Positive Topline Results of Posoleucel BKV Treatment Phase 2 Randomized, Double-Blind, Placebo-Controlled Study in Kidney Transplant Patients

AlloVir Investor Webcast
February 15, 2023

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Agenda

	Speaker
Opening remarks	Diana Brainard, MD CEO, AlloVir
Posoleucel Phase 2 BK viremia treatment study results	Diana Brainard, MD CEO, AlloVir
Q&A	Anil Chandraker, MD Director, Renal Transplant Medicine Brigham and Women's Hospital Diana Brainard, MD CEO, AlloVir

AlloVir Key Investment Highlights

Posoleucel franchise opportunity in stem cell (allo-HCT) and solid organ transplant (SOT) patients

- **3 ongoing global Phase 3 registrational trials for 3 first-to-market indications expected to complete enrollment in 2023**
  - Large and critically important unmet need: preventing or treating clinically significant viral infections post transplant
  - Multi-virus prevention strategy has potential to transform the transplant space
    - Compelling Phase 2 trial results presented at ASH 2021 and 2022
    - High need and strong support from transplant and infectious disease communities
    - Robust enrollment in Phase 3 trial in 2022 accelerates timing for trial completion and data readout
- **Positive topline Phase 2 data in kidney transplant support regulatory discussions and advancement of future SOT clinical trials**

Additional clinical and preclinical virus-specific T cell (VST) therapy candidates for pipeline advancement by AlloVir or a potential partner

$234M cash as of December 31, 2022

allo vir

Restoring Immunity: Off-the-Shelf, Multi-Virus-Specific T Cell Therapies

VSTs are a clinically validated approach to treating viral infections in HCT patients

- Restore the T cell deficit that leads to uncontrolled viral replication
- >300 transplant patients dosed to date in AlloVir treatment or prevention clinical trials

Advantages of AlloVir's VSTs

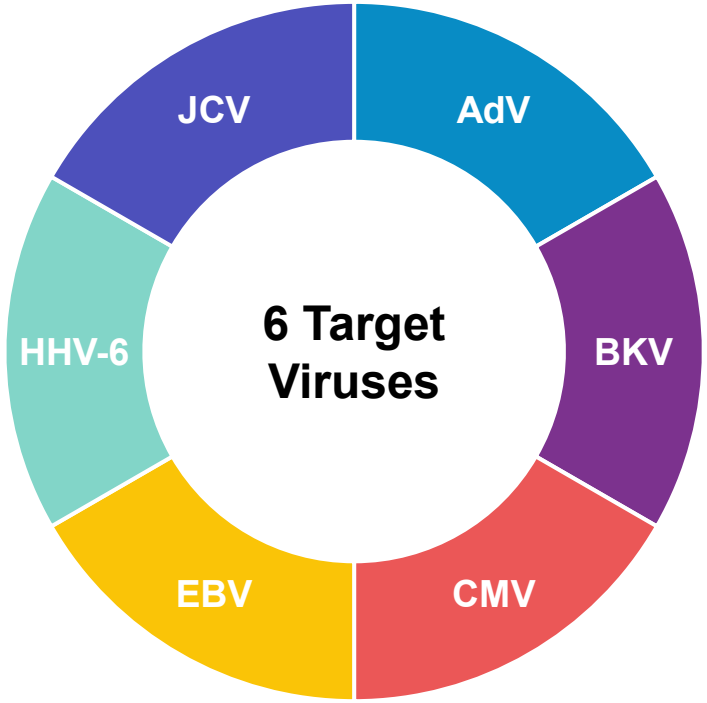
- Multi-virus targeting
- Third party, partial HLA matching
- Non-gene-modified, scalable manufacturing
- Off-the-shelf availability

AlloVir's innovation enhances the clinical utility of VSTs and enables on-demand delivery to patients

allo vir

Posoleucel: Lead Therapy with Franchise Potential

- Multi-VST therapy in Phase 3 development for 3 indications
- Targets 6 viruses that reactivate in 90% of allo-HCT patients[1]
  - Viruses associated with substantial morbidity and mortality
  - Limited to no effective treatments with substantial safety tradeoffs
- Phase 2 data demonstrate promising efficacy and safety profile as antiviral treatment in allo-HCT and SOT settings and as preventive therapy in allo-HCT
- Blockbuster opportunity in allo-HCT with expansion potential to SOT and other immunocompromised patients



