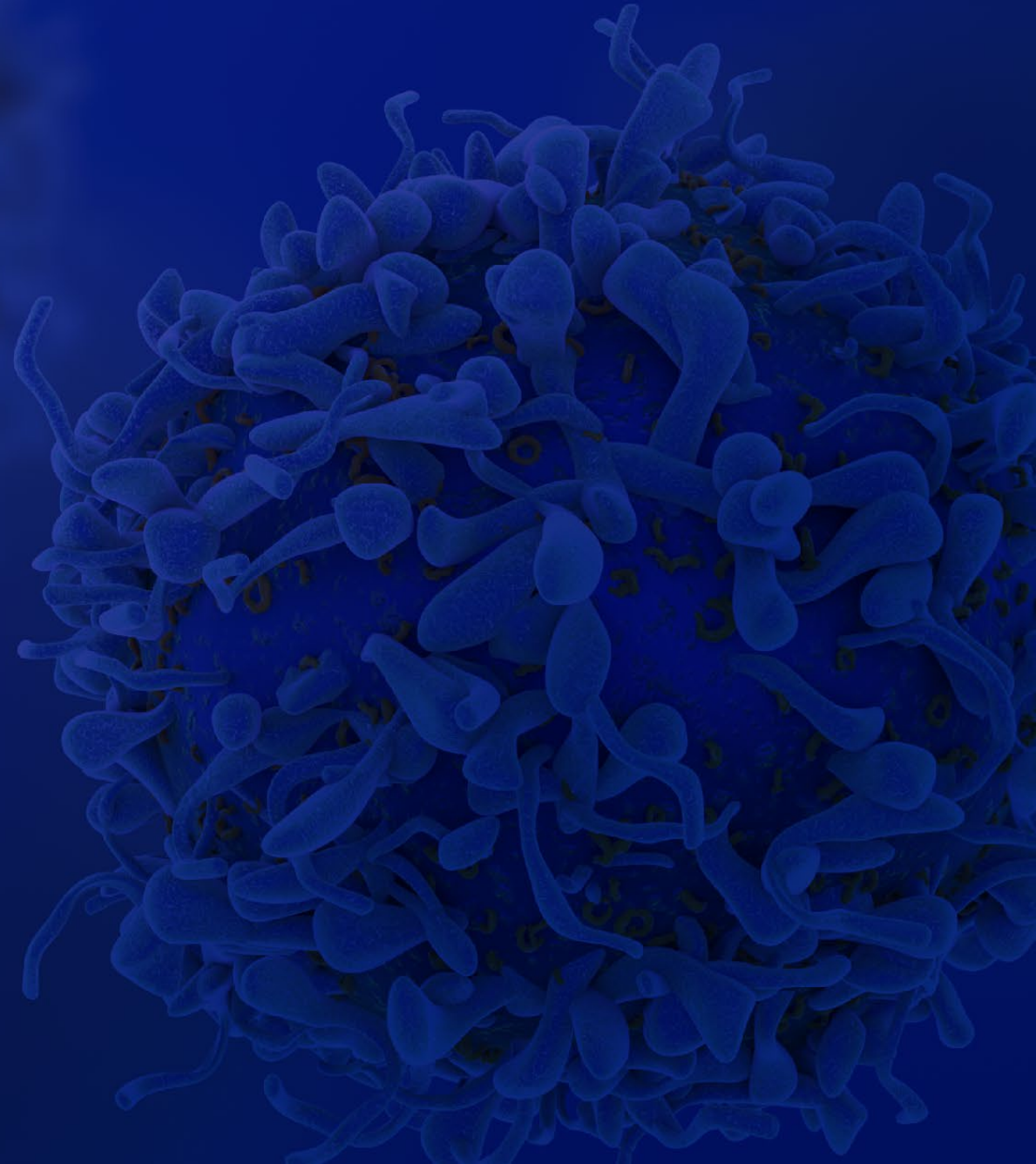




# A Leader in Allogeneic, Off-the-Shelf, Virus- Specific T Cell Therapies

August 2023



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# Restoring Immunity with our Off-the-Shelf, Multi-Virus-Specific T Cells (VSTs)

AlloVir's VST Platform is Clinically Validated, Streamlined, and Scalable

Posoleucel is a Pipeline Within a Product, Targeting 6 Devastating Viruses

Blockbuster Commercial Opportunity in Allo-HCT Patients

**Non-gene edited allogeneic** cell therapy with **low cost of goods**

**Rich pipeline** of clinical and preclinical programs

**Three global Phase 3 registrational trials** for 3 first-to-market indications with data readouts in 2H2024 for allo-HCT patients<sup>1</sup>:

- 1) Multi-virus prevention
- 2) Treatment of hemorrhagic cystitis, and
- 3) Treatment of adenovirus infection

**Positive topline Phase 2 data** in kidney transplant support advancement of future SOT clinical trials

**Blockbuster HCT commercial opportunity** with >40,000 annual addressable patients worldwide\*

Expansion to SOT patients adds **potential to double the market**

# Overview and Key Advantages of our Allogeneic Manufacturing Platform



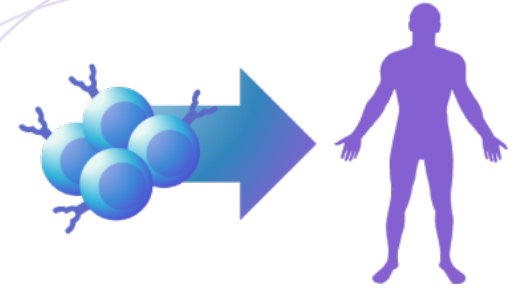
Carefully selected healthy seropositive donors



VST selective expansion using proprietary process



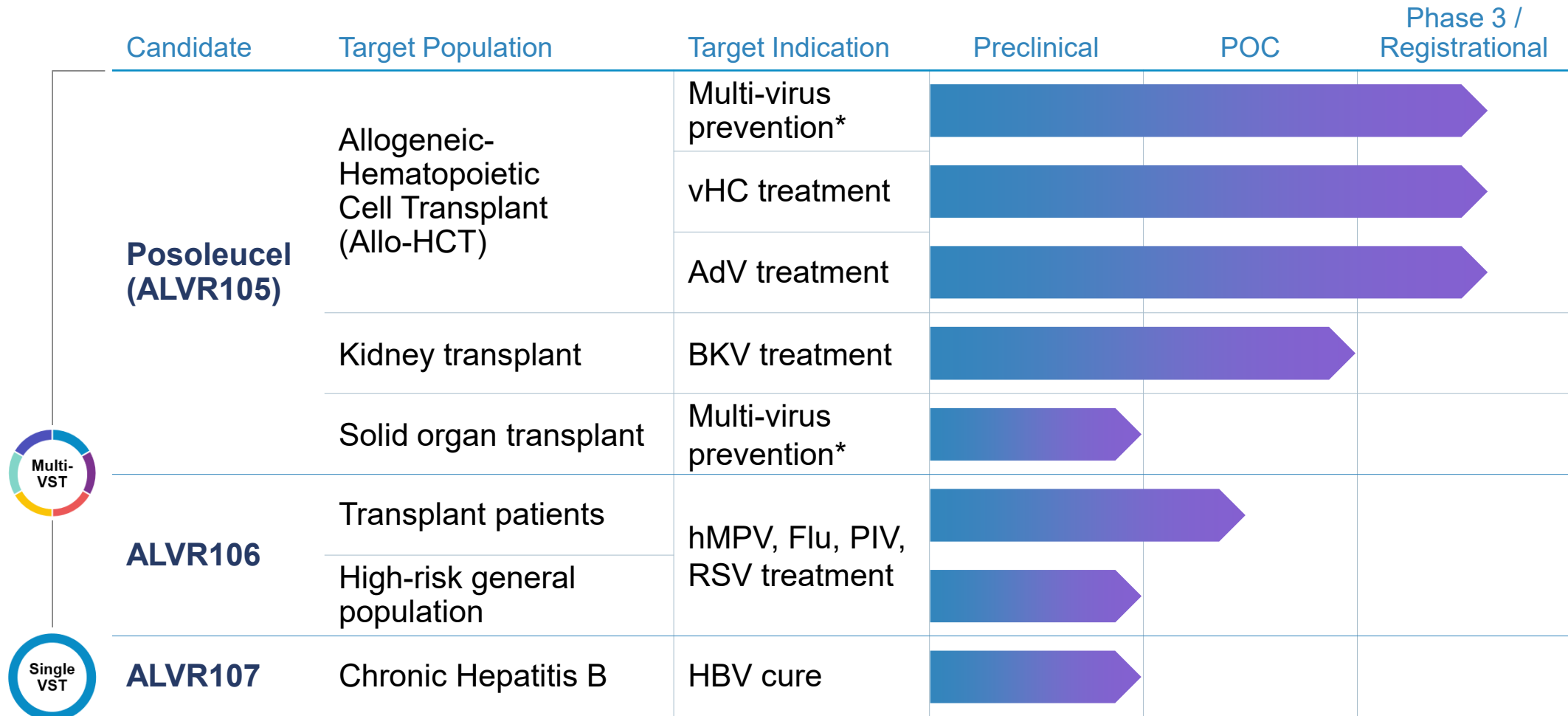
Cryopreservation and storage at global depots



Treatment of patient

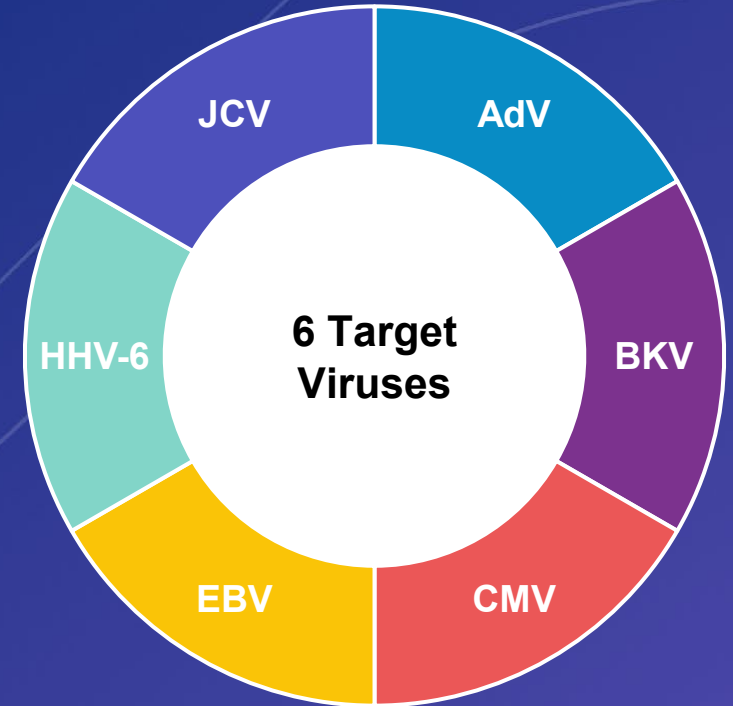
- Proprietary donor selection algorithm enables coverage of **>95% of patients** with small number of donors
- **Streamlined manufacturing** yields hundreds of VST doses from a single donor/production run
- VST potency confirmed against individual **target viruses** using functional assay
- Our VSTs have long-term stability, supporting **on-demand**, broad availability for patients

