



# AlloVir Virtual Investor Event

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December 13, 2021

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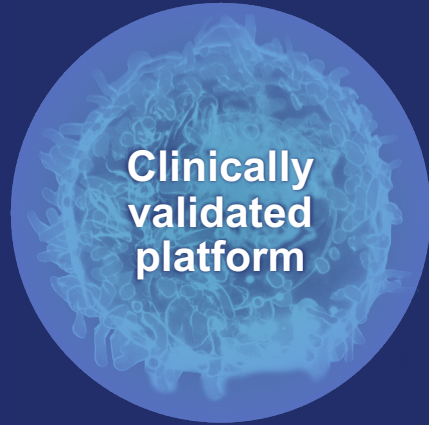
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## **Diana Brainard, M.D.**

Chief Executive Officer  
AlloVir, Inc. (Nasdaq: ALVR)

# AlloVir: A Leading Innovator in Allogeneic, Off-the-Shelf, Virus-Specific T Cell Immunotherapies



**Clinically  
validated  
platform**

93% overall response rate in  
Phase 2 study

Expedited regulatory review  
pathways (RMAT, PRIME)



**Rich  
pipeline**

4 products targeting 12 viruses  
with both treatment and  
prevention potential

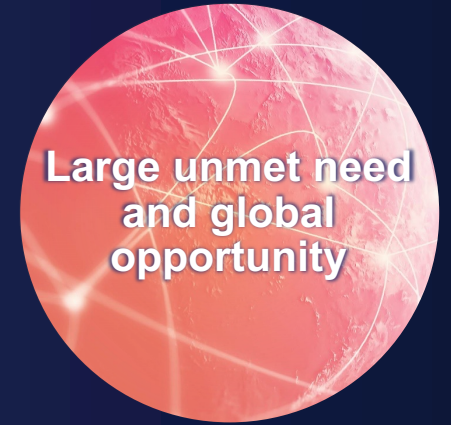
Posoleucel in 3 Phase 3 trials\*  
and 1 ongoing proof-of-concept  
study by 1H 2022



**Manufacturing  
at scale**

Simple, non-gene-edited,  
scalable process with  
manufacturing redundancy

Off-the-shelf delivery for patient  
access within 48 hours

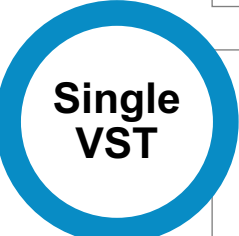
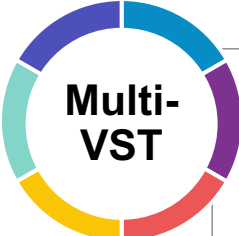


**Large unmet need  
and global  
opportunity**

Currently focused on stem cell  
and solid organ transplant  
patients

Expanding to additional patient  
populations

# Our Pipeline Targets 12 Unique Viruses



Candidate	Target Population	Target Indication	Preclinical	POC	Pivotal
<b>Posoleucel (ALVR105)</b>		vHC treatment	[Progress bar spanning Preclinical, POC, and Pivotal phases]		
	Allo-HCT	AdV treatment	[Progress bar ending in Dec '21]		
		Multi-virus prevention*	[Progress bar ending in 1H '22]		
	Kidney transplant	BKV treatment	[Progress bar spanning Preclinical and POC phases]		
	Solid organ transplant	Multi-virus prevention*	[Progress bar spanning Preclinical phase]		
<b>ALVR106</b>	Allo- / Auto-HCT	hMPV, Flu, PIV, RSV treatment	[Progress bar ending in Dec '21]		
	High-risk general population		[Progress bar spanning Preclinical phase]		
<b>ALVR107</b>	Chronic HBV	HBV cure	[Progress bar spanning Preclinical phase]		
<b>ALVR109</b>	Immunocompromised	COVID-19 treatment	[Progress bar spanning Preclinical and POC phases]		

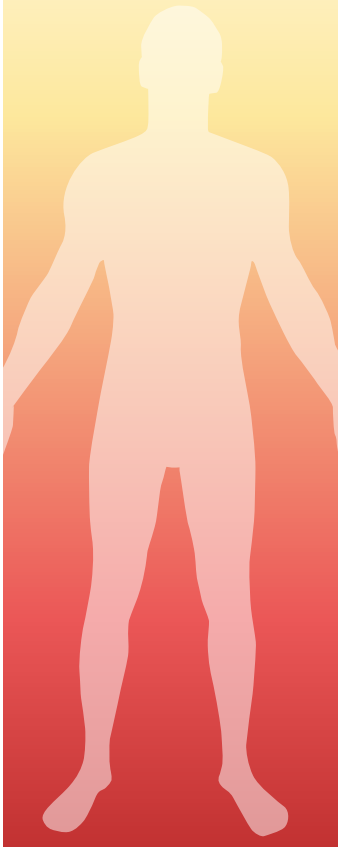
**Compassionate Use Access**



\*Prevention of adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus 6 (HHV-6), JC virus (JCV). Phase 3 trial in allo-HCT anticipated to initiate in 1H 2022, following FDA review of final protocol. Allo-HCT = allogeneic hematopoietic cell transplantation; Auto-HCT = autologous HCT; HBV = hepatitis B virus; hMPV = human metapneumovirus; Flu = influenza; PIV = parainfluenza virus; POC = proof-of-concept; RSV = respiratory syncytial virus; vHC = virus-associated hemorrhagic cystitis; VST = virus-specific T cell.

# AlloVir's Therapies Aim to Treat or Prevent Life-Threatening Viral Diseases For Immunocompromised Patients<sup>1-13</sup>

## Challenges



### Vulnerable Populations

Single and multiple viral infections are common in the immunocompromised:

- HCT & SOT recipients
- The elderly & the very young
- Patients on chemotherapy or immunomodulators

### Limited or No Treatment Options

Therapeutic options raise concerns about:

- Lack of efficacy for off-label treatments
- Significant toxicity
- Emergence of resistance

### Substantial Morbidity & Mortality

Uncontrolled viral diseases can:

- Prolong hospitalization
- Increase risk for GVHD or graft rejection
- Cause end-organ damage
- Result in death

