UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 15, 2023

ALLOVIR, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39409**	**83-1971007**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

AlloVir, Inc.
1100 Winter Street
Waltham, Massachusetts 02451
(Address of principal executive offices, including zip code)

(617) 433-2605
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ALVR	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 15, 2023, AlloVir, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02, including Exhibit 99.1, attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

On February 15, 2023, the Company issued a press release announcing positive final results from a Phase 2 study of posoleucel, an investigational, allogeneic, off-the-shelf, multi-virus-specific T cell therapy, being studied for the treatment of BK viremia in adult kidney transplant recipients. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01 including Exhibit 99.2 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated February 15, 2023
99.2	Press release dated February 15, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AlloVir, Inc.

Date: February 15, 2023

By: /s/ Edward Miller
Name: Edward Miller
Title: *General Counsel*

Exhibit 99.1

AlloVir Reports Full-Year 2022 Financial Results and 2023 Outlook

Completion of enrollment of all three posoleucel Phase 3 registrational trials for three distinct, first-to-market indications anticipated by end of 2023 and data readouts in 2024

Positive final results from randomized, double-blind, placebo-controlled Phase 2 study of posoleucel in kidney transplant recipients with BK viremia announced separately today; company to host investor webcast at 9:00 a.m. EST

Strong cash position, with $233.8 million as of year-end 2022

WALTHAM, Mass.—(BUSINESS WIRE)— Feb. 15, 2023 —AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today reported full-year 2022 financial results for the period ended December 31, 2022. The company also highlighted its progress and provided the outlook for 2023 and into 2024 across its allogeneic, off-the-shelf, virus-specific T cell (VST) programs, including its lead investigational therapy, posoleucel, for the treatment and prevention of life-threatening infections and diseases caused by six viruses that commonly impact patients following allogeneic hematopoietic cell transplant (allo-HCT).

“With the acceleration of the posoleucel multi-virus prevention study and continued enrollment in the viral hemorrhagic cystitis and adenovirus treatment Phase 3 studies in 2022, the posoleucel franchise is positioned for potentially significant value creation over the next 12-24 months,” said Diana Brainard, M.D., Chief Executive Officer, AlloVir. “During 2023, we plan to complete enrollment in our Phase 3 registrational studies, which would enable data readouts in 2024 and, with positive results, regulatory filings and acceleration of commercial preparations to follow.”

Dr. Brainard continued, “Today we also announced positive final Phase 2 results from our first study of posoleucel in the solid organ transplant setting, showing balanced safety across the posoleucel and placebo groups and clinically meaningful greater viral load declines with posoleucel versus placebo in kidney transplant patients with BKV. These results are important proof of concept for the use of posoleucel in the solid organ transplant setting. We look forward to working with regulatory authorities and transplant specialists on our future clinical development plans for this patient population with high unmet medical need.”

Recent Highlights

- In an oral presentation at the American Society of Hematology (ASH) Annual Meeting and Exposition in December 2022, final data were presented from the Phase 2 study evaluating posoleucel for the prevention of clinically significant infections or diseases from adenovirus, BK virus, cytomegalovirus, Epstein-Barr virus, human herpesvirus-6 and JC virus in allo-HCT patients. The data demonstrated a substantial reduction in the expected rate of clinically significant viral infections in this high-risk patient population despite the expected high rates of viral reactivation observed. Biomarker data showed the persistence of posoleucel and association between expansion of functional VSTs and viral control.