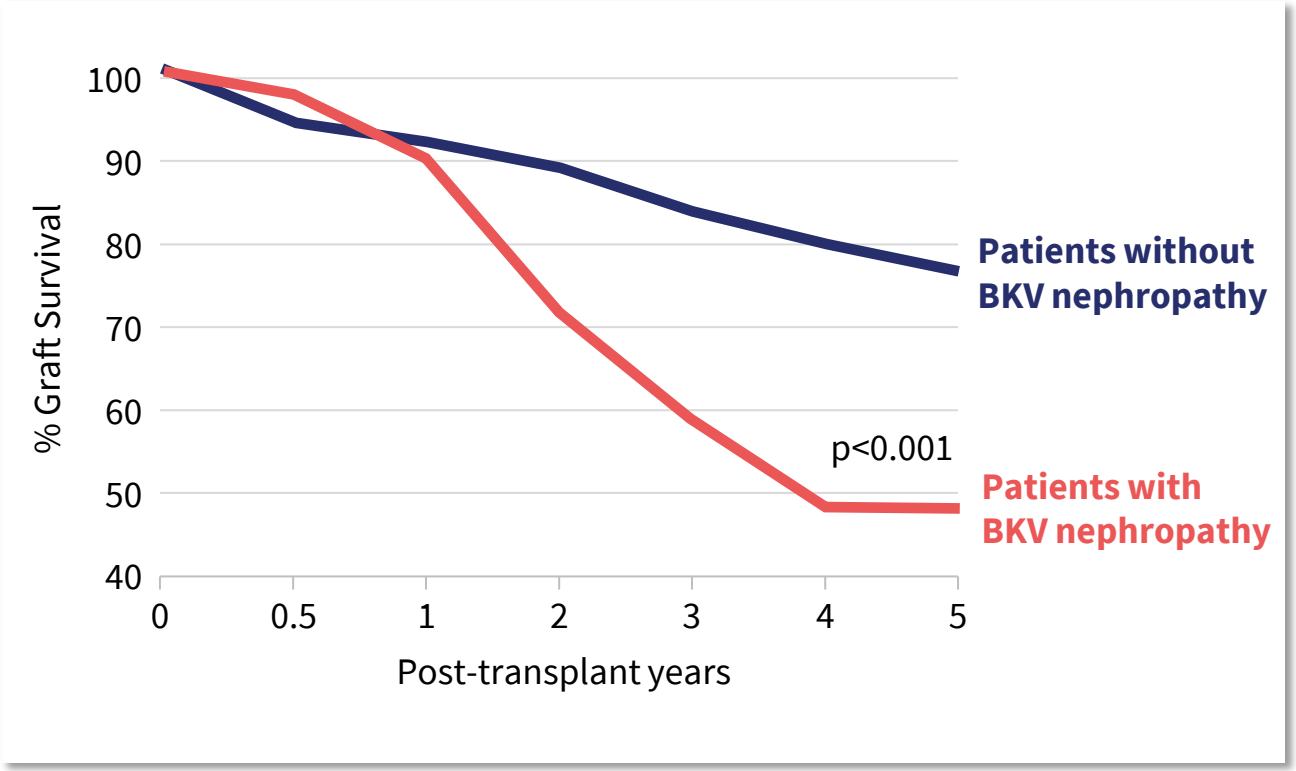
1. Hill J, et al. Blood. 2017;129:2316-25.