## Solution



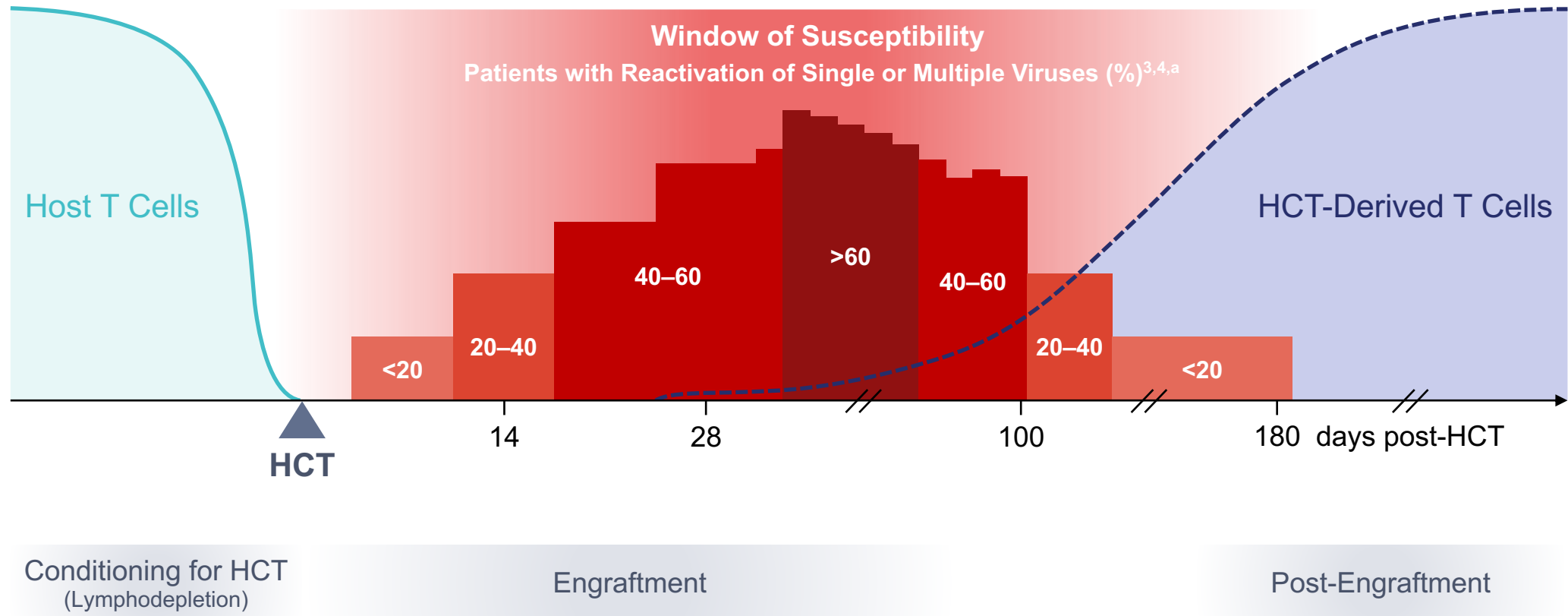
### Immunity Restored with VSTs

VSTs are a clinically validated approach to restoring protective T-cell immunity

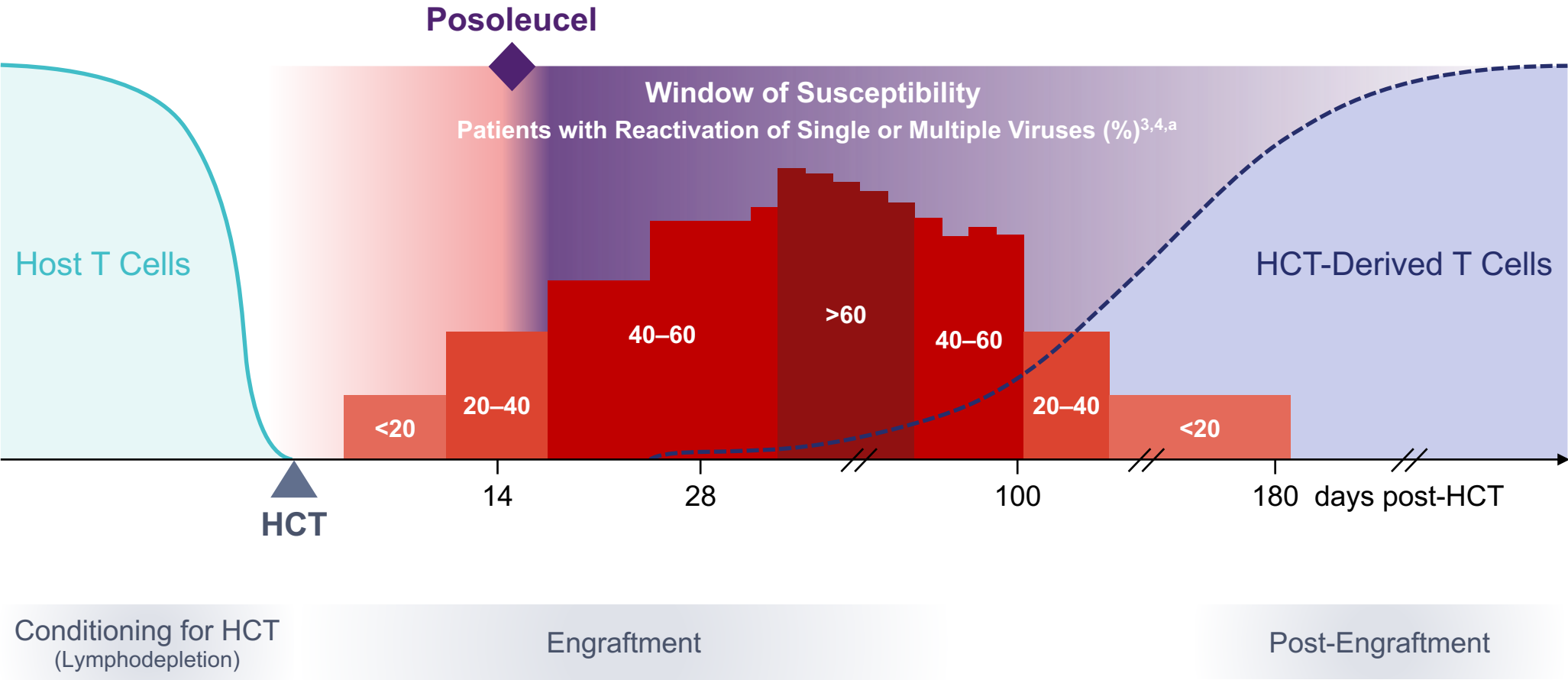
#### AlloVir's VSTs:

- Address the underlying immune deficit in high-risk patient populations
- Target multiple viruses with limited to no treatment options
- Offer off-the-shelf delivery to reach patients quickly

# Following HCT, Patients are Susceptible to Life-Threatening Viral Infections<sup>1-6</sup>



# Posoleucel is Designed to Treat and Prevent Viral Infections and Diseases Until the Patient's Own Immune System Recovers<sup>1-6</sup>



<sup>a</sup>Post 100-day data for proportion of patients with viral detection is from Huang YT, et al, as Hill J, et al only measured out to 100 days.  
 1. Kedia S, et al. *J Stem Cell Res Ther* 2013;S3; 2. Ison M, Hirsch H. *Clin Microbiol Rev* 2019;32:e00042-19; 3. Hill J, et al. *Blood* 2017;129:2316-25; 4. Huang YT, et al. *Biol Blood Marrow Trans* 2017;23:1759-66; 5. Stern L, et al. *Front Immunol* 2018;9:1672; 6. Hill J, et al. *Clin Infect Dis* 2018;66:368-75.



