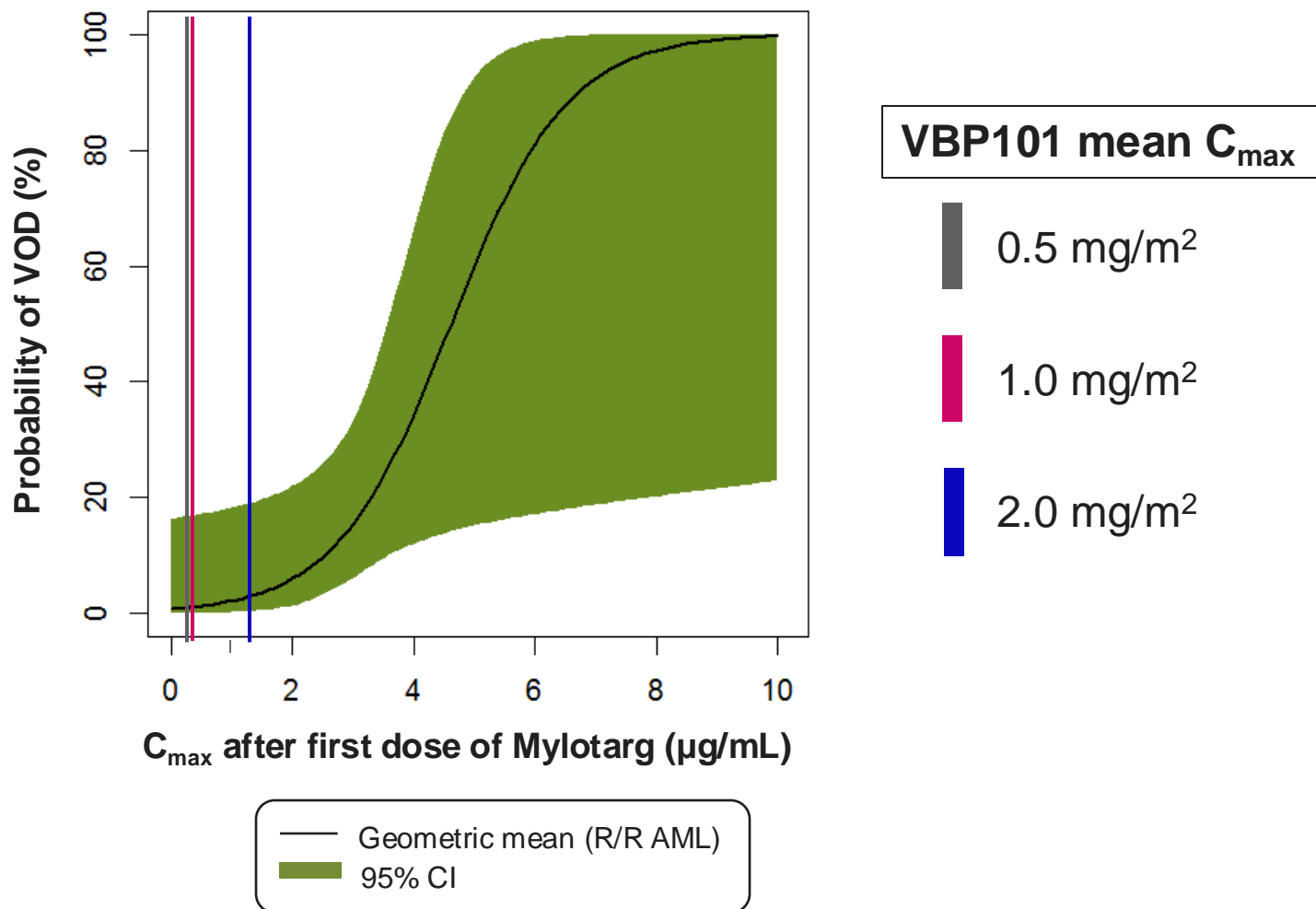
\*Mean % (range), Editing and flow data from peripheral blood monocytes and myeloid cells respectively  
N/E: not evaluated





# Risk of Veno-Occlusive Disease Related to Mylotarg $C_{max}$

Probability of Veno-occlusive Disease in Patients with Prior Transplant





# Selected Precedent Randomized Trials in AML

## AML Studies

## Transplant Studies

	MORPHO	SIERRA	ALFA-0701	Precision-T	Omidubicel
<b>Drug and Comparisons</b>	Gilteritinib vs placebo	<sup>131</sup> I-apamistamab + Flu-TBI + alloHCT vs conventional care	Daunorubicin + cytarabine ± Mylotarg (D1, 4, 7)	Orca-T transplant vs SoC alloHCT	Omidubicel vs double cord graft
<b>Treatment Setting</b>	Post-HCT maintenance, FLT3-ITD AML	R/R AML	Newly-diagnosed de novo AML	Transplant-eligible AML, ALL, MDS	Transplant-eligible high-risk malignancies
<b>1° Endpoint</b>	RFS	Rate of dCR (CR/CRp ≥ 180 days)	EFS (induction failure, relapse, or death)	Survival free of moderate-to-severe chronic GVHD (cGFS)	Time to neutrophil engraftment
<b>2° Endpoints</b>	OS (key), EFS, Time to NRM, Relapse, GVHD, MRD	OS, EFS	Rate of CR/CRp, OS, RFS, Safety	Time to moderate-to-severe GVHD, GRFS, OS	Platelet engraftment by 42 days, grade 2-3 bacterial or invasive inf, NRM, OS
<b>Sample Size</b>	178 per arm	76 per arm	140 per arm	85 per arm	62 per arm