# Our Pipeline Targets 11 Devastating Viruses With No or Limited Treatment Options<sup>1</sup>



# Posoleucel

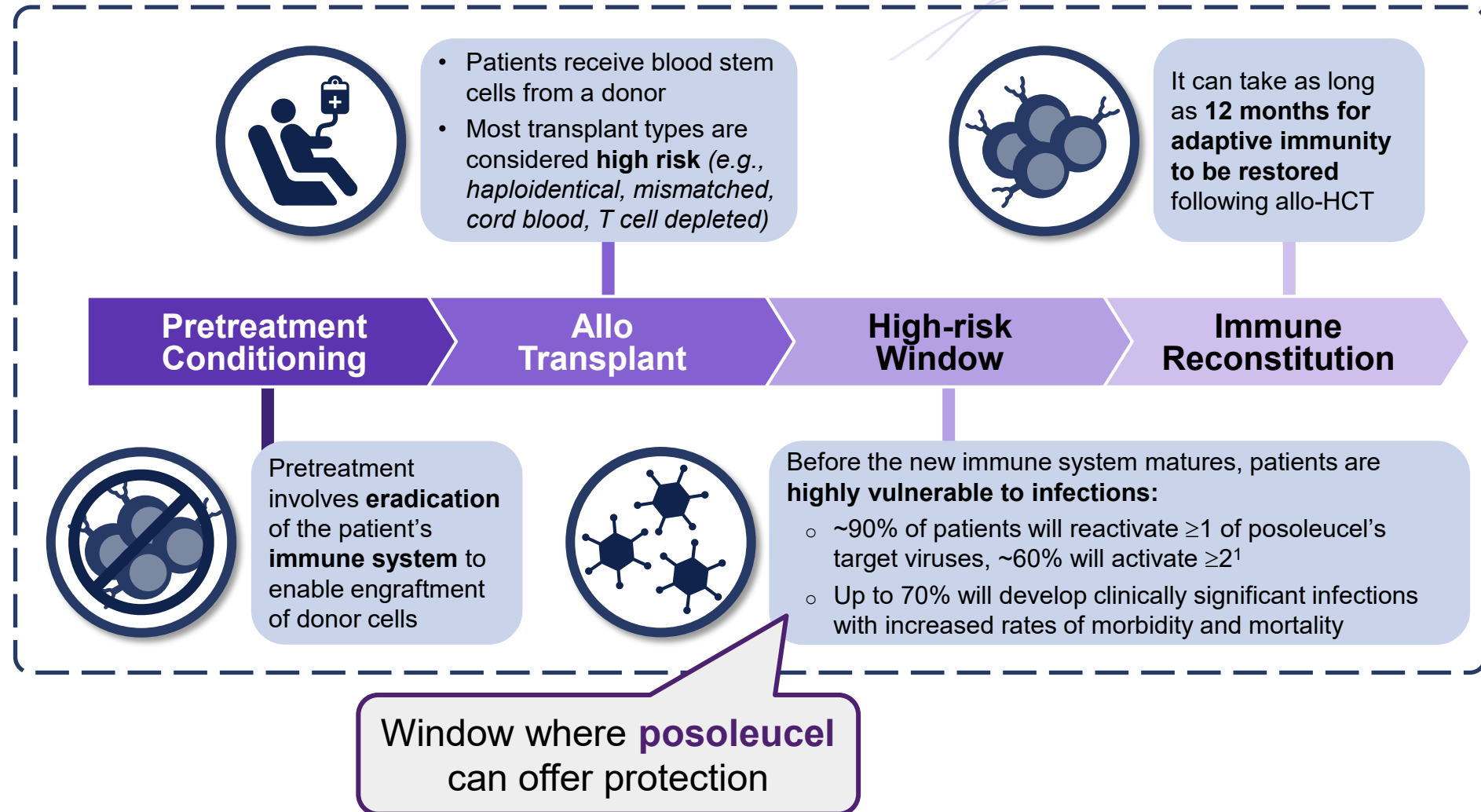
Prevention and Treatment of Clinically Significant Viral Infections Post-Transplant



# Allogeneic Hematopoietic Cell Transplantation (Allo-HCT): Patient Journey



- Allo-HCT is used to treat patients with conditions including:
  - Blood cancers (e.g., *leukemias*)
  - Blood disorders (e.g., *sickle cell disease*)
  - Primary immunodeficiencies (e.g., *SCID*)
- >40,000 allo-HCTs performed annually\*



# Posoleucel has the Potential to Prevent and Treat the Devastating Consequences of Post-transplant Viral Infection

Where could Posoleucel play a role in the Allo-HCT patient journey?

*Before clinically significant infection*



*After clinically significant infection*

## PREVENTION

- Averting disease and negative clinical sequelae
- Phase 3 pivotal trial ongoing
  - Prevention of clinically significant infections or end-organ disease from AdV, BKV, CMV, EBV, HHV-6, or JCV

## TREATMENT

- High unmet need
- Two ongoing Phase 3 pivotal trials
  - Treatment of virus-associated hemorrhagic cystitis
  - Treatment of adenovirus

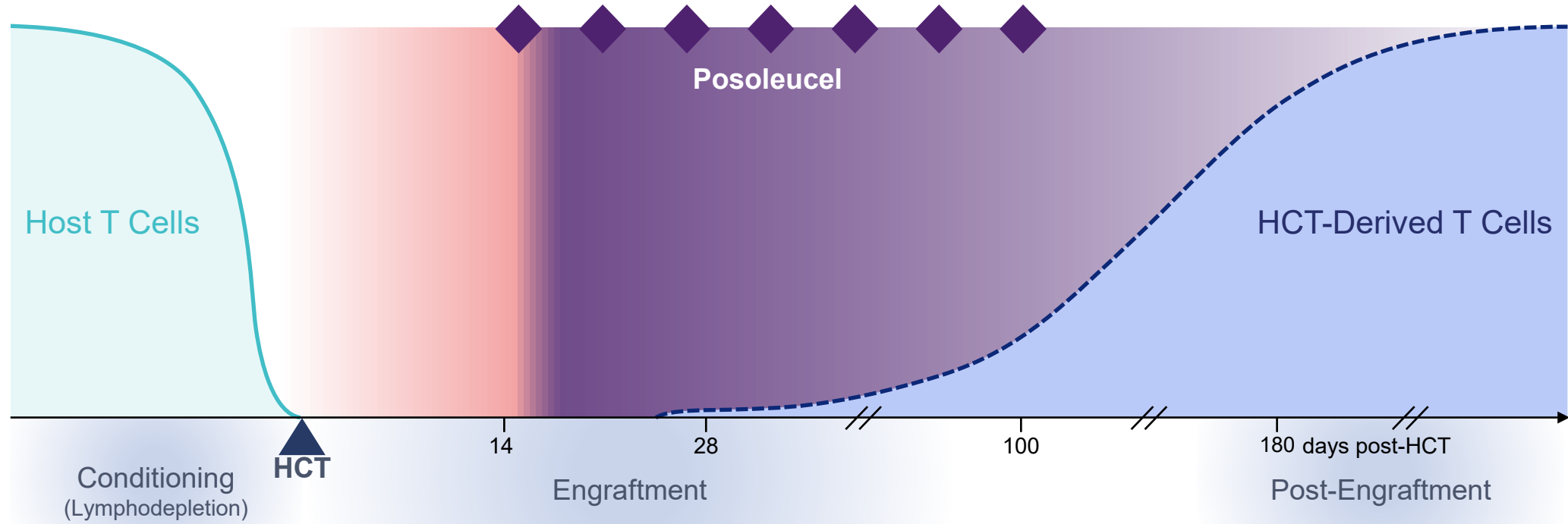
Three ongoing Phase 3 studies are supported by **strong Phase 2 efficacy and safety data**

**Topline data** for Phase 3 studies expected **2H2024**



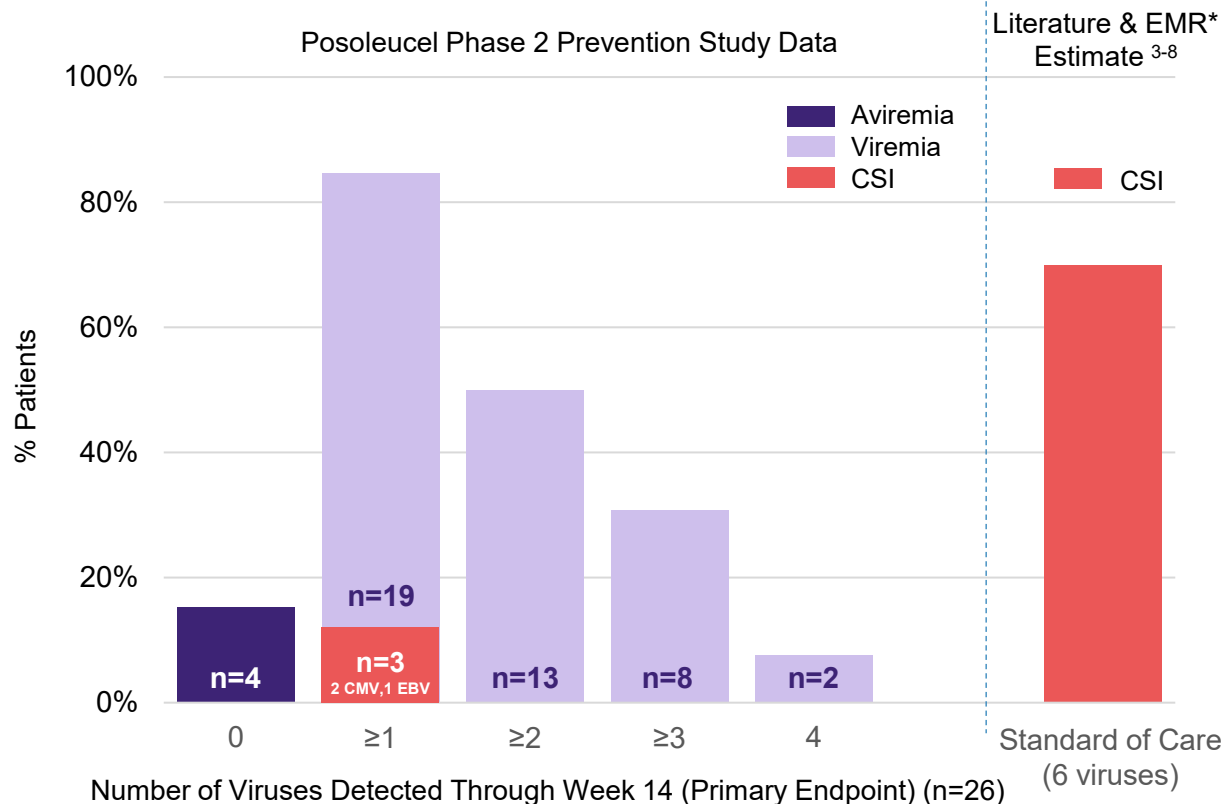
# Posoleucel Aims to Prevent Viral Infections and Disease Following Allogeneic Hematopoietic Cell Transplantation<sup>1-6</sup>

Posoleucel is designed to act as an **immunological bridge** in the highest-risk window of susceptibility post allo-HCT, **to prevent the progression of viral reactivation to clinically significant infections**