# Sanjeet Dadwal, M.D.

Chief, Division of Infectious Diseases and  
Professor of Medicine  
City of Hope



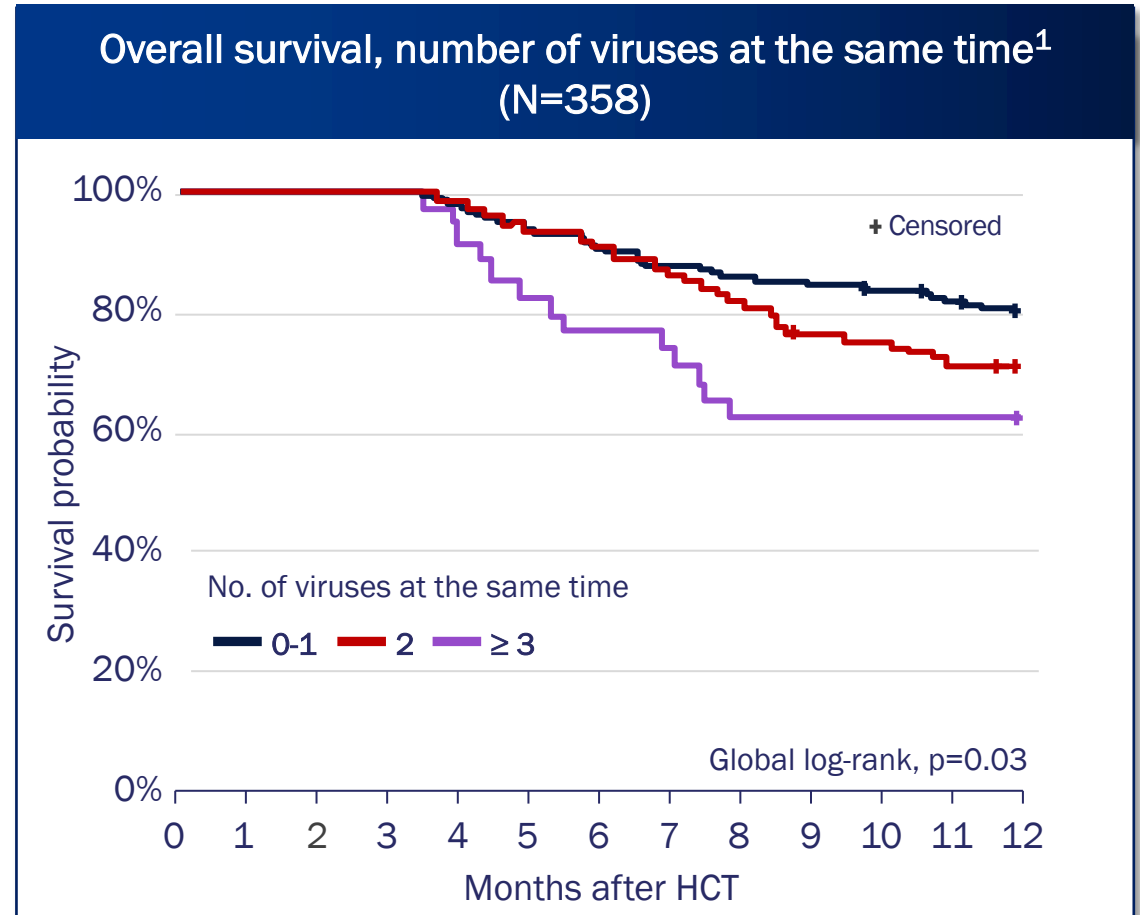
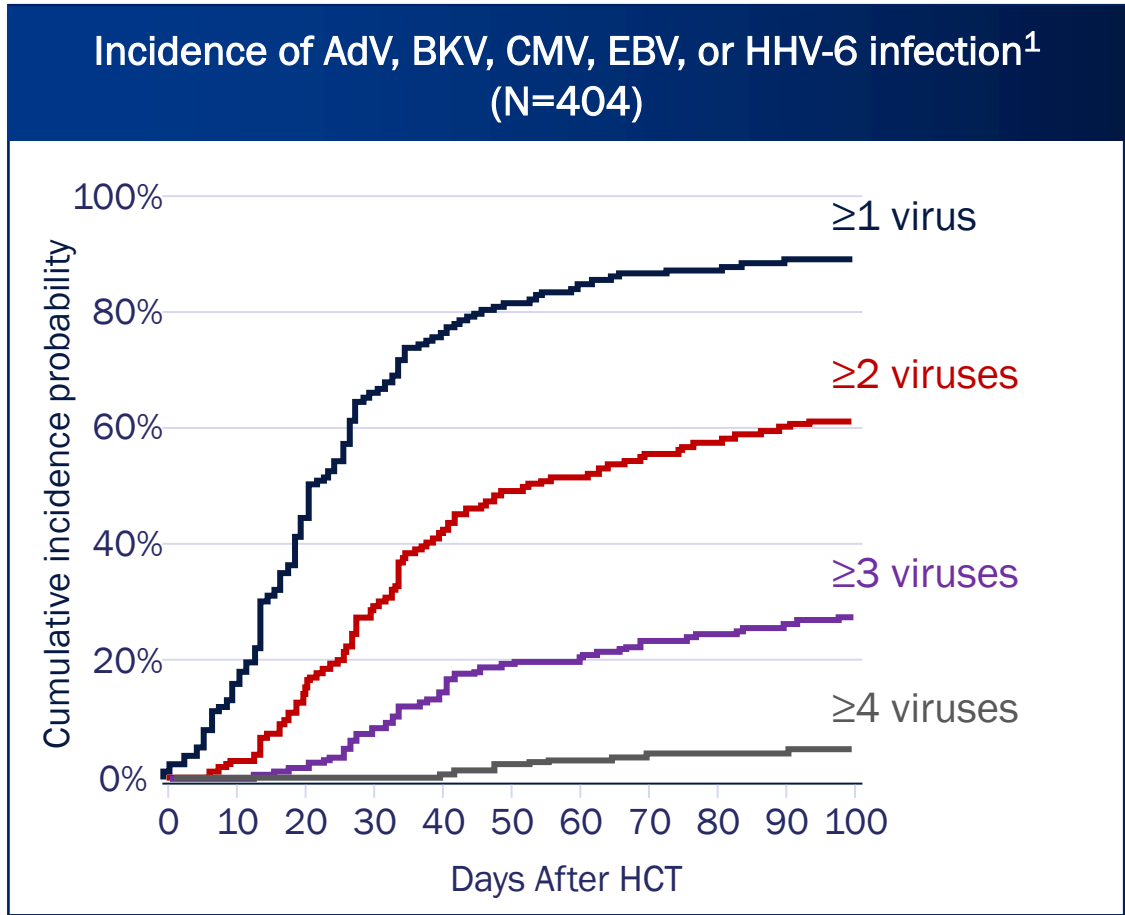
# **Posoleucel (ALVR105), an Off-the-Shelf, Multivirus-Specific T-Cell Therapy, for the Prevention of Viral Infections Post-HCT**

