



## **AlloVir Presents Positive Final Results From A Phase 2 Randomized, Placebo-Controlled Trial Evaluating Posoleucel Treatment of BK Infection in Kidney Transplant Recipients at the American Transplant Congress (ATC 2023)**

June 5, 2023

*Posoleucel demonstrated clinically meaningful reductions in BK viral load as compared to placebo with the greatest antiviral activity seen among patients with higher viral loads and those who received more frequent posoleucel dosing*

*At Week 24, the percentage of patients with a  $\geq 1$ -log viral load reduction in the biweekly dosing group was 50% (10/20) vs. 28% (5/18) in the monthly dosing group and 14% (2/14) in the placebo group*

*In the high viral load stratum ( $\geq 10,000$  copies/mL), 69% (11/16) of patients who received posoleucel overall and 75% (6/8) of patients in the biweekly dosing group, achieved a  $\geq 1$ -log viral load reduction vs. 25% (1/4) of patients in the placebo group*

*Biomarker data demonstrate that BK viral load reductions coincided with substantial expansion of functional BK-directed T cells specific for both posoleucel-targeted and non-targeted antigens – indicating both direct and bystander T cell benefit not observed in placebo patients*

*Repeat administration of posoleucel was generally well tolerated, with balanced safety across posoleucel dosing groups and placebo*

WALTHAM, Mass.--(BUSINESS WIRE)--Jun. 5, 2023-- AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today announced the presentation of final results from a Phase 2 study of posoleucel, an investigational, allogeneic, off-the-shelf, multi-virus-specific T cell (VST) therapy, being studied for the treatment of BK viremia in adult kidney transplant recipients. The findings, presented yesterday at the American Transplant Congress (ATC 2023) in San Diego, CA, during a late-breaking oral abstract session (LB001), support the safety and antiviral activity of posoleucel in adult kidney transplant recipients with BK virus (BKV) infection. Currently, there are no effective treatment options for BKV infection. Top line data were [shared](#) earlier this year.

"Our virus-specific T cell therapies have the potential to offer new hope to immunocompromised patients by preventing or treating devastating viral infections such as that caused by BKV," said Diana Brainard, M.D., CEO, AlloVir. "The Phase 2 data presented at ATC continue to support the potential benefits of posoleucel use across transplant indications. The patients treated with posoleucel had greater increases in BKV-specific T cells as compared to placebo patients, and these cells persisted through week 24 post-dose, which reinforces posoleucel's mechanism of action. Additionally, in posoleucel-infused patients we see bystander benefit with endogenous BKV-specific T cell activation, increasing the likelihood of durable benefit. As we continue enrollment in three Phase 3 clinical studies exploring the potential of posoleucel to prevent or treat infections in allo-HCT patients, we are also consulting with key opinion leaders and preparing to meet with the FDA to gain alignment on a Phase 3 clinical study design to evaluate posoleucel's treatment of BKV infection in kidney transplant patients."

BKV infection poses a significant threat to kidney graft survival. Over 90,000 kidney transplants are currently performed each year globally<sup>i</sup>, and the virus reactivates in up to 20% of these patients.<sup>ii</sup> In patients who have reactivated BKV, a substantial portion will develop high-level viremia. Approximately half of those will develop BKV-associated nephropathy (BKVAN)<sup>iii</sup>, which can lead to decreased kidney survival and a return to end-stage renal disease and dialysis.

### **About the Phase 2 Study**

The Phase 2 study evaluated the safety and efficacy of posoleucel to treat BKV infection in adult kidney transplant recipients with plasma BK viral load between 350-10,000,000 copies/mL (stratified by low (<10,000 copies/mL) or high ( $\geq 10,000$  copies/mL) viral load at study screening). Consensus groups, including the American Society of Nephrology and the American Society of Transplantation, consider BK viral load of greater than or equal to 10,000 copies/mL to be presumptive BKVAN. The primary endpoint of the study was the safety and tolerability of posoleucel versus placebo, and the secondary endpoint of the study was the change in BK viral load in patients receiving posoleucel versus those receiving placebo. Top line results from this study were [shared](#) earlier this year.

### **About BK Viremia in Kidney Transplant Recipients**

Due to the long-term immunosuppression required to prevent graft rejection, solid organ transplant recipients are at high risk for reactivating common viruses that are typically controlled by the body's natural immune system. Uncontrolled, these viruses can have devastating consequences.