Posoleucel Phase 2 BK Viremia Treatment Study Results

BKV Infection Threatens Kidney Graft Survival

- Kidney transplant (KT) is most common solid organ transplant type
  - >25,000 KTs in US in 2022
  - >100,000 KTs projected worldwide in 2030
- BKV reactivation is dreaded KT complication with no approved therapy
  - High-level viremia (>10^4 copies/mL) occurs in up to 15% patients
  - Currently managed with reduction of immunosuppression, which increases the risk of graft rejection

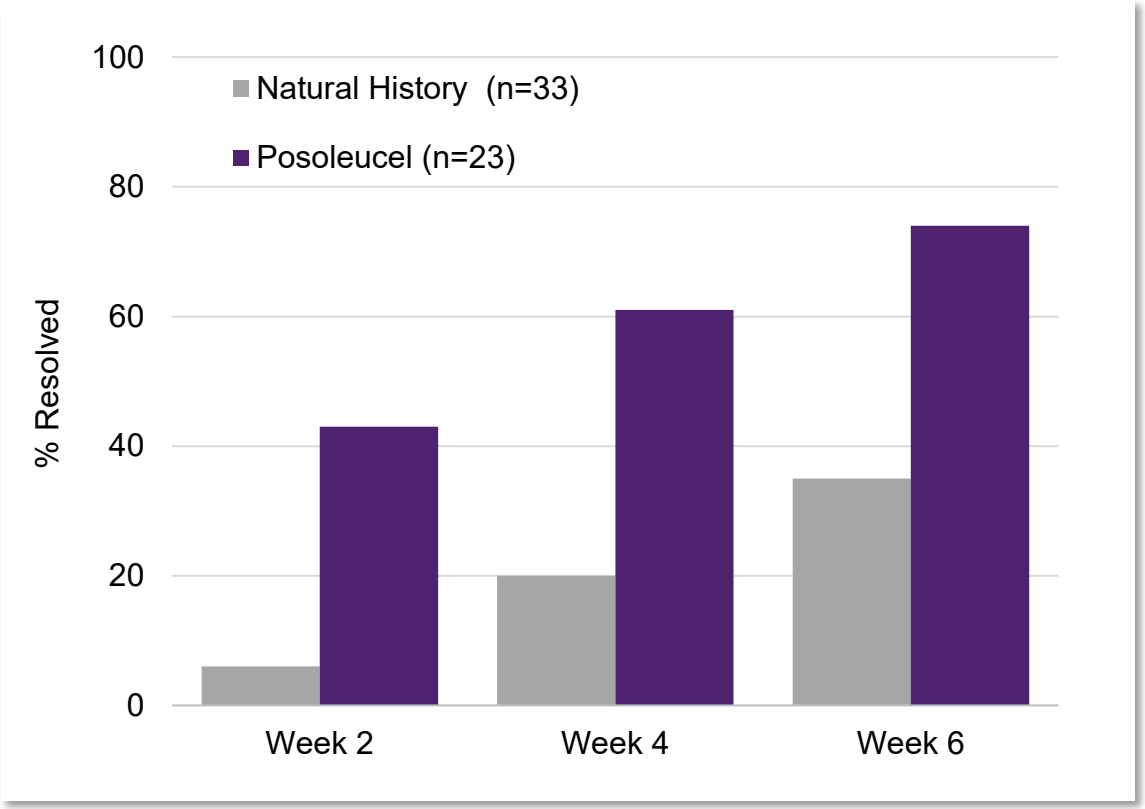
BKVAN Is Associated with Reduced Graft Survival



https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/; Nankivell 2017; Hirsch 2013; Vasudev 2005.