## **Results from an Open-Label Cohort of a Phase 2 Trial**

Sanjeet S. Dadwal<sup>1</sup>, Michael Schuster<sup>2</sup>, Gary Douglas Myers<sup>3</sup>, Keith Boundy<sup>4</sup>,  
Marshelle Warren<sup>5</sup>, Elizabeth Stoner<sup>4</sup>, Thuy Truong<sup>1</sup>, Joshua A. Hill<sup>6</sup>

<sup>1</sup>City of Hope National Medical Center, Duarte, CA; <sup>2</sup>Stony Brook Cancer Center, Stony Brook, NY; <sup>3</sup>Children's Mercy Hospital, Kansas City, MO;  
<sup>4</sup>AlloVir, Cambridge, MA; <sup>5</sup>Glacier Bio, North Bend, WA; <sup>6</sup>Fred Hutchinson Cancer Research Center, Seattle, WA

# Multi-Virus Infections Are Common in Allogeneic HCT Patients and Contribute to Significant Mortality

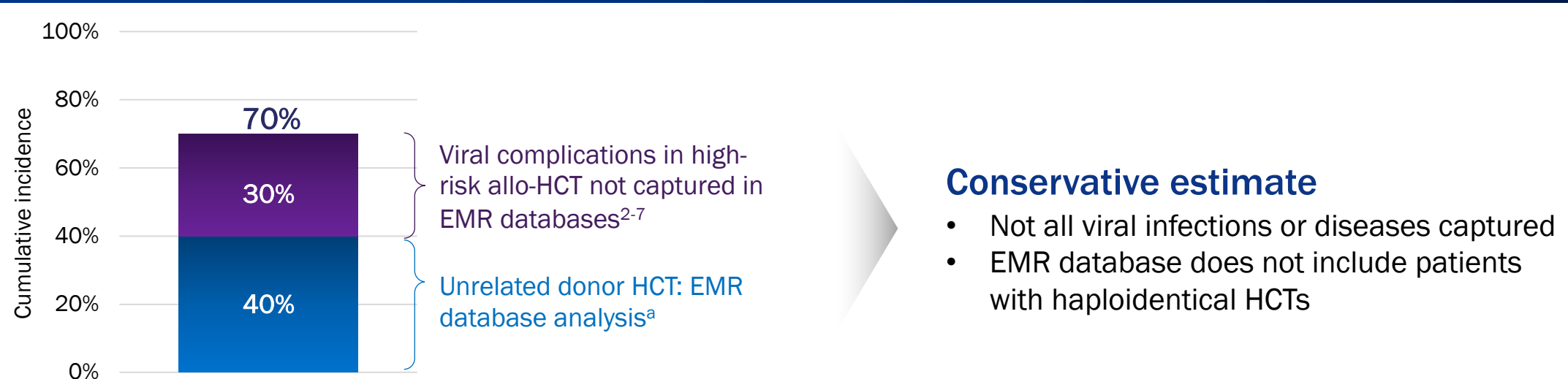


- 61% of patients were treated with antiviral therapies, excluding rituximab, within the first 100 days

# Approximately 70% Incidence of Clinically Significant Infection and Disease due to AdV, BKV, CMV, EBV, HHV-6, or JCV in High-Risk Allo-HCT Patients

- Allogeneic HCT (allo-HCT) patients are at high risk for common dsDNA infections: AdV, BKV, CMV, EBV, HHV-6, and JCV
- Allo-HCT patients at highest risk: haploidentical donor, UCB, MMUD, MUD, MMRD, T cell depletion (~75% of total allo-HCT patients<sup>1</sup>)

## Estimated incidence of clinically significant viral infection or disease

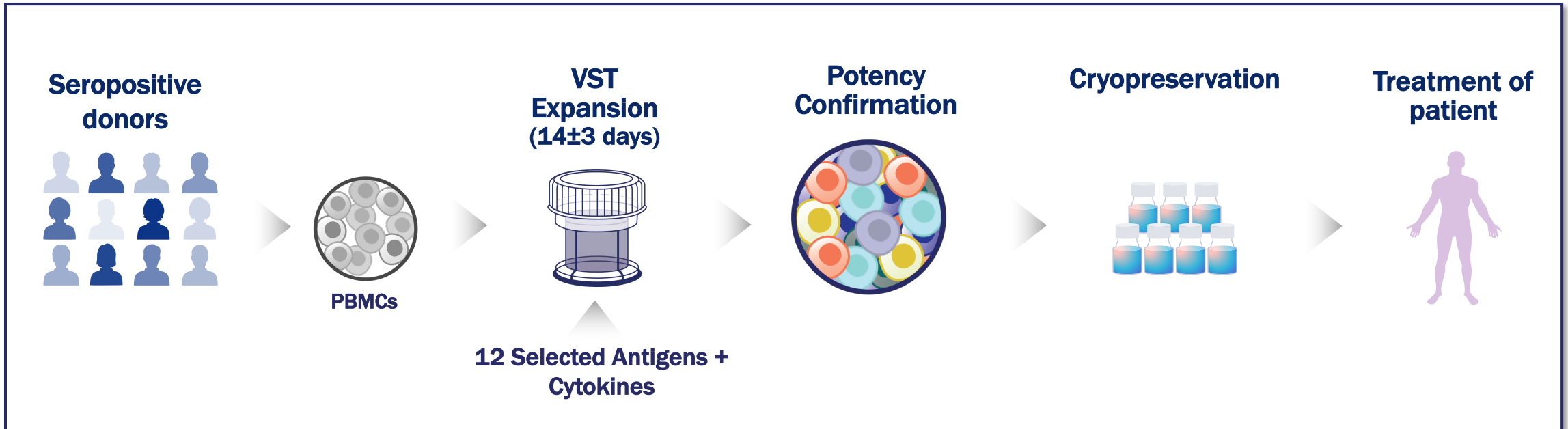


<sup>a</sup>>1400 patients identified between Jan 2018 and Apr 2021 through use of ganciclovir, valganciclovir, foscarnet, cidofovir, or rituximab or ICD-9/10 code for viral disease where available (e.g., does not include virus associated hemorrhagic cystitis)