- Final topline data from the posoleucel Phase 2 BKV treatment study in kidney transplant patients were reported earlier today. Posoleucel was generally well tolerated in the study and demonstrated clinically meaningful antiviral efficacy consistenly across multiple BK viral load measures. The greatest effect was observed with biweekly posoleucel dosing in patients with screening viral load ≥10,000 copies/mL, who are at highest risk for BKV-associated graft loss.
- In January 2023, final data from the CHARMS Phase 2 study of posoleucel for the treatment of viral infections in treatment-refractory allo-HCT patients were published in *Clinical Cancer Research.* The data demonstrated that 95% of patients with one or more treatment-refractory infections achieved a clinical response with posoleucel.
- A compassionate use case report of posoleucel therapy for BKV nephropathy in a kidney transplant patient was presented in a poster at the annual meeting of the American Society of Nephrology in November 2022. Following posoleucel therapy, the patient experienced a significant reduction in BK viral load.
- In November 2022, a manuscript was published in *Haematologica* describing the development and first clinical use of ALVR109 for the treatment of COVID-19. The data underscore the company's ability to rapidly develop VSTs for emerging viral threats and the potential application of these VSTs for the treatment of respiratory viruses.
- In the fourth quarter of 2022, the company established a scientific advisory board comprised of experts in cell therapies, stem cell and solid organ transplantation and infectious diseases. The standing group of advisors will provide insights and external perspective that will guide the advancement of the company's science and pipeline.
- AlloVir's scientific advisory board members are as follows:
    - Michael Boeckh, M.D., Ph.D., Head of the Infectious Disease Sciences Program of the Vaccine and Infectious Disease Division at Fred Hutchinson Cancer Center
    - Anil Chandraker, M.D., Director of Renal Transplant Medicine at Brigham and Women's Hospital, and Associate Professor of Medicine at Harvard Medical School
    - Stella Davies, MBBS, Ph.D., MRCP, Director of the Division of Bone Marrow Transplantation and Immune Deficiency at Cincinnati Children's Hospital Medical Center
    - John F. DiPersio, M.D., Ph.D., Director of the Center for Gene and Cellular Immunotherapy and a Professor of Medicine, Pathology & Immunology at Washington University School of Medicine
    - John W. Mellors, M.D., Distinguished Professor of Medicine, Chief of Infectious Diseases, and Endowed Chair for Global Elimination of HIV and AIDS, at the University of Pittsburgh School of Medicine and UPMC Health System
    - Gérard Socié, M.D., Ph.D., Head of Hematology-Transplantation at AP-HP Hospital Saint-Louis in Paris

Outlook – 2023 and Into 2024

Posoleucel: AlloVir's lead investigational therapy, posoleucel, offers a franchise opportunity, with three indications being evaluated in Phase 3 registrational trials.

- The posoleucel Phase 3 multi-virus prevention trial is enrolling adult and pediatric patients globally. Enrollment is expected to complete by year-end 2023, enabling topline data in mid-2024.
- Global enrollment is ongoing in Phase 3 studies of posoleucel for the treatment of virus-associated hemorrhagic cystitis and adenovirus infection, both in adult and pediatric allo-HCT patients. Both studies are expected to complete enrollment by year-end 2023, with topline data anticipated in 2024.
- The company plans to present comprehensive results from the BKV Phase 2 study at a scientific congress later this year, and will work with regulatory authorities and transplant specialists to inform next steps for this program and AlloVir's broader solid organ transplant strategy.

Earlier Stage Pipeline: AlloVir's early clinical and preclinical VST therapy candidates provide portfolio expansion opportunities, with pipeline advancement led by AlloVir or a potential partner.

- A Phase 1b/2 proof-of-concept clinical study of ALVR106 for the treatment of respiratory syncytial virus, human metapneumovirus, parainfluenza, and influenza, is enrolling auto- and allo-HCT patients in the U.S. into the dose escalation part of this two-part study.
- Preclinical and IND-enabling studies of ALVR107 for chronic HBV have been completed and continue to support the potential for ALVR107 to achieve functional HBV cure. The company expects to initiate clinical development of ALVR107 after completion of the posoleucel Phase 3 registrational studies.