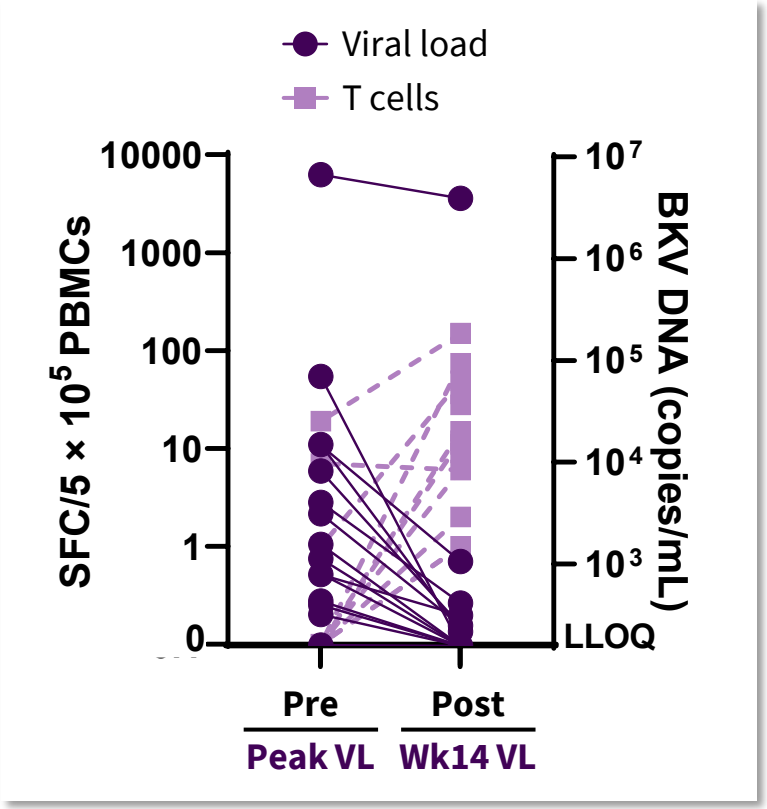
Posoleucel Has Demonstrated Efficacy in HCT Patients for Treatment and Prevention of BK Virus

CHARMS Phase 2 Treatment Study



Resolution of macroscopic hematuria in BKV patients treated with posoleucel vs. matched historical controls receiving SOC