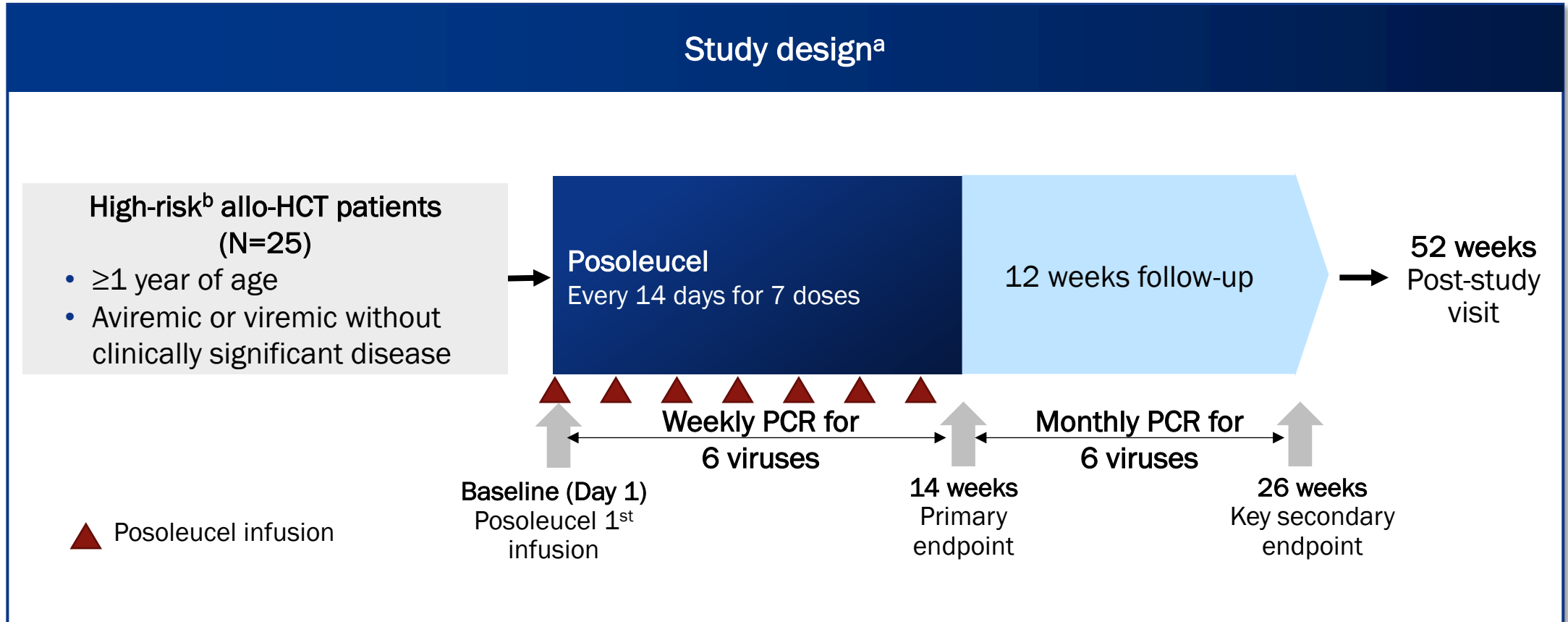
**There is an unmet need for preventive therapies targeting multiple viruses in high-risk allo-HCT patients**

# Posoleuceal (ALVR105)

- Allogeneic, off-the-shelf, multivirus-specific T-cell (VST) therapy targeting AdV, BKV, CMV, EBV, HHV-6, and JCV<sup>a</sup>
- 93% response rate in Phase 2 CHARMS study<sup>1</sup>



# Phase 2 Multi-Virus Prevention Open-Label Study Design



# Endpoint

**Primary endpoint:** The number of new onset clinically significant infections or episodes of end-organ disease through Week 14

Clinically significant viral infection

Above viral load threshold

- CMV: >910 IU/mL
- EBV/AdV: >10,000 copies/mL OR >1,000 copies/mL and rising<sup>a</sup>

AND

Initiation of preemptive antiviral therapy

End-organ disease

Signs or symptoms of organ damage from AdV, BKV, CMV, EBV, HHV-6, or JCV

# Baseline Demographics

Characteristic	N=23
Age, median years (range)	59 (14-73)
Female, n (%)	12 (52%)
Non-Caucasian or Latino, n (%)	11 (48%)
<b>Diagnosis, n (%)</b>	
Leukemia	14 (61%)
Myelodysplasia/Myelofibrosis	3 (13%)
Lymphoma	2 (9%)
Sickle cell anemia	2 (9%)
Other <sup>a</sup>	2 (9%)

Characteristic	N=23
<b>Donor type, n (%)</b>	
Haploidentical	14 (61%)
Mismatched unrelated	6 (26%)
Matched unrelated <sup>b</sup>	2 (9%)
Umbilical cord blood	1 (4%)
<b>Myeloablative conditioning, n (%)</b>	12 (52%)
<b>Baseline viremia<sup>c</sup>, n (%)</b>	10 (43%)
<b>Letemovir prophylaxis, n (%)</b>	14 (61%)

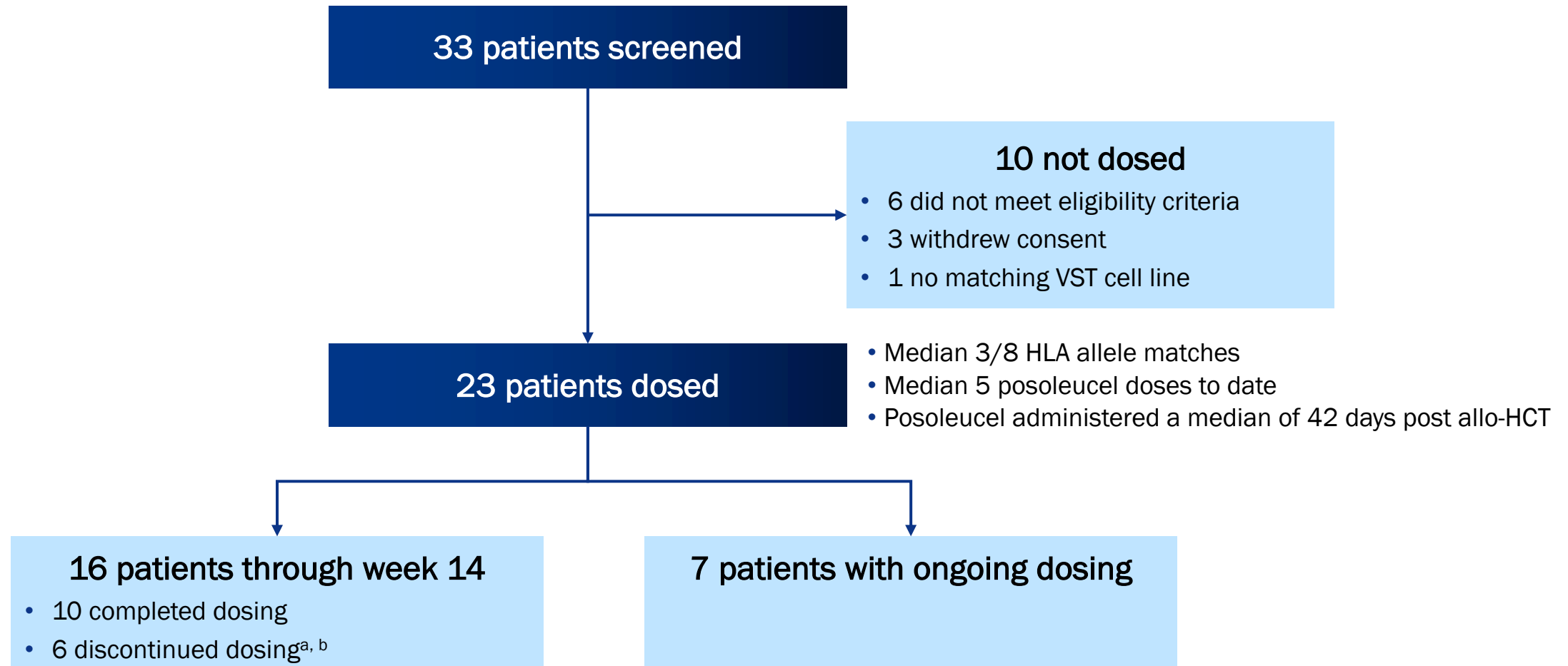
<sup>a</sup>Multiple myeloma and adrenoleukodystrophy