# Final Open-Label Phase 2 Prevention Study Results Demonstrate Low Rates of Clinically Significant Infection (CSI) and 0% Non-Relapse Mortality<sup>1,2</sup>

## Infections in Allo-HCT Patients



## Low Rates of Clinically Significant Infection

- 23/26 (88%) patients CSI-free through Week 14
- 22/26 (85%) patients reactivated  $\geq 1$  target virus

## 0% Day 400 Non-Relapse Mortality

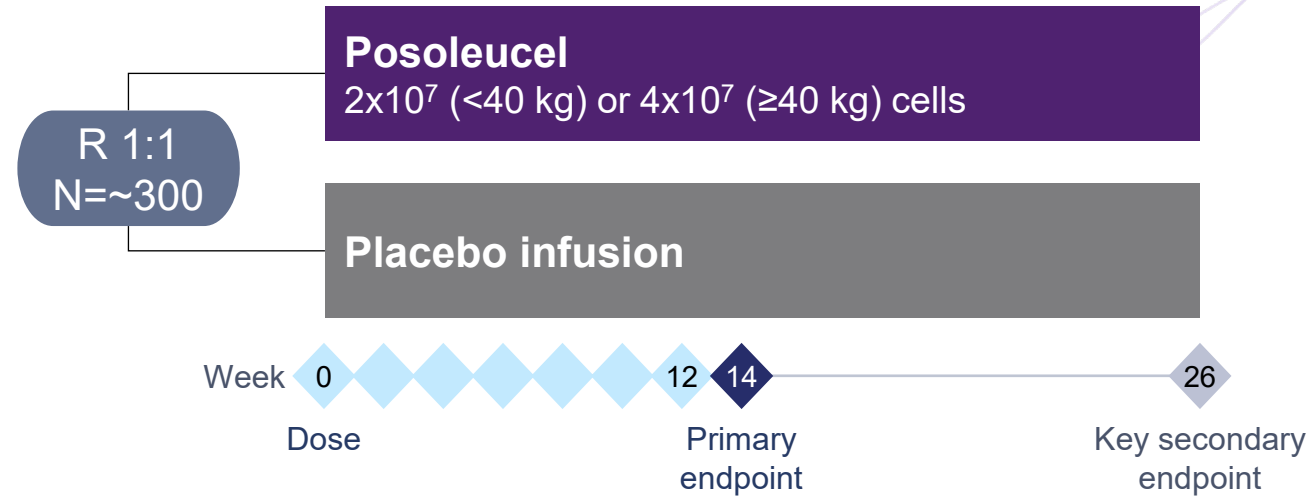
## Repeat Dosing Generally Well Tolerated

- No unanticipated TEAEs or SAEs
- No cytokine release syndrome
- 5 cases (19%) of acute GVHD (grades II-IV)

## Biomarker Data Support Mode of Action

- VST cell expansion coincident with viral load declines
- Presence of posoleucel confirmed during and after infusion period

# Phase 3 Registrational Multi-Virus Prevention Trial is Ongoing

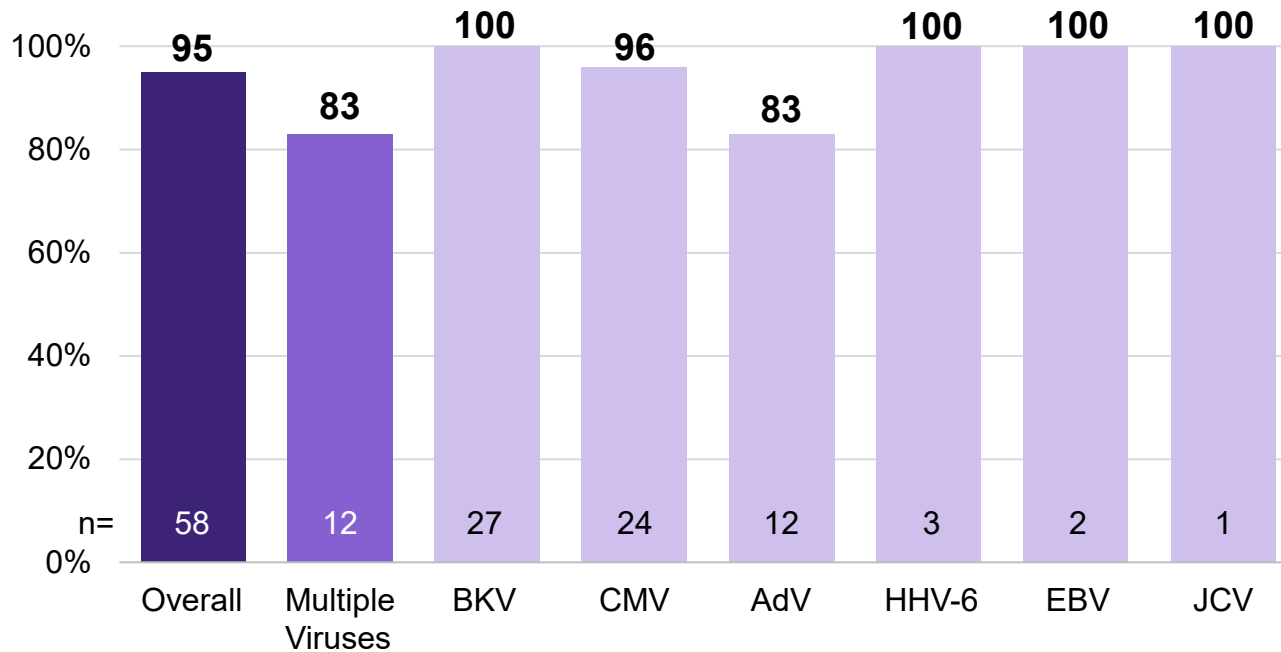


- Phase 3, multicenter, randomized, double-blind, placebo-controlled
- Key eligibility criteria: high-risk\* allo-HCT recipients, including matched unrelated donor
  - Age  $\geq 1$  year
  - Aviremic or viremic without clinically significant disease
- Primary endpoint: reduction in clinically significant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

**Topline data expected 2H2024**

# Phase 2 CHARMS Treatment Study Demonstrated 95% Efficacy In Treatment-Refractory Patients<sup>1</sup>

## Efficacy: Posoleucel Response Rate\*



CR = Viral load return to normal range and resolution of clinical signs/symptoms  
PR =  $\geq 50\%$  decrease in viral load and/or  $\geq 50\%$  improvement of clinical signs/symptoms

## Efficacy: High Response Rates

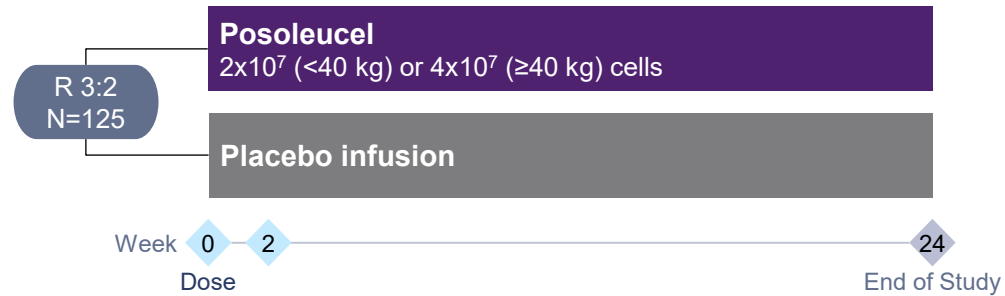
- 95% of patients who had no available treatment options experienced a clinical response by Week 6
- High response rate seen in patients with multiple infections

## Safety: Posoleucel Well Tolerated

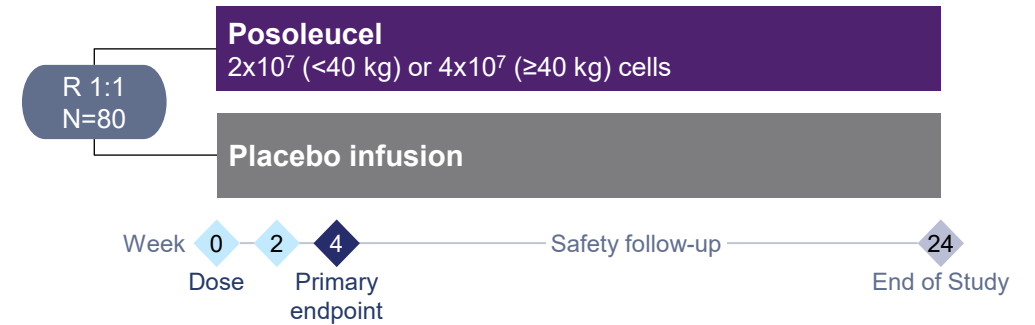
- Infusion reactions limited to fever (n=3)
- GVHD consistent in rate and severity to that expected in allo-HCT population
- No cytokine release syndrome

# Phase 3 Registrational Trials for Treatment of Virus-Associated Hemorrhagic Cystitis and Adenovirus are Enrolling Patients Globally

## Virus-Associated Hemorrhagic Cystitis Treatment



## Adenovirus Treatment



### Study Design:

Phase 3, multicenter, double-blind, placebo-controlled

### Key Eligibility Criteria:

Patients with vHC following allogeneic HCT

- Macroscopic hematuria (Grade ≥3)
- Viruria
- Dysuria, lower abdominal pain and/or pain associated with spasm

### Primary Endpoint:

Time to resolution of macroscopic hematuria through Week 24

Patients with adenovirus reactivation following allogeneic HCT

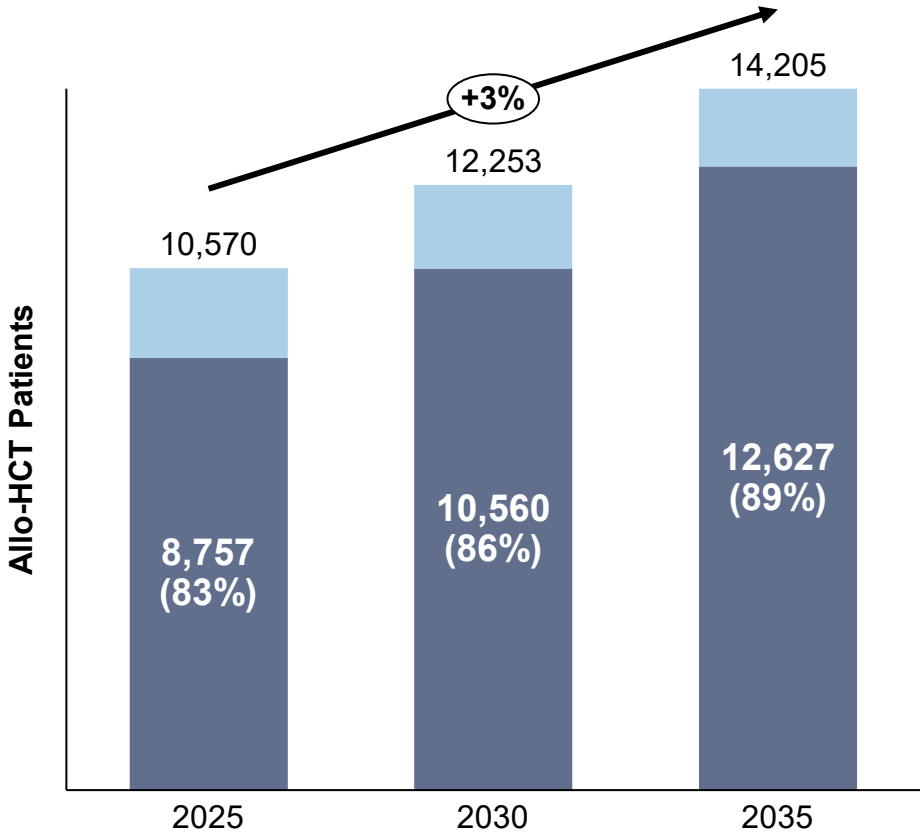
- AdV viremia ≥10,000 copies/mL, OR
- 2 consecutive, rising AdV viremia ≥1,000 copies/mL and lymphopenia or T-cell depletion