2022 Financial Highlights

- Research and development expenses were $118.9 million for the year ended December 31, 2022, compared with $120.7 million for the year ended December 31, 2021. The decrease year-over-year is primarily attributable to a reduction in costs related to the outsourcing of manufacturing, offset by an increase in costs related to the development of clinical trials to advance product candidates.
- General and administrative expense was $52.3 million for the year ended December 31, 2022, compared with $49.1 million for the year ended December 31, 2021. Stock-based compensation expense was $41.3 million and $44.0 million for the years ended December 31, 2022 and 2021, respectively.
- As of December 31, 2022, AlloVir had cash, cash equivalents, and marketable securities of $233.8 million, compared with cash, cash equivalents, and marketable securities of $248.1 million as of December 31, 2021.
- For the year ended December 31, 2022, net loss was $168.7 million or $2.20 per share, compared with a net loss of $172.0 million or $2.74 per share for the year ended December 31, 2021.

2023 Financial Guidance

- For fiscal year 2023, AlloVir expects operating expenses to be in the range of $150 million to $170 million, excluding non-cash expenses.

Investor Webcast Details

The company will host an investor webcast today at 9:00 a.m. EST to discuss the BKV study findings and the potential clinical impact of using posoleucel to treat viral infections in the solid organ transplant setting. The webcast will feature remarks from AlloVir CEO Diana Brainard, M.D., and from renal transplant specialist Anil K. Chandraker, M.D., Brigham and Women's Hospital.

A live audio webcast of the presentation will be available on the Investors & Press section of the AlloVir website at https://ir.allovir.com/events-and-presentations. An archived replay of the presentation will be available on the website for 30 days following the event.

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 or follow us on Twitter or LinkedIn.

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 safety, efficacy and regulatory and clinical progress of our product candidates, including posoleucel, the planned conduct of its preclinical studies, and clinical trials and its prospects for success in those studies and trials, the financial outlook for the full-year 2023, including estimates of operating expenses, 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 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, or FDA, or other foreign regulatory authorities, competition from other biopharmaceutical companies, the impact of the COVID-19 pandemic on AlloVir's product development plans, supply chain, and business operations and other risks identified in AlloVir's Securities and Exchange Commission (SEC) filings, including but not limited to the risks discussed in AlloVir's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 and in our other filings with the SEC. 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.

ALLOVIR, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$233,795	$248,120
Other current assets	9,257	5,228
Total current assets	243,052	253,348
Other assets	34,027	33,246
Total assets	$277,079	$286,594
Liabilities and stockholders' equity		
Current liabilities	$ 24,338	$ 37,853
Long-term liabilities	28,222	23,475
Total liabilities	52,560	61,328
Total stockholders' equity	224,519	225,266
Total liabilities and stockholders' equity	$277,079	$286,594

ALLOVIR, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except share and per share data)

	Years Ended December 31, 2022	Years Ended December 31, 2021
Operating expenses:		
Research and development	118,870	120,735
General and administrative	52,332	49,083
Total operating expenses	171,202	169,818
Loss from operations	(171,202)	(169,818)
Total other income (loss), net:		
Interest income	1,876	1,315
Other income (loss), net	351	(2,452)
Loss before income taxes	(168,975)	(170,955)
Income tax (benefit) expense	(265)	1,007
Net loss	$ (168,710)	$ (171,962)
Net loss per share — basic and diluted	$ (2.20)	$ (2.74)
Weighted-average common shares outstanding—basic and diluted	76,654,856	62,782,126

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Media and Investor Contact:

Sonia Choi
AlloVir
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Exhibit 99.2

AlloVir Announces Positive Final Results from Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of Posoleucel in Kidney Transplant Recipients with BK Viremia

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

In Week 24 efficacy analysis, 39% (15/38) of patients who received posoleucel experienced a ≥1-log viral load reduction, more than double the placebo rate (14%; 2/14)

Posoleucel dose response was observed, with a ≥1-log viral load reduction in the biweekly dosing group of 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 (≥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 ≥1-log viral load reduction vs. 25% (1/4) of patients in the placebo group

First demonstration of therapeutic potential of posoleucel for solid organ transplant patients

Company to host investor webcast at 9:00 a.m. EST today including Anil K. Chandraker, M.D., Director of Renal Transplant Medicine, Brigham & Women's Hospital

WALTHAM, Mass. – February 15, 2023 – AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today announced positive 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 (BKV) in adult kidney transplant recipients. The data support the safety and antiviral activity of posoleucel in this population, which has no effective BKV treatment options. In the randomized, double-blind, placebo-controlled study, posoleucel was shown to be generally well tolerated, with balanced safety across the two posoleucel dosing groups and placebo. Patients who received posoleucel achieved a clinically meaningful greater decline in BK viral load compared with those receiving placebo. The study results showed an even greater antiviral effect with posoleucel in patients with BK viral load ≥10,000 copies/mL at screening and in the biweekly posoleucel dosing group, identifying a dosing regimen and patient population to advance into a future trial.