<sup>b</sup>Matched unrelated transplant recipients included if also met another high-risk criterion: T cell depletion or persistent lymphopenia

<sup>c</sup>1 AdV, 7 BKV, 2 EBV and/or 4 HHV-6 viremia(s) detected in 10 patients



# Patient Disposition



# Safety and Tolerability

- No unexpected treatment-emergent adverse events (TEAEs) or serious adverse events (SAEs) were reported
- 6/23 (26%) grade II-IV acute GVHD
  - Consistent with 35-50% of grade II-IV GVHD reported in high risk allo-HCTs<sup>1-3</sup>
  - No association between reported GVHD and number of HLA matches for posoleucel
  - No association between reported GVHD and number of posoleucel doses

Events	N=23
Common adverse events (AEs)	
Diarrhea	7 (30%)
Weight decrease	5 (22%)
SAEs	11 (48%)
Treatment-related SAE	2 (9%) <sup>a</sup>
Deaths	1 (4%) <sup>b</sup>
Posoleucel DC due to TEAEs	3 (13%) <sup>c</sup>
Adverse events of interest	
Acute GVHD II-IV	6 (26%)
Grade II	2 (9%)
Grade III	4 (17%)
Grade IV	0 (0%)
Cytokine release syndrome	0 (0%)
Infusion reaction	1 (4%) <sup>d</sup>

<sup>a</sup>1 patient with infusion reaction; 1 patient with acute GVHD

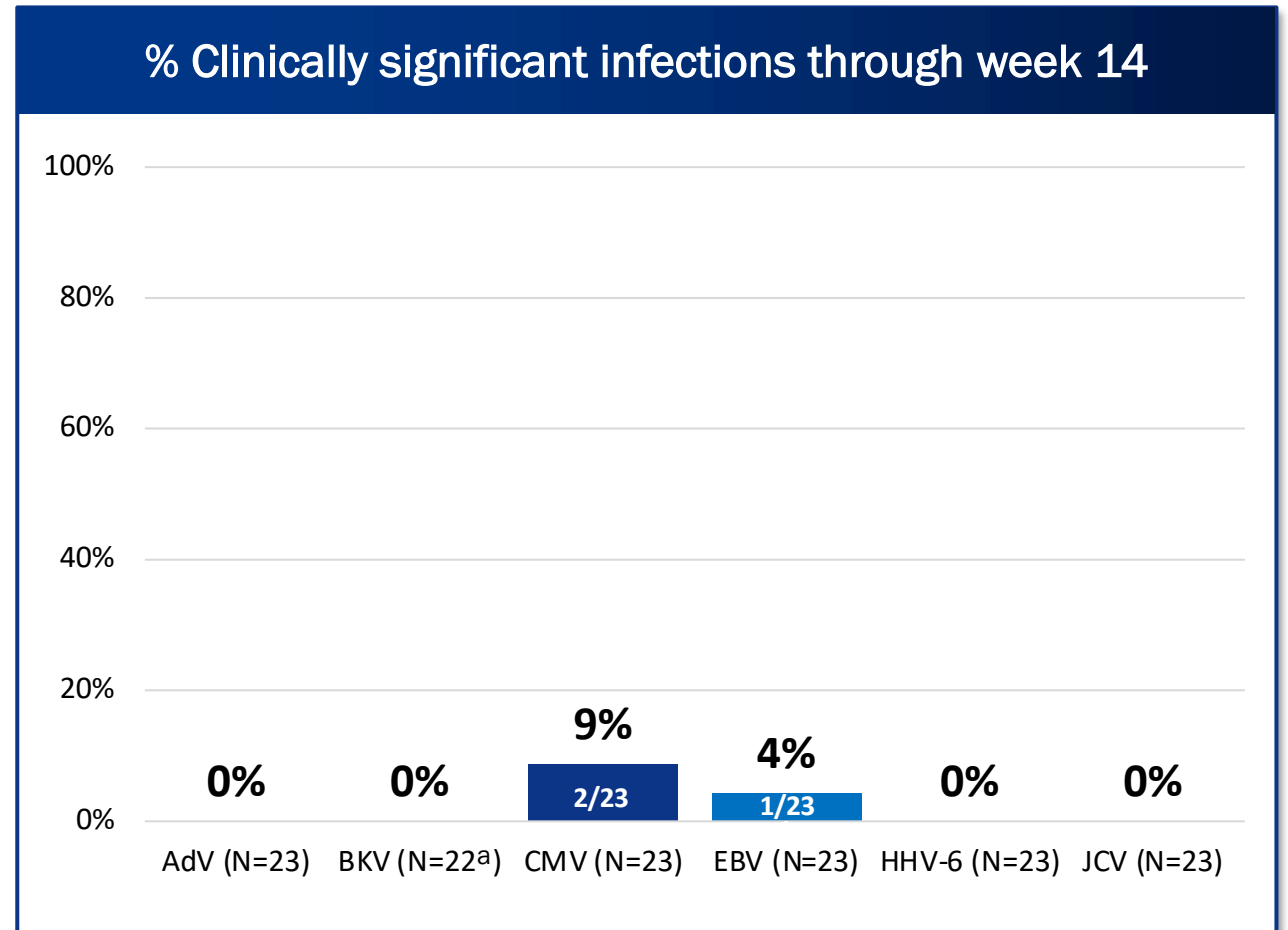
<sup>b</sup>Relapse of primary malignancy ~2 months after the 7<sup>th</sup> dose of posoleucel

<sup>c</sup>2 patients assessed as not related to posoleucel; 1 patient assessed as possibly related to posoleucel

<sup>d</sup>Tolerated subsequent posoleucel doses with pre-medication (diphenhydramine).