Proportion of patients with undetectable viremia at Day 29

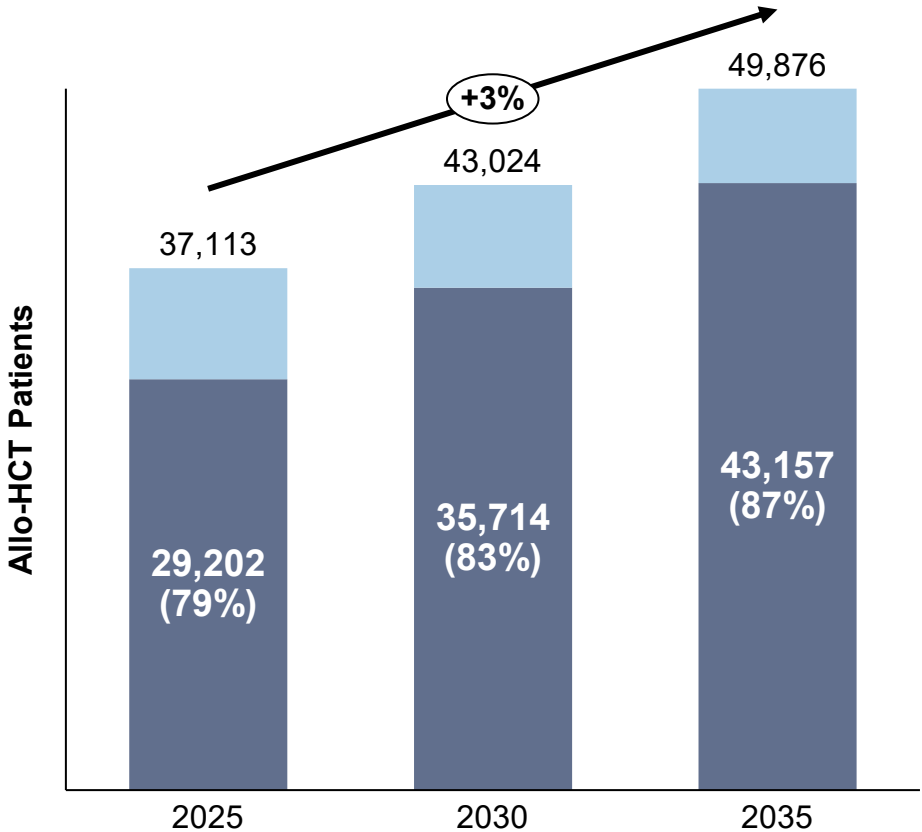
**Topline data expected 2H2024**

# Anticipated Growth in Allogeneic Stem Cell Transplants and % Addressable by Posoleucel for Multivirus Prevention, 2025-2035

## United States



## Global



■ Not addressable (i.e., low risk patients, patients with high grade GVHD)  
■ Addressable with posoleucel

# Foundation Set for >\$1B Commercial Opportunity in Allo-HCT

## Strong Clinical & Economic Value Proposition

Positive Phase 2 data in treatment and prevention of viral infections  
Published US claims analyses<sup>1,2</sup> illustrating burden in allo-HCT

## Concentrated Prescriber Base Overlapping with Phase 3 Trial Sites

80% of U.S. allo-HCTs performed in 70 centers  
Similar distribution in major EU markets

## Supportive Reimbursement Landscape

60% U.S. patients commercially insured  
CAR-T DRG code includes other immunotherapies

## Large Addressable Patient Population

Over 40,000 allo-HCT patients annually\*  
Potential addition of SOT & other immunocompromised patients

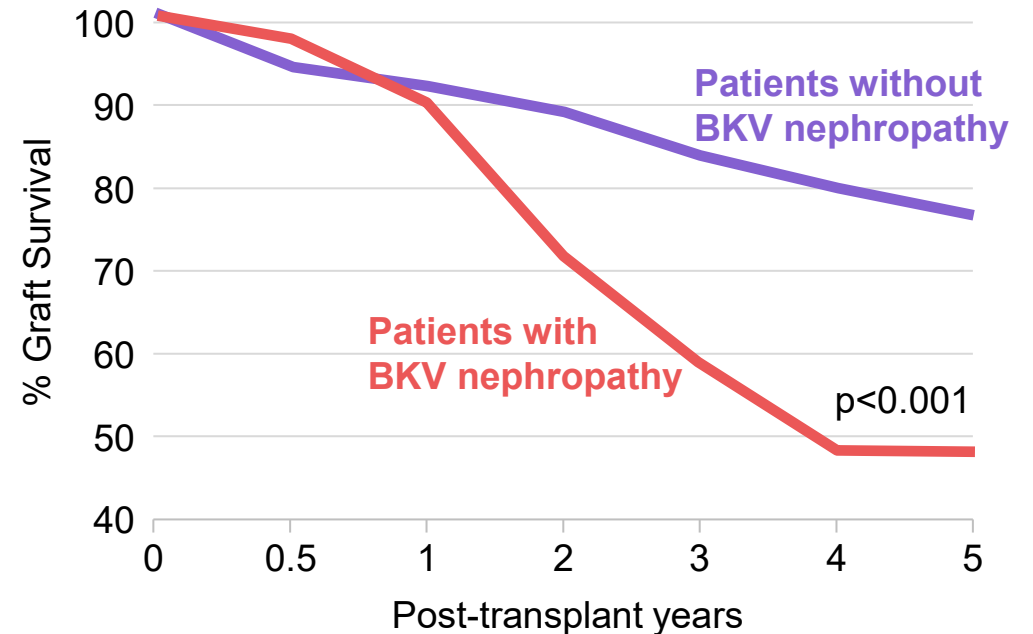
# Treatment of BK Viremia in Kidney Transplant Patients Represents the First Step in Addressing Unmet Need in Solid Organ Transplant Patients

**Kidneys** are the most common solid organ transplant and **BK virus nephropathy** is a **leading cause of graft loss**

- 90,000+ kidney transplants performed annually world-wide<sup>1</sup>
- ~15% KT patients reactivate BK virus with half of those progressing to BK nephropathy<sup>2</sup>
- High level BK viremia associated with decreased graft function<sup>3</sup> and reduced graft survival<sup>4</sup>
- No approved or effective treatments



## BKV Nephropathy Associated with Poor Graft Survival<sup>4</sup>





# Positive Phase 2 BKV Study Demonstrates Therapeutic Potential of Posoleucel in Kidney Transplant Patients

## Greater viral load reduction with posoleucel vs. placebo

- Clinically meaningful differences from placebo observed across BK viral load measures:  $\geq 1$  log BK VL reduction: PSL 39% vs. PBO 14%
- Treatment effect most pronounced in high viral load patients with biweekly posoleucel dosing:  $\geq 1$  log BK VL reduction: PSL 75% vs. PBO 25%
- Posoleucel antiviral response increased over time; largest difference from placebo at Week 24

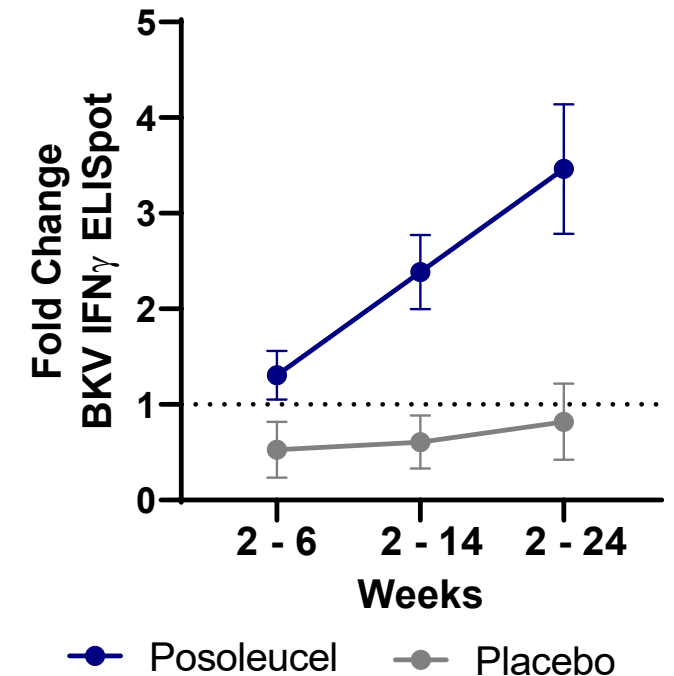
## Posoleucel Well Tolerated Through 12 Weeks of Dosing

- Balanced safety across posoleucel and placebo groups
- 3 cases of acute graft rejection<sup>1</sup>, none assessed as treatment-related
- No deaths, GVHD or cytokine release syndrome

## BK-specific T Cell Responses Increased in Posoleucel-treated Patients

- Presence and persistence of posoleucel confirmed by TCR $\nu\beta$  sequencing
- De novo host BK-specific T-cell responses in posoleucel but not placebo patients