There are no approved or effective antiviral treatments for BKV infection. The only approach to managing BKV infection is a reduction in immunosuppression to allow the body's immune system to fight the virus; this is typically triggered by a plasma BK viral load that nears or exceeds 10,000 copies/mL. However, this reduction in immunosuppression can also lead to graft rejection, mediated by alloreactive T cells, and the

development of donor-specific antibodies, putting the success of the kidney transplant at risk.

BK virus-specific T cells appear to play a key role in protection against disease. Kidney transplant recipients who do not develop BKVAN have been shown to have approximately 10-fold higher BKV-specific T cell responses versus those with BKVAN. Kidney transplant recipients with BK viremia who develop robust BKV-specific T cell responses have also been shown to clear the virus, while those who progressed to BKVAN required interventions such as a reduction in immunosuppression. These data suggest that VST therapy may help manage BKV infection and BKVAN.

### About Posoleucel

AlloVir's lead product, posoleucel, is in late-stage clinical development as an allogeneic, off-the-shelf, multi-virus-specific T cell therapy targeting six viral pathogens in immunocompromised individuals: adenovirus (AdV), BKV, cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). In a Phase 2 open-label study of posoleucel for the *prevention* of clinically significant infections due to the six viruses posoleucel targets, 88% of allo-HCT patients who received posoleucel remained free of clinically significant infections through week 14, the primary endpoint. Moreover, the non-relapse mortality rate in patients who received posoleucel was 0% through the 52-week follow-up visit. Additionally, in the positive Phase 2 proof-of-concept CHARMS *treatment* study which enrolled allo-HCT recipients infected by one or more of the six viruses posoleucel targets, more than 90% of patients who failed conventional treatment and received posoleucel demonstrated a complete or partial clinical response based on predefined criteria.

Based on the strength of the posoleucel Phase 2 data for both prevention and treatment, the FDA has granted posoleucel Regenerative Medicine Advanced Therapy (RMAT) designation for each of the three indications being evaluated in Phase 3 clinical trials – for the treatment of hemorrhagic cystitis (HC) caused by BKV, for the treatment of AdV infection in adults and children following allo-HCT, and for the prevention of clinically significant infections and disease caused by posoleucel's six target viruses. The FDA also granted posoleucel Orphan Drug Designation for the treatment of virus-associated HC. The European Medicines Agency (EMA) has granted posoleucel PRiority MEdicines (PRIME) designation for the treatment of serious infections with AdV, BKV, CMV, EBV and HHV-6, and Orphan Medicinal Product designation as a potential treatment of viral diseases and infections in patients undergoing HCT.

### About AlloVir

AlloVir is a leading late-clinical stage, cell therapy company with a focus on restoring natural immunity against life-threatening viral diseases in pediatric and adult patients with weakened immune systems. The company's innovative and proprietary technology platforms leverage off-the-shelf, allogeneic, single- and multi-virus-specific T cells for patients with T cell deficiencies who are at risk from the life-threatening consequences of viral diseases. AlloVir's technology and manufacturing process enable the potential for the treatment and prevention of a spectrum of devastating viruses with each single allogeneic cell therapy. The company is advancing multiple mid- and late-stage clinical trials across its product portfolio. For more information, visit [www.allovir.com](http://www.allovir.com) or follow us on [Twitter](https://twitter.com/allovir) or [LinkedIn](https://www.linkedin.com/company/allovir).

### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the potential of posoleucel as a treatment of BKV in kidney transplant recipients, the safety and antiviral activity of posoleucel in adult kidney transplant recipients with BK infection, AlloVir's development and regulatory status of our product candidates, the planned conduct of its preclinical studies, and clinical trials and its prospects for success in those studies and trials, and its strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to the safety and efficacy of posoleucel as a treatment of BKV in kidney transplant patients, AlloVir's financial results, the timing for the initiation and successful completion of AlloVir's clinical trials of its product candidates, whether and when, if at all, AlloVir's product candidates will receive approval from the U.S. Food and Drug Administration (FDA), or other foreign regulatory authorities, competition from other biopharmaceutical companies, supply chain, and business operations and other risks identified in AlloVir's SEC filings. AlloVir cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. AlloVir disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent AlloVir's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

<sup>i</sup> Kidney transplants worldwide by region 2021 | Statista

<sup>ii</sup> Gras J, Le Flécher A, Dupont A, et al. Characteristics, risk factors and outcome of BKV nephropathy in kidney transplant recipients: a case-control study. *BMC Infect Dis.* 2023;23:74.

<sup>iii</sup> Hirsch HH, Randhawa PS. BK polyomavirus in solid organ transplantation-Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant.* 2019;33:e13528.

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