# Preliminary Results: Primary Endpoint (Week 14)

- 3 clinically significant infections
  - 2 patients started on pre-emptive valganciclovir for CMV post letermovir withdrawal
  - 1 patient started on rituximab for EBV in the setting of high-dose steroids
- No end-organ disease<sup>a</sup>

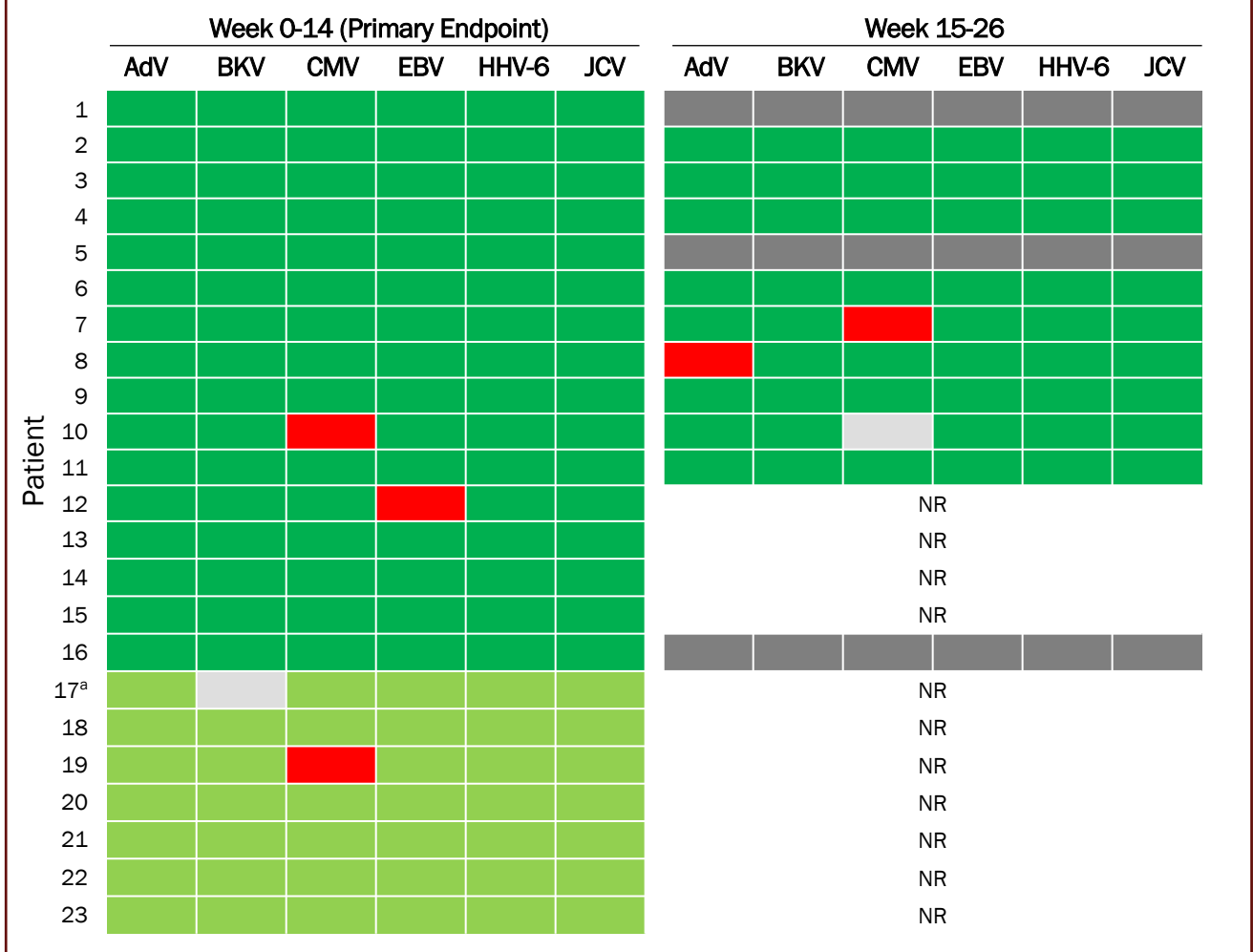


<sup>a</sup>One patient excluded due to BKV hemorrhagic cystitis at baseline

# Preliminary Results: Secondary Endpoint (Week 26)

- 2 additional clinically significant infections
  - 1 patient started on pre-emptive valganciclovir for CMV post letermovir withdrawal
  - 1 patient started cidofovir for AdV in the setting of high-dose steroids
- No end-organ disease

Clinically significant infections by 6 target viruses in high-risk allo-HCT patients receiving posoleucel

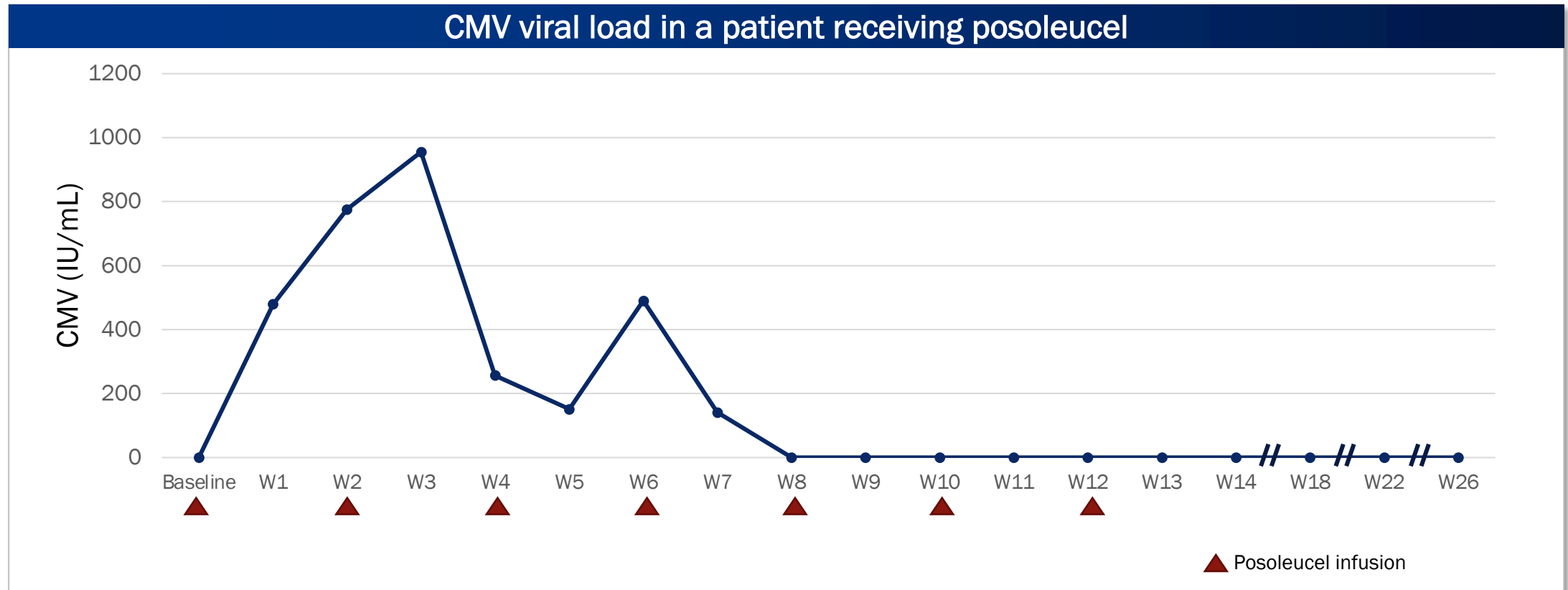


■ Patients with completed or stopped dosing who did not develop clinically significant infection or disease  
■ Patients with ongoing dosing/monitoring who have not developed clinically significant infection or disease  
■ Patients who developed newly onset clinically significant infection or disease  
■ Patients sample not collected  
■ Previous clinically significant infection or disease  
NR Week 18 timepoint not yet reached