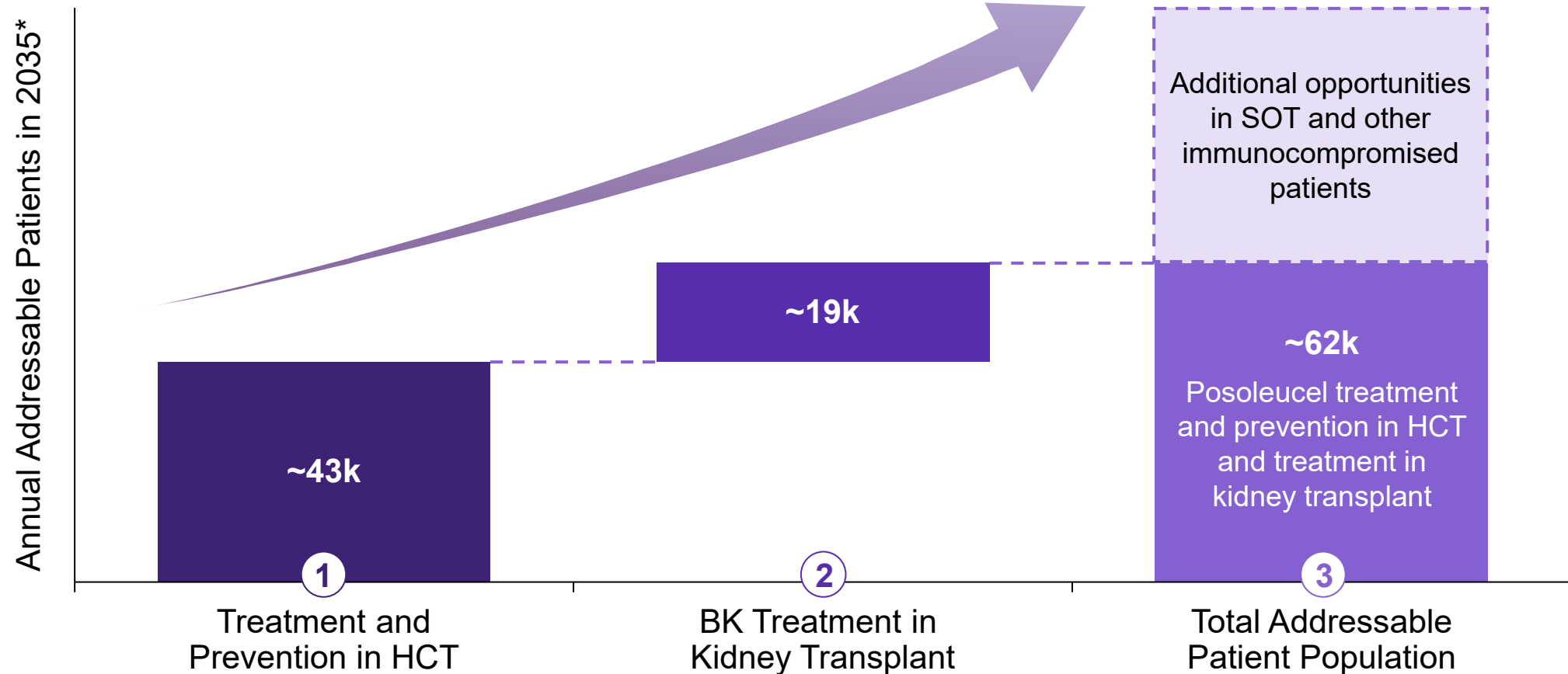
Change BKV IFN $\gamma$ + T cells over time



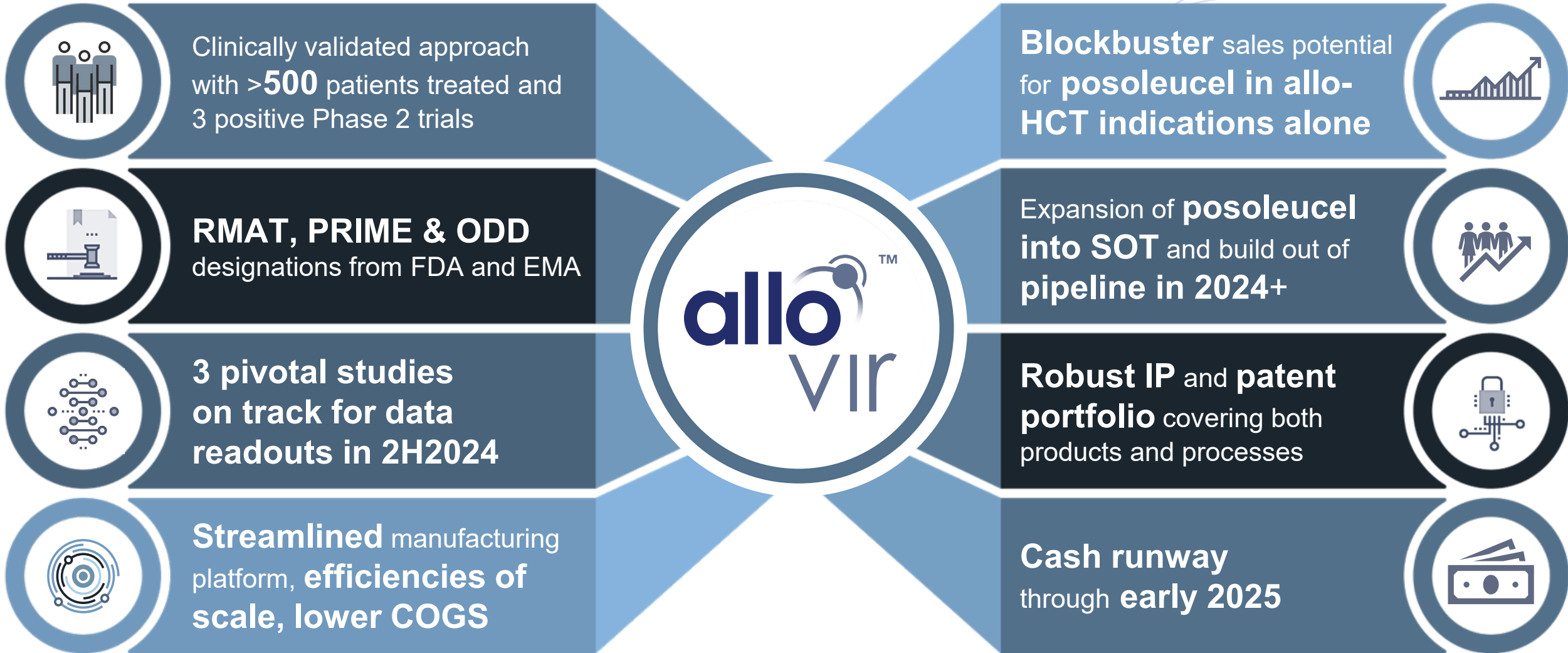
## Next Steps: Alignment with regulators on registrational trial design

# Posoleucel: Large Addressable Patient Population for the Treatment and Prevention of Devastating Viral Diseases

## Annual Commercial Opportunity for Posoleucel



# AlloVir: Leading in Allogeneic, Off-the-shelf, Multi-virus-Specific T-Cell Immunotherapies






# Appendix

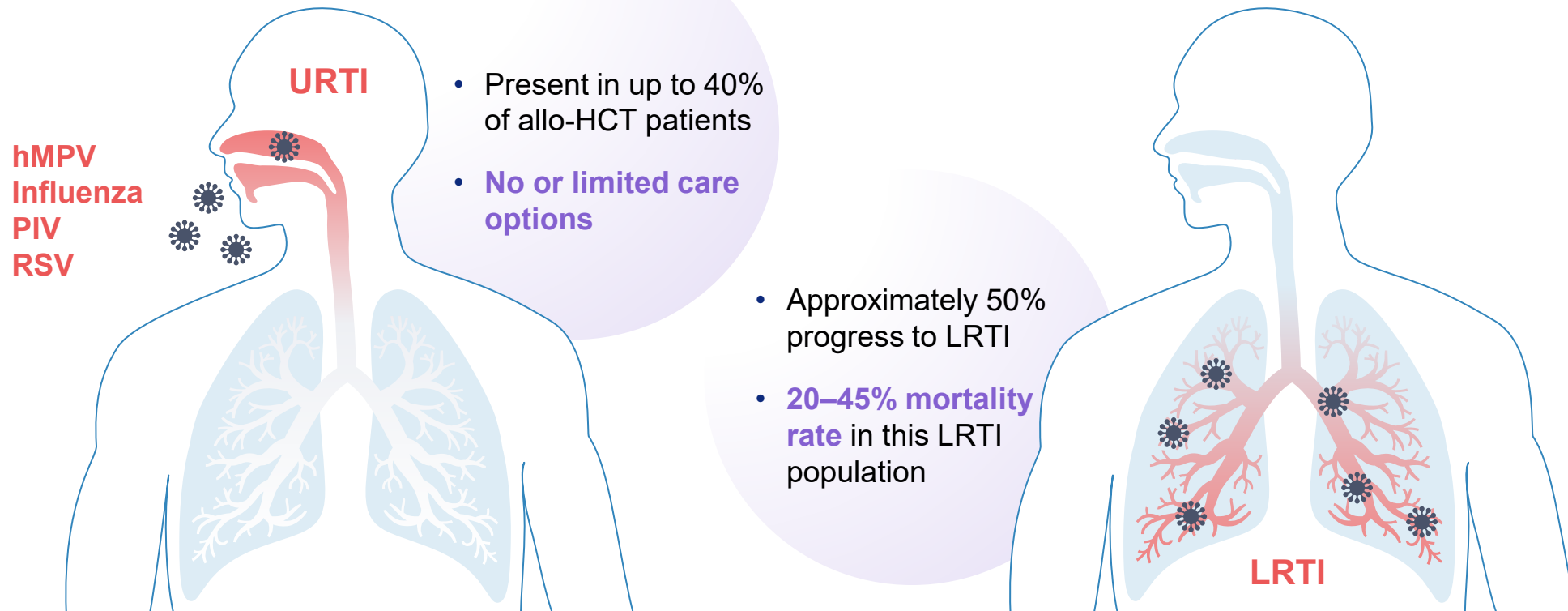
# Early-Stage Pipeline

Respiratory Viruses and Hepatitis B

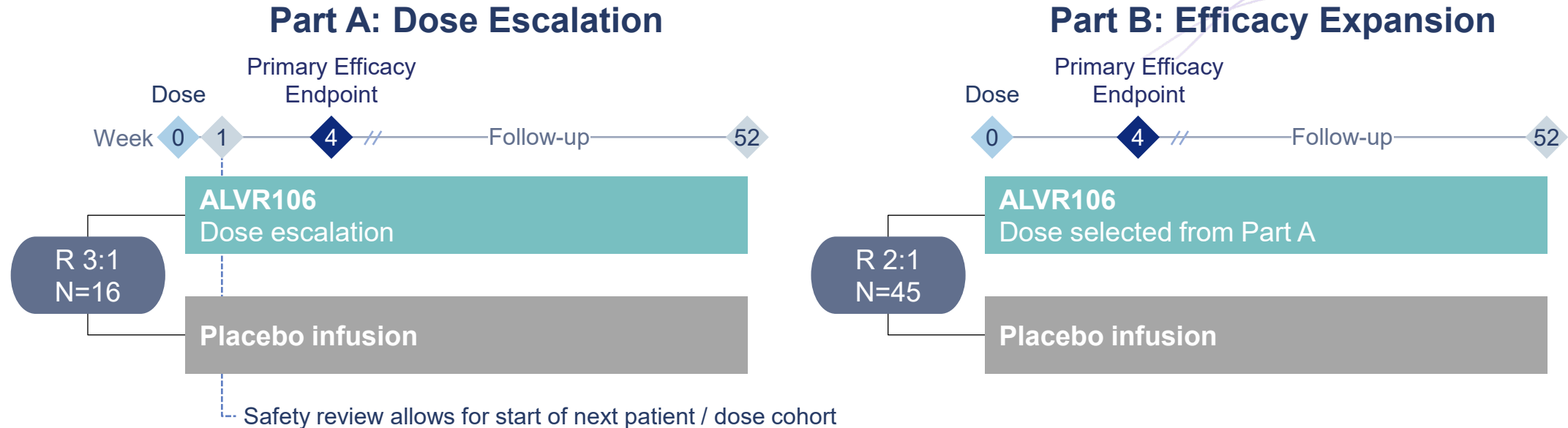
# VST Platform Provides Pipeline and Partnering Opportunities