"BKV is one of the most feared transplant-associated viral infections, due to the lack of available effective antiviral therapies and its profoundly negative impact on transplant outcomes," said Anil K. Chandraker, M.D., Director of Renal Transplant Medicine, Brigham and Women's Hospital, and principal investigator of the posoleucel BKV treatment study. "The safety profile of posoleucel and its antiviral activity, which is amplified in high viral load patients who have the greatest unmet need, suggest it could potentially offer a transformative treatment option for kidney transplant patients with BK viremia."

“This study is the first to evaluate a virus-specific T cell therapy in solid organ transplant patients, with the primary goal of exploring the safety of posoleucel treatment for BK viremia in kidney transplant patients. We are pleased with the consistency of posoleucel’s safety profile across solid and stem cell transplant patient populations and with the important antiviral efficacy results in kidney transplant patients at highest risk for BKV-associated graft loss observed in this study,” said Diana Brainard, M.D., CEO, AlloVir. “We believe today’s results are an important and compelling milestone not just for AlloVir but for the entire kidney transplant community.”

Dr. Brainard continued, “ These safety and efficacy data in solid organ transplant patients provide important insights into the potential of posoleucel, which is also being studied in our three ongoing Phase 3 registrational trials in allo-HCT patients. We look forward to working with regulatory authorities and transplant specialists on our forward-looking clinical development strategy in kidney transplant patients, and potentially other solid organ transplant recipients.”

This Phase 2 study evaluated the safety and efficacy of posoleucel to treat BK viremia in adult kidney transplant recipients with BK viral load between 350-10,000,000 copies/mL (stratified by low (<10,000 copies/mL) or high (≥10,000 copies/mL) viral load at study screening). Sixty-one patients were randomized 1:1:1 to receive one of two dosing regimens of posoleucel – weekly administration of posoleucel for three weeks, then every two weeks, or weekly administration of posoleucel for three weeks, then once a month – or placebo over 12 weeks. Following this dosing period, patients were followed through Week 24. Of the 61 enrolled patients, 58 patients completed the study through Week 24; two patients were lost to follow-up and one patient withdrew consent.

The primary endpoint of the study was safety and tolerability of posoleucel versus placebo. Across all patients who received at least a single dose of study drug, posoleucel was well tolerated. The incidence and severity of adverse events were consistent with the underlying patient population and background immunosuppression. Low rates of infusion reactions were observed in patients receiving posoleucel (2%) and those receiving placebo (5%). There were no deaths or reports of graft versus host disease or cytokine release syndrome. Emergence of donor-specific antibodies was uncommon and occurred with similar frequency in patients receiving posoleucel (7%) or placebo (5%). Three patients who received posoleucel were reported to have acute rejection per biopsy report by a central reader: one who was clinically diagnosed with, and successfully treated for, renal tuberculosis, one who had rejection on a biopsy prior to posoleucel dosing during the screening window, and one who developed rejection at Week 22 of the trial. None of these cases were assessed by the investigator as related to study drug.

The key secondary endpoint of the study was the change in BK viral load in patients receiving posoleucel versus those receiving placebo. The efficacy analysis excluded six patients in whom significant reductions in immunosuppression were made immediately prior to study entry. Posoleucel achieved greater viral load reductions versus placebo consistently across multiple BK viral load measures. This clinically meaningful treatment effect was strongest among patients receiving posoleucel every two weeks and among those with high viral loads. Antiviral responses among

posoleucel patients increased over time, with maximal responses observed at Week 24. Renal function in this group remained stable throughout the study, with a median change in estimated glomerular filtration rate from baseline to Week 24 of 0 mL/min/1.73m^2 in the overall posoleucel group and 0 mL/min/1.73m^2 in the placebo group.