<sup>a</sup>BKV hemorrhagic cystitis at baseline

# CMV Infection Controlled without Letermovir or Pre-Emptive Therapy while on Posoleucel

- 61YO / Cutaneous T cell lymphoma / Myeloablative conditioning / MMUD HCT
- CMV serostatus: D-/R+
- Last dose of letermovir was 1 day prior to 1<sup>st</sup> posoleucel dose
- No pre-emptive therapy during study
- Completed all 7 posoleucel doses



# Biomarker Summary

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- Preliminary assessment of T cell activity by IFN $\gamma$  ELISpot (N=4) shows increased T cell activity against the infecting target viruses in patients with clinically significant infection
- Preliminary data from TCR sequencing (N=6) demonstrate posoleucel can be detected throughout the 14-week dosing period

# Conclusions

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- Approximately 70% of high-risk allo-HCT patients develop clinically significant viral infections or disease due to AdV, BKV, CMV, EBV, HHV-6, or JCV
- In the ongoing, open-label cohort of the Phase 2 Multi-Virus Prevention study:
  - **High-risk allo-HCT patients receiving posoleucel had low rates of clinically significant viral infections and no end-organ disease**
  - **Repeat dosing of posoleucel was generally safe and well tolerated**
- These results support the evaluation of posoleucel for the prevention of infections and diseases from the 6 targeted viruses in the upcoming randomized, placebo-controlled Phase 3 trial



## **Diana Brainard, M.D.**

Chief Executive Officer  
AlloVir, Inc. (Nasdaq: ALVR)

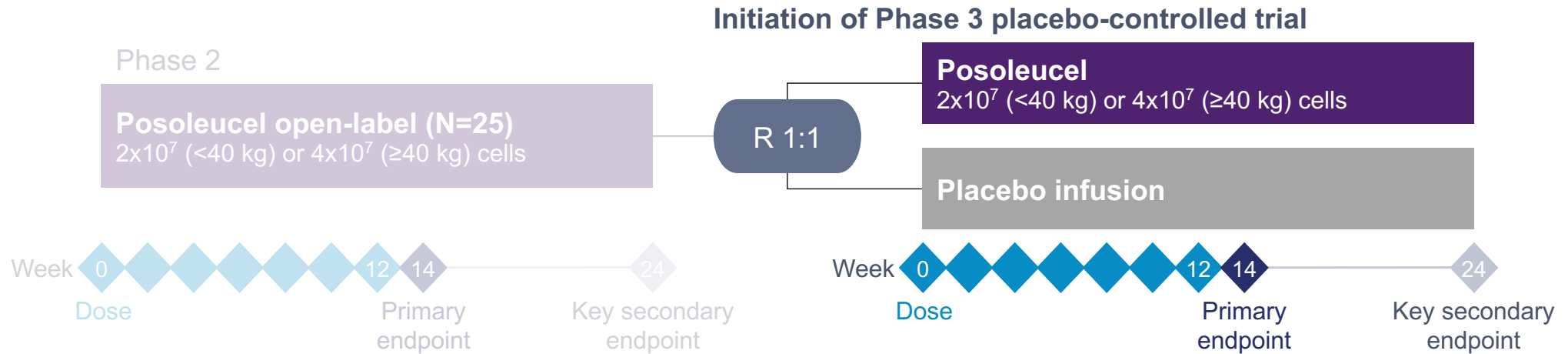


# Multi-Virus Prevention Data Underscore the Potential of AlloVir's Virus-Specific T Cell Platform and Posoleucel

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- Further validation of our VST platform and programs
- Opportunity to transform both patient outcomes and the overall management of HCT recipients
- Phase 3 clinical development for both treatment and prevention anticipated by first half of 2022

# Ongoing Posoleucel Trial for Multi-Virus Prevention Anticipated to Progress to Phase 3 Registrational Study in 1H 2022



- Phase 3, multicenter, randomized, double-blind, placebo-controlled
- Key eligibility criteria: high-risk allo-HCT\* recipients, including matched unrelated donor
  - Age ≥1 year
  - Aviremic or viremic without clinically significant disease
- Primary endpoint: reduction in clinically significant viral infection and disease

# Three Ongoing Phase 3 Studies of Posoleucel Anticipated By 1H 2022



Candidate	Target Population	Target Indication	Preclinical	POC	Pivotal
Posoleucel (ALVR105)	Allo-HCT	vHC treatment	[Progress bar: Preclinical, POC, Pivotal]		
		AdV treatment	[Progress bar: Preclinical, POC, Pivotal]		
	Kidney transplant	BKV treatment	[Progress bar: Preclinical, POC, Pivotal]		
	Solid organ transplant	AdV, BKV, CMV, EBV, HHV-6, JCV prevention*	[Progress bar: Preclinical, POC, Pivotal]		
		AdV, BKV, CMV, EBV, HHV-6, JCV prevention	[Progress bar: Preclinical, POC, Pivotal]		

# We Are Delivering on a Broad Set of Preclinical, Regulatory and Clinical Milestones

	Recent Milestones	Remaining 2021 Catalysts	Future Activities
<b>Posoleucel</b>	<ul style="list-style-type: none"> <li>✓ Pivotal trial initiation in vHC</li> <li>✓ FDA orphan drug designation for vHC treatment</li> <li>✓ POC trial initiation in multi-virus prevention and initial data</li> <li>✓ POC trial initiation in BKV in kidney transplant</li> <li>✓ <b>Abstract submission for early data from BKV in kidney transplant trial</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Pivotal trial initiation for AdV</b></li> </ul>	<ul style="list-style-type: none"> <li>• Phase 3 trial initiation for multi-virus prevention in HCT patients</li> <li>• POC trial initiation for multi-virus prevention in SOT patients</li> </ul>
<b>ALVR106</b>	<ul style="list-style-type: none"> <li>✓ IND clearance by FDA for POC trial in multiple respiratory viruses</li> </ul>	<ul style="list-style-type: none"> <li>• <b>POC trial initiation for multiple respiratory viruses</b></li> </ul>	
<b>ALVR107</b>	<ul style="list-style-type: none"> <li>✓ <i>In vitro</i>, preclinical, IND-enabling studies</li> </ul>		<ul style="list-style-type: none"> <li>• POC trial initiation for HBV cure</li> </ul>
<b>ALVR109</b>	<ul style="list-style-type: none"> <li>✓ Initial data for SARS-CoV-2</li> </ul>		<ul style="list-style-type: none"> <li>• Compassionate use access</li> </ul>

# Q&A



**Diana Brainard, M.D.**  
Chief Executive Officer  
AlloVir



**Sanjeet Dadwal, M.D.**  
Chief, Division of Infectious Diseases  
Professor of Medicine  
City of Hope



**Vikas Sinha, MBA**  
President & Chief Financial Officer  
AlloVir



**Jeroen van Beek, Ph.D.**  
Chief Commercial Officer  
AlloVir



**Sonia Choi**  
Senior Vice President,  
Corporate Affairs & Investor Relations  
AlloVir