Candidate	Target Population	Target Indication	Preclinical	POC	Phase 3 / Registrational	Status
<b>ALVR106</b>	Transplant recipients	hMPV, Flu, PIV, RSV treatment				Continued enrollment in U.S.
	High-risk general population					
<b>ALVR107</b>	Chronic Hepatitis B (HBV)	HBV cure				POC study following completion of posoleucel Phase 3 studies

# ALVR106 Offers Potent, Selective Antiviral Activity Against Respiratory Viruses of Significant Concern for HCT Patients<sup>1-3</sup>



# ALVR106 POC Study Targeting hMPV, Flu, PIV and RSV in Transplant Patients



- Phase 1/2, double-blind, placebo-controlled, dose escalation and expansion study
- Key eligibility criteria: transplant recipients 17–75 years with hMPV, influenza, PIV or RSV detected, and new respiratory symptoms  $\leq 4$  days before screening
- Primary efficacy endpoint: reduction in viral load

**Part A has completed enrollment**

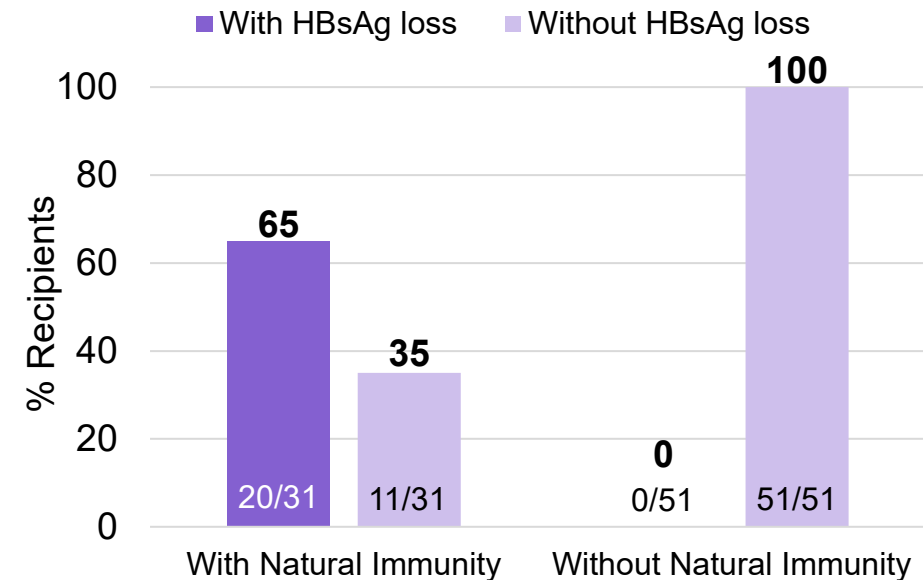


# ALVR107: Proof-of-Concept Has Been Established for Potential of Adoptive T Cell Therapy to Achieve Functional HBV Cure

## Significant Unmet Medical Need for Curative Therapies

- Nearly 300 million people globally have chronic hepatitis B infection<sup>1</sup>
- Chronic infection can lead to cirrhosis and cancer
- Life-long suppressive antiviral therapy is the only treatment option: **no curative therapies exist**

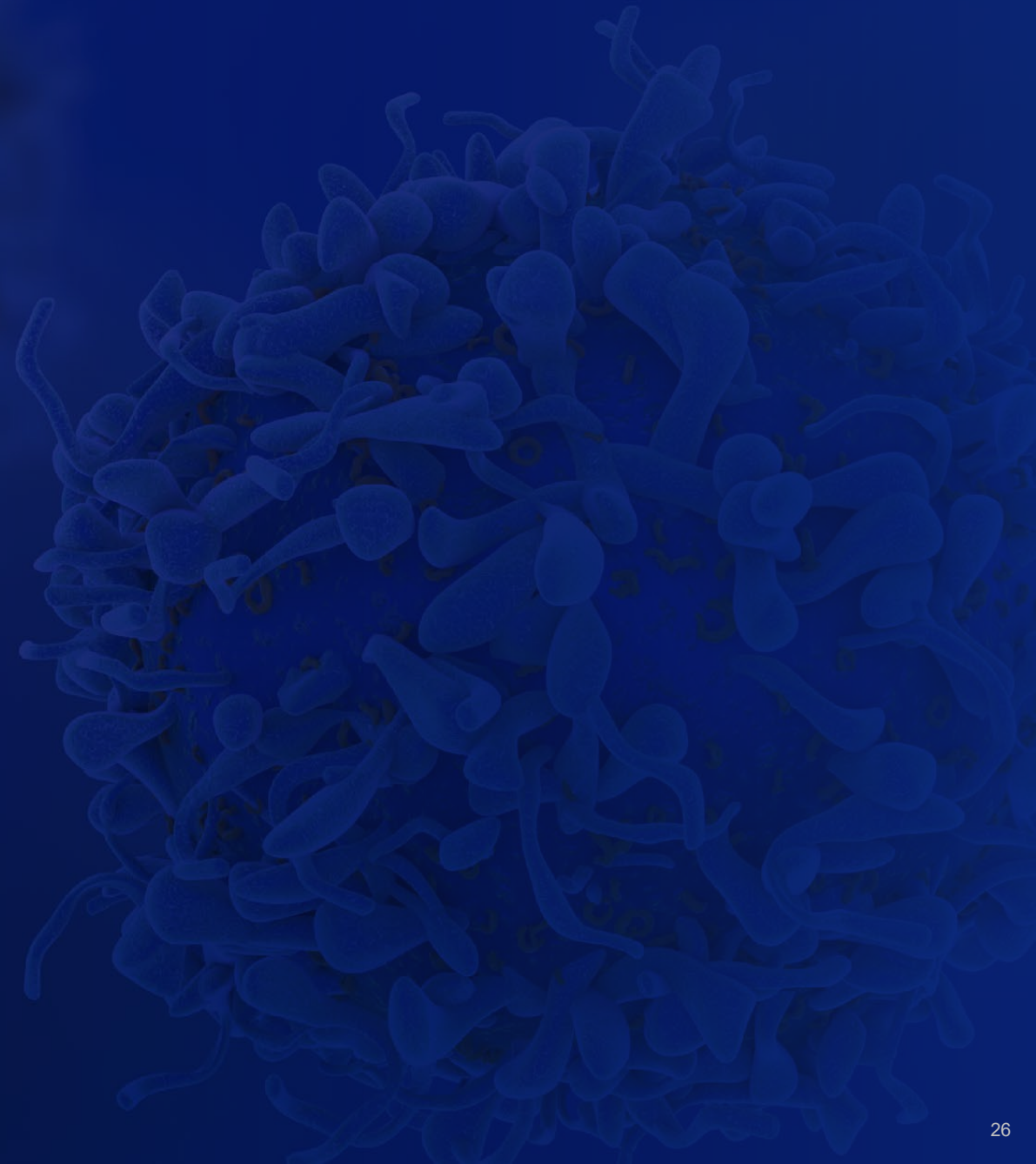
## HBsAg+ Allo-HCT Patients Achieved Functional Cure Post-transplant<sup>2</sup>



- 65% (20/31) HBsAg+ recipients achieved sustained HBsAg loss post-transplant

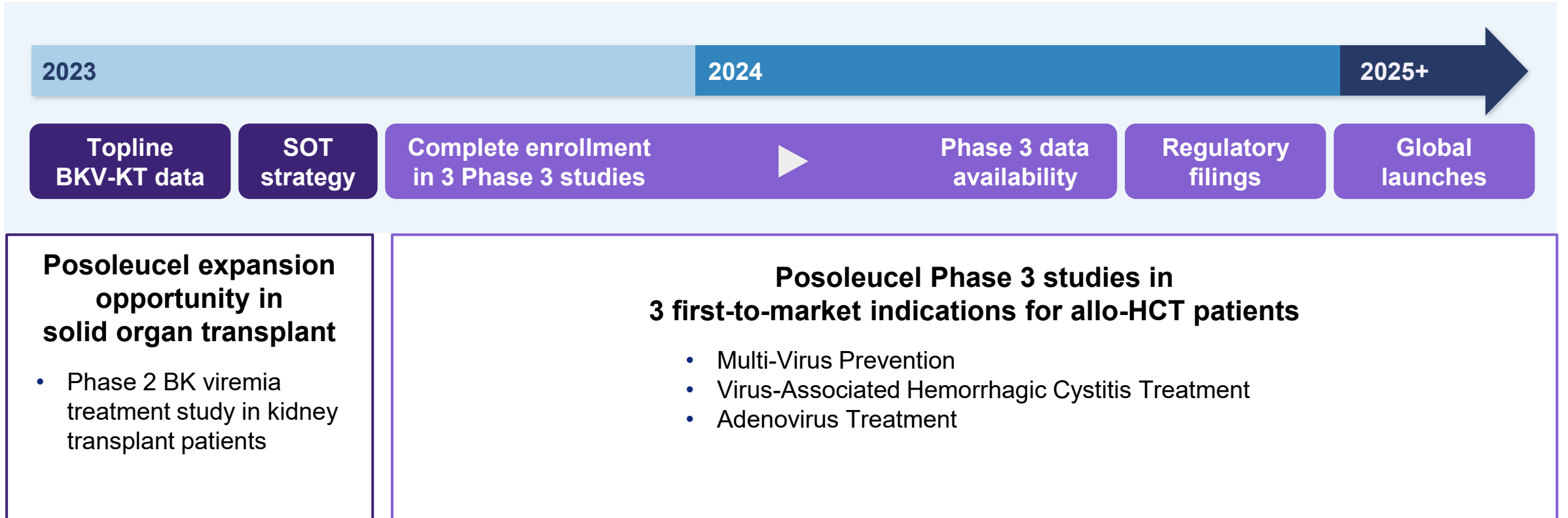
Preclinical data presented at the International Liver Conference (EASL) in June 2022

# Additional Slides



# Posoleucel: Transformative Milestones Ahead

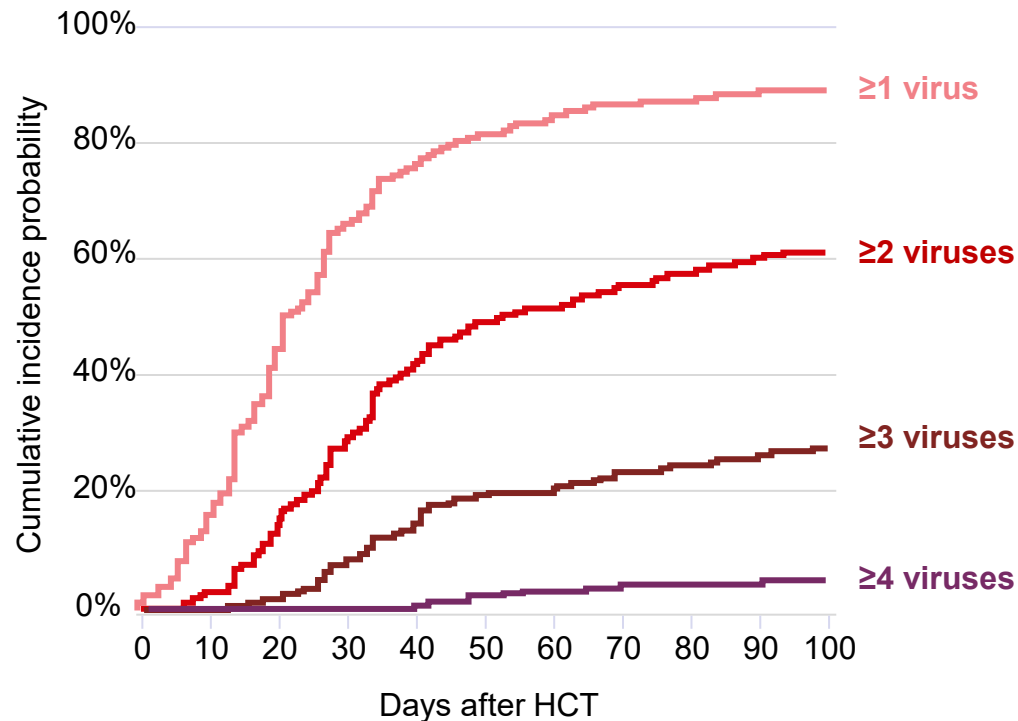
Posoleucel franchise positioned for significant value creation over the next 12-24 months<sup>1</sup>