Summary of Week 24 Virologic Changes Among Patients With Stable Immunosuppression Prior to Randomization*

	Overall (N=52)				High VL Stratum (N=20)			
	PSL Biweekly (N=20)	PSL Monthly+ (N=18)	PSL Overall (N=38)	PBO (N=14)±	PSL Biweekly (N=8)	PSL Monthly (N=8)	PSL Overall (N=16)	PBO (N=4)
% Patients with ≥1 log_{10} copies/mL reduction	50	28	39	14	75	63	69	25
BK VL change 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)	-1.4 (-2.1, 0.1)	-1.5 (-1.8, -0.2)	-1.4 (-2.1, 0.1)	-0.4 (-2.1, -0.01)
% Patients with ≥50% VL copies/mL reduction	85	56	71	43	88	88	88	50

* PSL = posoleucel; PBO = placebo; VL = viral load
\+ Excludes two patients who discontinued study
± Excludes one patient who discontinued study

The company plans to present comprehensive results from the BKV Phase 2 study at a scientific congress later this year, and will work with regulatory authorities and transplant specialists to inform next steps for this program and AlloVir's broader solid organ transplant strategy.

Investor Webcast Details

The company will host an investor webcast today at 9:00 a.m. EST to discuss the study findings and the potential clinical impact of using posoleucel to treat viral infections in the solid organ transplant setting. The webcast will feature remarks from Dr. Brainard and Dr. Chandraker.

A live audio webcast of the presentation will be available on the Investors & Press section of the AlloVir website at https://ir.allovir.com/events-and-presentations. An archived replay of the presentation will be available on the website for 30 days following the event.

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.

BK viral infection poses a significant threat to kidney graft survival. Approximately 80,000 kidney transplants are performed each year globally, and the virus reactivates in up to 20% of these patients. In patients who have reactivated BKV, a substantial portion will develop high-level viremia, and approximately half of those will develop BKV-associated nephropathy (BKVAN), which can lead to decreased kidney survival and a return to end-stage renal disease and dialysis. 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.[i]

There are no approved or effective antiviral treatments for BK viremia. The only approach to managing BK viremia is a reduction in immunosuppression to allow the body's immune system to fight the virus; this is typically triggered by a BK viral load of greater than or equal to 10,000 copies/mL. However, this reduction in immunosuppression can also lead to graft rejection and the development of donor-specific antibodies, putting the success of the kidney transplant at risk.

Data suggest that VST therapy may play a role in managing BK viremia and BKVAN. 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.

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), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). In the positive Phase 2 proof-of-concept CHARMS study, more than 90% of patients who failed conventional treatment and received posoleucel demonstrated a complete or partial clinical response based on predefined criteria, most with complete elimination of detectable virus in the blood and resolution of major clinical symptoms.

Based on the strength of the posoleucel Phase 2 data for both treatment and prevention, 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 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 allogeneic T cell immunotherapy 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 or follow us on Twitter or LinkedIn.

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 efficacy of posoleucel as a treatment for BK viremia, AlloVir's development plans and the regulatory status of AlloVir's 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 potential of posoleucel as a treatment for BKV, the potential of posoleucel as a transformative treatment option for kidney transplant patients with BK viremia, 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, or FDA, or other foreign regulatory authorities, competition from other biopharmaceutical companies, the impact of the COVID-19 pandemic on AlloVir's product development plans, supply chain, and business operations and other risks identified in AlloVir's SEC filings, including but not limited to the risks discussed in AlloVir's Annual Report on Form 10-K for the year ended December 31, 2021, and in our other filings with the SEC. 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.

Media and Investor Contact:

Sonia Choi
AlloVir
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[i] Imlay et al. CID 2022.