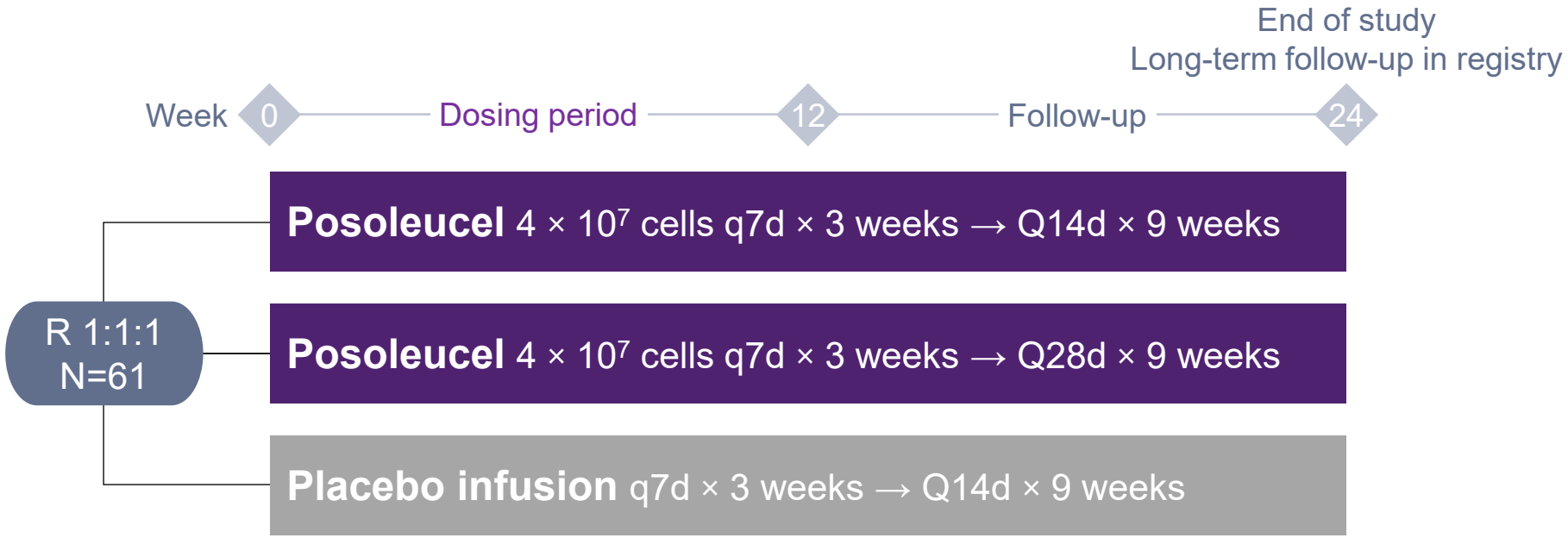
Multivirus Prevention Phase 2 Study



T cell expansion and reduction in BK viral load

Pfeiffer T, et al. *Clin Cancer Res.* 2023 (in press); ELISpot data shown from patients with available samples at Pre (Day 0) and/or Post (peak response on treatment Wk 1 – Wk 14) timepoints. Viral load (VL) data shown as peak viral load during primary endpoint period (Pre, Day 0 – Wk 14) and viral load at primary endpoint (Post, Wk 14 or last available time point), Viral load data from CSIs excluded.

Posoleucel BKV Study Design



- Phase 2, multicenter, randomized, double-blind, placebo-controlled, multiple dosing interval, 2-period study
- Key eligibility criteria: adults with kidney transplant ≥28 days prior to enrollment, stratified by BK viral load[1]
- Primary endpoint: safety and tolerability through Week 24
- Key secondary endpoint: reduction in BK viremia

ClinicalTrials.gov NCT04605484.
1. Low BK viral load: 350 to <10,000 copies/mL; High BK viral load: ≥10,000 copies/mL.

Demographics and Baseline Characteristics

Patients, n (%)	PSL (Q14d & Q28d) N=42	PBO N=19
Median age, years (range)	58 (21-75)	59 (47-75)
Female, n (%)	8 (19%)	4 (21%)
Latino or non-Caucasian, n (%)	24 (57%)	10 (53%)
Years from KT to day 1, median (range)	1.3 (0.3-7)	1.1 (0.2-14)
Median day 1 eGFR, mL/min/1.73 m^2 (range)	46 (19-61)	39 (20-61)
Median day 1 BK VL, cps/mL (range)	8383 (242-5,421,939)	5299 (327-7,837,086)
≥50% Decrease in immunosuppression within 30d randomization, n (%)*	2 (5%)	4 (21%)
Patient & Cell Line HLA Matching # median (range)	2 (1-5)	
Donor & Cell Line HLA Matching # median (range)	3 (2-5)	

Treatment groups well balanced except for rates of significant pre-randomization immunosuppression reduction

* Patients with <50% IS reduction w/ 30 (+/- 2) days prior to randomization (N=55)

Posoleucel Antiviral Response Greater Than Placebo

	Week 24			
	PSL Q14d N=20	PSL Q28d N=18	PSL N=38	PBO N=14
Pts w/ VL decreased by ≥1 log_{10} BKV DNA copies/ml vs baseline, n (%)	10 (50)	5 (28)	15 (39)	2 (14)
BKV VL reduction – median log_{10} BKV DNA copies/mL (min, max)	-0.9 (-2.1, 0.1)	-0.45 (-1.8, 0.5)	-0.6 (-2.1, 0.5)	-0.15 (-2.1, 0.3)
VL ≥50% reduction, n (%)	17 (85)*	10 (56)	27 (71)	6 (43)
Change in eGFR[+] – median mL/min/1.73m^2 (min, max)	-2.5 (-11, 7)	0 (-16, 20)	0 (-16, 20)	0 (-21, 9)

Patients with <50% IS reduction w/ 30 (+/- 2) days prior to randomization (N=55); 3 patients did not complete study due to loss to follow-up (n=2) or consent withdrawal (n=1).
*p<0.05
[+] eGFR = estimated glomerular filtration rate.

Posoleucel Antiviral Activity Even Greater in Patients with High BK Viral Load

	High VL Stratum, Week 24			
	PSL Q14d N=8	PSL Q28d N=8	PSL N=16	PBO N=4
VL decreased by ≥1 log_{10} BKV DNA copies/ml vs baseline, n (%)	6 (75)	5 (63)	11 (69)	1 (25)
BKV VL reduction – median log_{10} BKV DNA copies/mL (min, max)	-1.4 (-2.1, 0.1)	-1.5 (-1.8, -0.2)	-1.4 (-2.1, 0.1)	-0.4 (-2.1, -0.01)
VL ≥50% reduction, n (%)	7 (88)	7 (88)	14 (88)	2 (50)
Change in eGFR – median mL/min/1.73m^2 (min, max)	-5 (-11, 6)	0 (-16, 9)	-3 (-16, 9)	-7 (-21, 9)