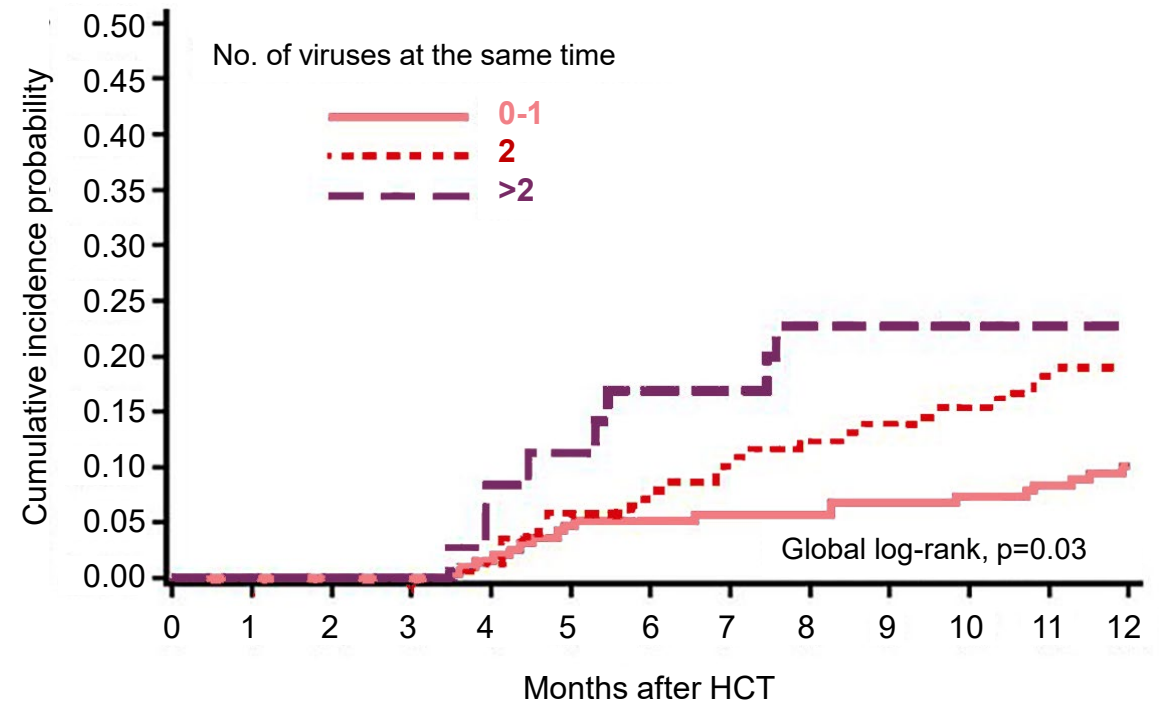
**Potential >\$1B market opportunity in allo-HCT alone**

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

Incidence of AdV, BKV, CMV, EBV or HHV-6 infection<sup>1</sup> (N=404)



Non-relapse mortality\*, number of viruses at the same time<sup>1</sup> (N=358)

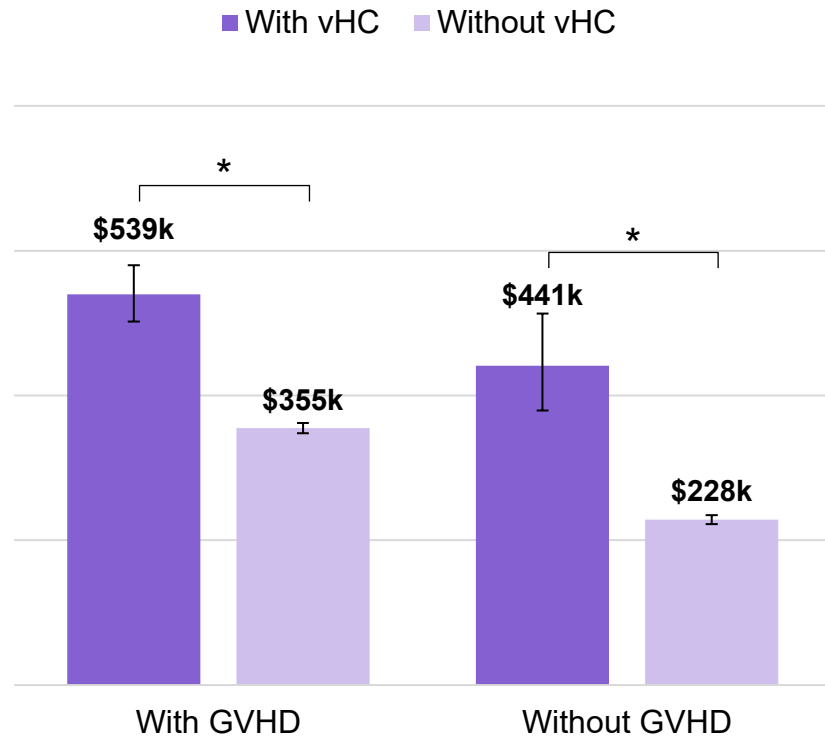


- 61% of patients were treated with antiviral therapies, excluding rituximab, within the first 100 days

# Virus-Associated HC Treatment and Multi-Virus Prevention Have Potential to Reduce Economic Burden of Disease While Improving Clinical Outcomes

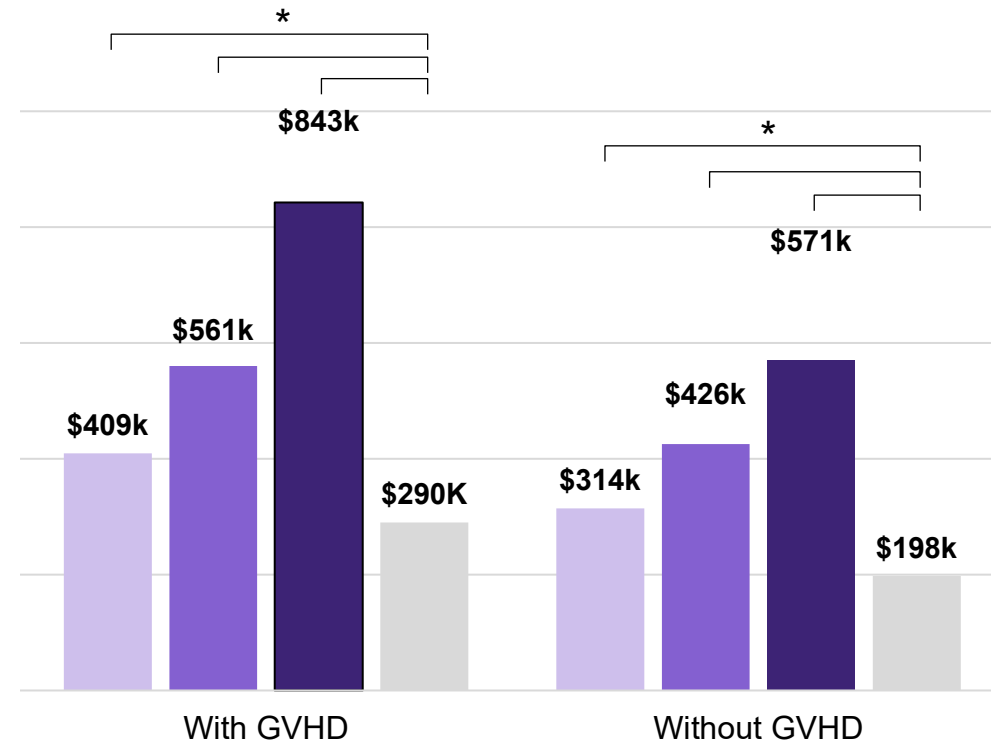
## Allo-HCT Recipients with vHC<sup>1</sup>

### Mean Adjusted Total Reimbursements

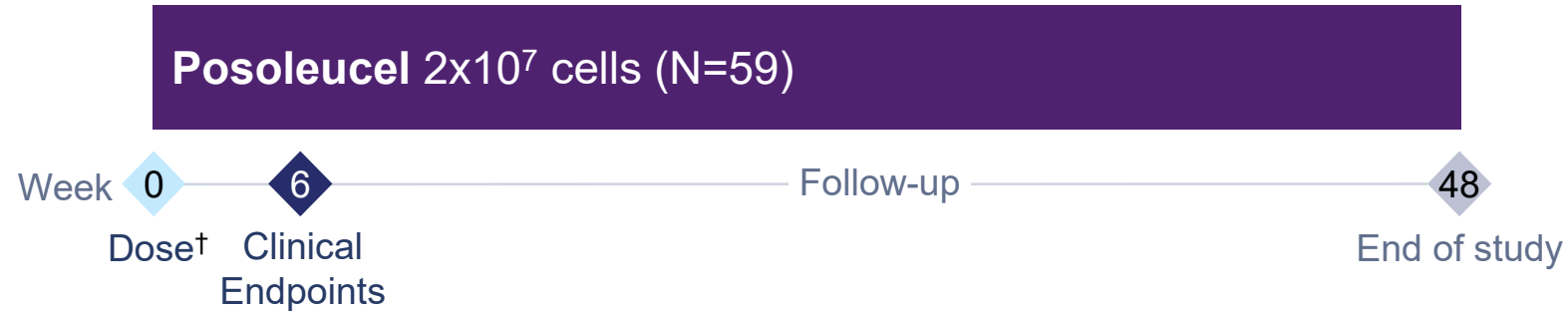


## Allo-HCT Recipients with Multi-Virus Infections<sup>2</sup>

### 1 infection ■ 2 infections ■ ≥3 infections ■ No infection



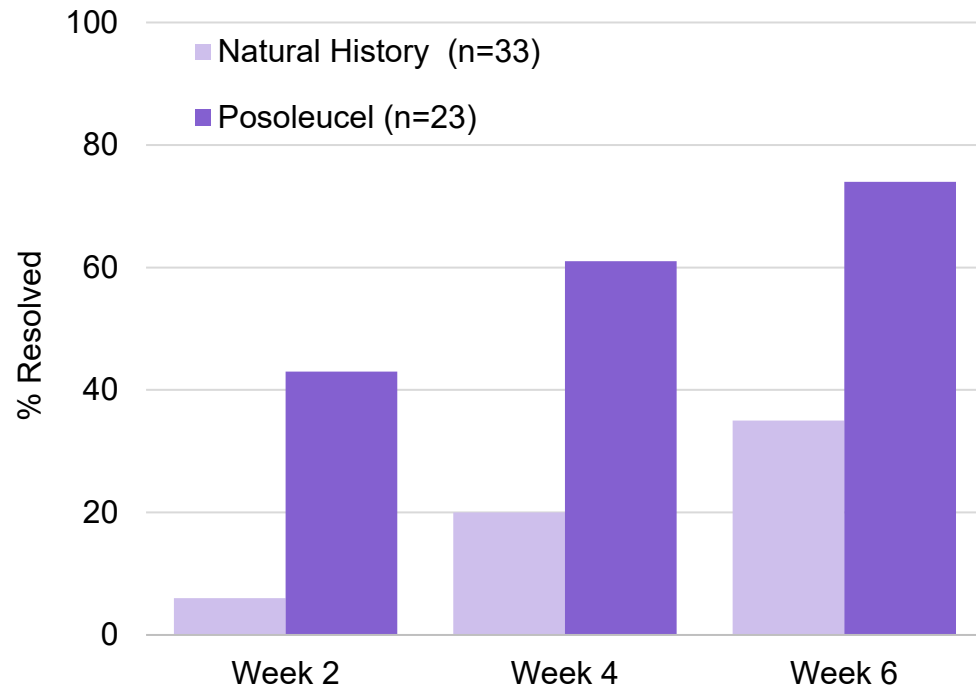
# Posoleucel Phase 2 Proof-of-Concept Study, CHARMS, Generated Promising Preliminary Disease Outcome and Safety Data