High Viral Load Stratum = BK viral load ≥10,000 copies/mL at screening; Patients with <50% IS reduction w/ 30 (+/- 2) days prior to randomization

Post-Randomization Immunosuppression Reductions Were Uncommon and Did Not Impact Virologic Outcomes

Patients with post-randomization immunosuppression reduction*	
Posoleucel (N=42)	5 (12%)
Placebo (N=19)	3 (16%)

*≥50% of one of the major immunosuppressive medications

- Among these 5 posoleucel-treated patients:
  - 2 patients had >1 log BK viral load reductions that **preceded** IS reduction
  - 3 patients did not have a >1 log BK viral load reduction

- Among these 3 patients receiving placebo:
  - 1 patient had a >1 log BK viral load reduction; this patient also had a 50% IS reduction prior to randomization
  - 2 patients did not have a >1 log BK viral load reduction

Immunosuppression reductions during the study were allowed if BK VL ≥10,000 copies/mL and guided by a stepwise algorithm.

Safety Results

Patients, n (%)	PSL N=42	PBO N=19
Adverse events (AEs) related to study drug	8 (19)	5 (26)
Related AEs in ≥5% of patients		
• Headache	3 (7)	3 (16)
Grade 3-4 AEs (all assessed by PI as unrelated to study drug)[1]	5 (12)	1 (5)
Serious AEs related to study drug	0	0
Treatment D/C due to AEs[2]	1 (2)	0
Infusion reactions	1 (2)	1 (5)
GVHD	0	0
CRS	0	0
De novo donor specific antibodies	3 (7)	1 (5)
Acute rejection (all assessed by PI as unrelated to study drug)[3]	3 (7)	0
Death	0	0

1. Grade 3-4 SAEs: enterococcal bacteremia, urosepsis, proteinuria/rejection. Grade 3 non-serious AEs: uveitis, gout, BKVAN. 2. One patient discontinued study treatment due to TB after 5 doses. 3.One pt with renal TB, no rejection noted on local biopsy read; one pt with pre-existing rejection during screening on biopsy; one pt with *de novo* rejection at Week 22.

Key Takeaways from Positive Top-Line Results for Posoleucel

- **Posoleucel was generally well-tolerated**, with consistent profile between posoleucel treatment groups and placebo group
  - No ≥Grade 3 AEs, SAEs or episodes of acute rejection assessed as drug-related
  - Safety profile in kidney transplant recipients consistent with that observed in hematopoietic cell transplant patients
- Posoleucel demonstrated **consistently strong antiviral efficacy as compared to placebo**
  - Posoleucel patients overall had more than 2x the rate of ≥1 $\log_{10}$ BK VL reductions than placebo
  - Biweekly posoleucel patients had more than 3x the rate of ≥1 $\log_{10}$ BK VL reductions than placebo
  - Posoleucel patients in the pre-specified high VL stratum (≥ 10,000 copies/mL) experienced the most profound median viral load reductions (more than 3x vs placebo) and highest rates of ≥1 $\log_{10}$ BK VL decline
- Data provide foundation for engaging regulators in discussions on next steps for kidney transplant recipients with BK viremia, for whom there are **no currently approved therapies**

Q&A

Diana Brainard, MD
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Three Phase 3 Registrational Trials Underway in HCT; Positive Phase 2 BKV Data Support Future SOT Opportunity

Target Population	Target Indication	Preclinical / POC / Pivotal	Status
Allo-HCT	Multi-virus prevention*		Complete enrollment by end of 2023; data in 2024
	vHC treatment		
	AdV treatment		
Kidney transplant	BKV treatment		**Positive results; proof of concept achieved**
Solid organ transplant	Multi-virus prevention*		

*Prevention of clinically significant infections or end-organ disease caused by AdV, BKV, CMV, EBV, HHV-6 and JCV.