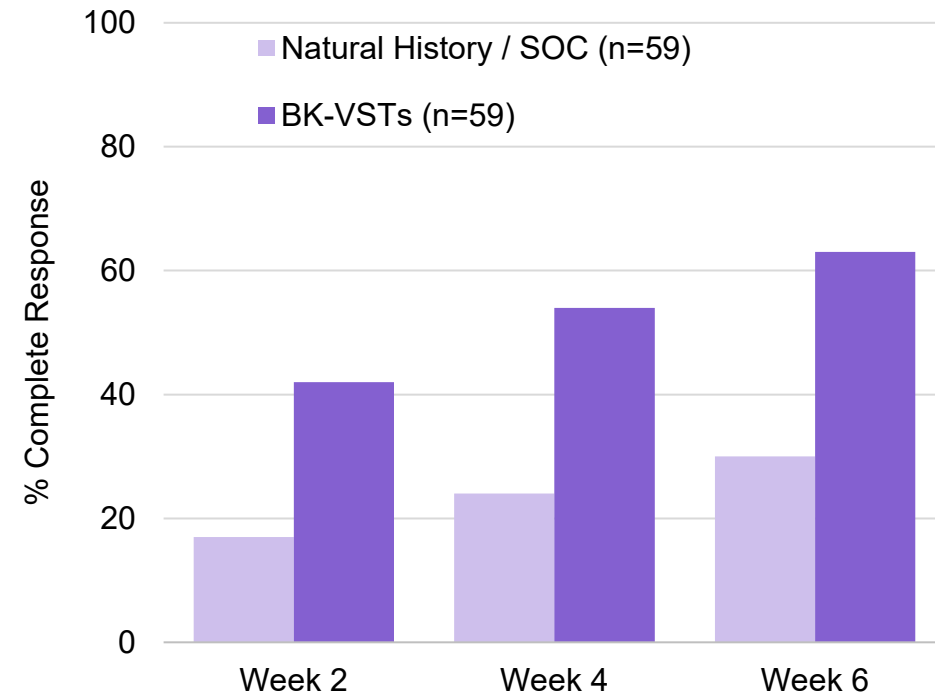
- Phase 2, proof-of-concept, open label study to assess the safety and clinical effects of posoleucel in allogeneic HCT recipients with  $\geq 1$  treatment-refractory infections
- Key eligibility criteria: refractory AdV, BKV, CMV, EBV, HHV-6 and/or JCV
  - Failure of antiviral therapy OR
  - Unable to tolerate standard antivirals
- Study endpoint: safety
- Clinical endpoints: viral load, clinical and virologic responses

# Patients Treated with Posoleucel or BK-VSTs Have Achieved Rapid Resolution of Macroscopic Hematuria

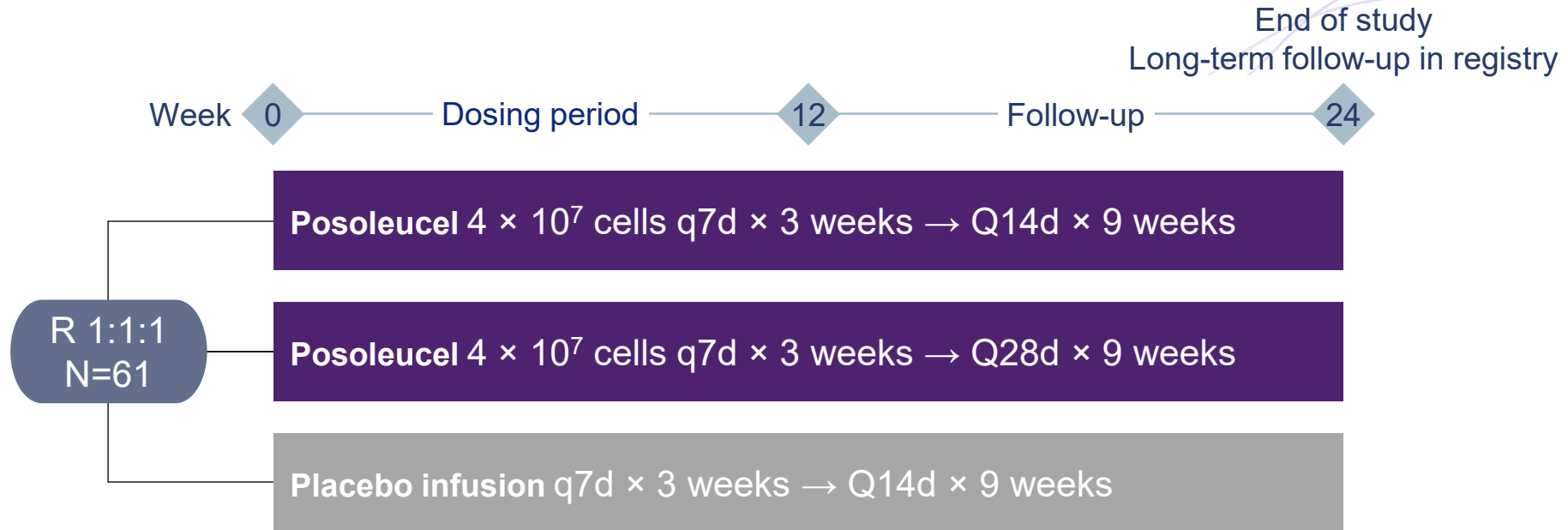
## CHARMS Study Patients Treated With Posoleucel vs. Historical Controls Receiving SOC<sup>1</sup>



## MDACC Patients Treated with BK-VSTs vs. Matched-pair Historical Controls Receiving SOC<sup>2</sup>



# Final Results of Phase 2 BKV-Kidney Transplant Study Reported in Q1 2023

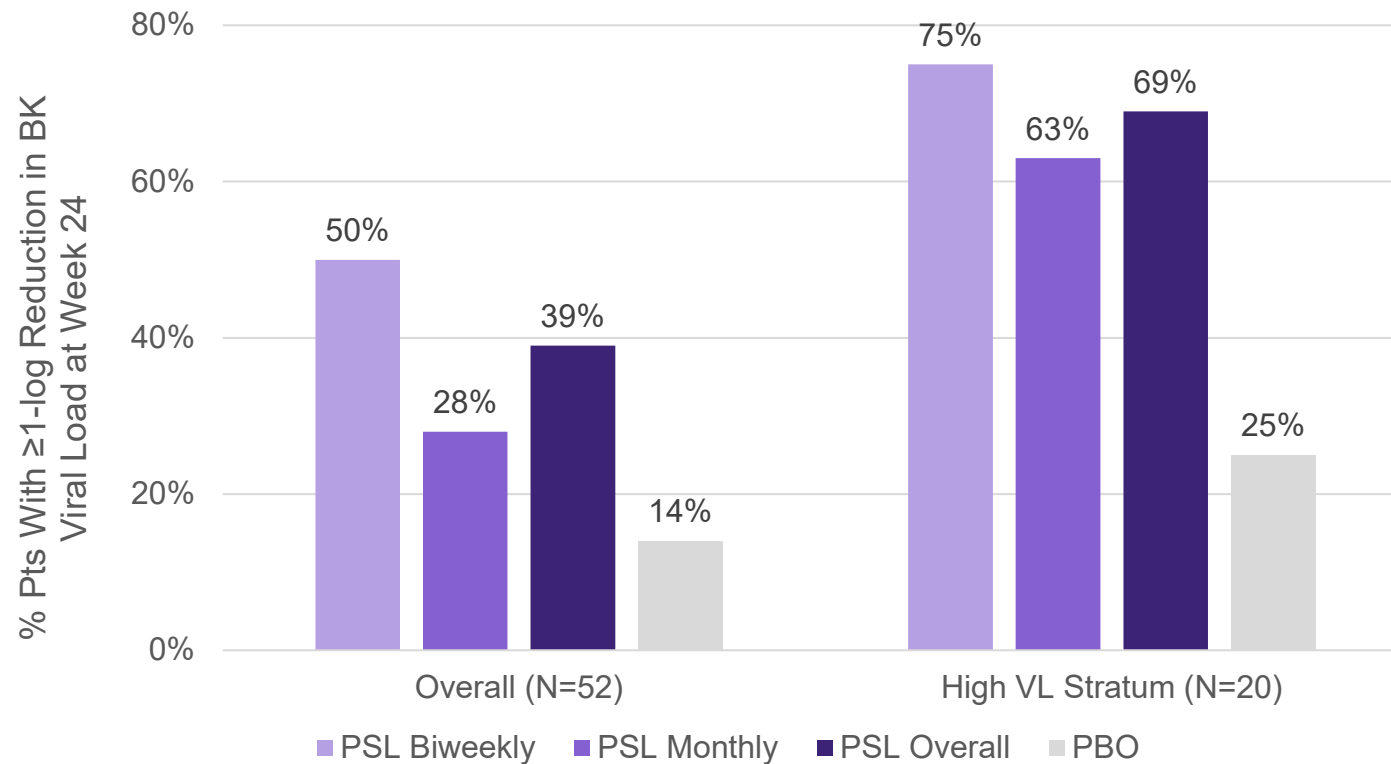


- Phase 2, multicenter, randomized, double-blind, placebo-controlled, multiple dosing interval, 2-period study
- Key eligibility criteria: adults with kidney transplant  $\geq 28$  days prior to enrollment, stratified by BK viral load
- Primary endpoint: safety and tolerability through Week 24
- Key secondary endpoint: reduction in BK viremia



# Clinically Meaningful Differences From Placebo Observed Across BK Viral Load Measures in Posoleucel Phase 2 BKV Study

Treatment effect most pronounced in high viral load patients with biweekly posoleucel dosing



Thank You