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): December 11, 2021

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	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 Par Value	**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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 7.01 Regulation FD Disclosure.

On December 11, 2021, AlloVir, Inc. (the "Company") issued a press release announcing preliminary data from the open-label portion of a Phase 2 study assessing the safety and efficacy of posoleucel (Viralym-M, ALVR105) for the prevention of clinically significant infections and end-organ disease from six potentially life-threatening viruses in high-risk patients following allogeneic hematopoietic cell transplantation. The Company presented the preliminary data at the 63rd American Society of Hematology Annual Meeting and hosted a virtual investor event on December 13, 2021. Copies of the press release and presentation are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

The information in this Item 7.01 and Exhibits 99.1 and 99.2 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

Overview of the Multi-Virus Prevention Study Open-Label Preliminary Data

On December 11, 2021, the Company announced preliminary data from the open-label portion of its ongoing Phase 2 two part multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of posoleucel for the prevention of six viral infections – AdV, BKV, CMV, EBV, HHV-6 and JCV. The Phase 2 open-label portion of this study is enrolling 25 high-risk allo-HCT patients. Patients receive up to seven biweekly posoleucel infusions and are tested for viremia by polymerase chain reaction (PCR) on a weekly basis against all six viruses over a period of 14 weeks. Following this dosing period, patients receive follow-up through Week 26.

At the time of the data cut-off for this preliminary analysis, 23 high-risk allo-HCT patients received at least a single dose of posoleucel, including 13 patients who had completed through Week 14, one patient who discontinued the study and nine patients whose evaluation for the primary endpoint is ongoing. Of these patients, 14 (61%) received cells from haploidentical donors, six (26%) from mismatched unrelated donors, two (9%) from matched unrelated donors with T cell depletion or with lymphopenia, and one (4%) from umbilical cord blood.

In the preliminary analysis, high-risk allo-HCT patients receiving posoleucel experienced no end-organ disease and had rates of clinically significant viral infections substantially lower than the expected rate estimated through an analysis of peer-reviewed published data and electronic medical record reviews.

The primary study endpoint is the number of new onset clinically significant infections or end-organ disease through Week 14. Among the 23 patients who received at least a single dose of posoleucel, only three of 138 possible clinically significant infections from these six common and life-threatening viruses were observed up to 14 weeks. Three out of 23 patients experienced one clinically significant viral infection each. Specifically, two patients initiated preemptive CMV treatment with valganciclovir following withdrawal of letermovir, and one patient started rituximab for EBV in the setting of receiving high-dose steroids.

Repeat posoleucel dosing was generally well-tolerated, with no unanticipated safety signals. The observed rates and severity of graft versus host disease did not exceed those expected in this high-risk allo-HCT patient population. Two (9%) treatment-related serious adverse events were reported.

The Company plans to advance from the Phase 2 open-label study into a Phase 3 registrational trial in the first half of 2022, following FDA review of the final protocol.

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the Company'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 Form 8-K 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 Form 8-K, including, without limitation, those related to the Company’s financial results, the timing for the initiation and successful completion of the Company’s clinical trials of its product candidates, whether and when, if at all, the Company’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 the Company’s product development plans, supply chain, and business operations and other risks identified in the Company’s EC filings. the Company cautions investors not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company 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 Form 8-K represent the Company’s views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated December 11, 2021
99.2	Investor Presentation dated December 13, 2021
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: December 13, 2021

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

For Immediate Release

AlloVir Announces Positive Preliminary Data from the Ongoing Phase 2 Posoleucel Multi-Virus Prevention Study at the 63rd American Society of Hematology Annual Meeting

Of the 23 high-risk allogeneic hematopoietic cell transplant patients in this analysis, no end-organ viral disease was observed

Of the 13 patients who completed through the Week 14 primary endpoint, 11 remained free of clinically significant infection

Strength of these preliminary efficacy and safety data support advancement of posoleucel into a Phase 3 registrational trial expected to initiate in 1H 2022

Company to host virtual investor event on December 13

Waltham, Mass., December 11, 2021 – AlloVir (Nasdaq: ALVR), a late-clinical stage allogeneic T-cell immunotherapy company, today announced preliminary data from the ongoing open-label portion of a Phase 2 study assessing the safety and efficacy of posoleucel (Viralym-M, ALVR105) for the prevention of clinically significant infections and end-organ diseases from six potentially life-threatening viruses in high-risk patients following allogeneic hematopoietic cell transplantation (allo-HCT). Out of 23 patients who received at least one dose of posoleucel in the ongoing study, including those who completed, discontinued or are continuing posoleucel, only three clinically significant infections were observed through Week 14 and no patients developed end-organ viral disease as of the data cut-off for this preliminary analysis. Of the 13 patients who completed through the Week 14 primary endpoint, 11 remained free of clinically significant infection. These initial results represent a substantial reduction in the expected rate of clinically significant viral infections or diseases in this high-risk patient population. Repeat dosing of posoleucel was generally well-tolerated. These data were presented today at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition.

Based on preliminary data from this Phase 2 study, the U.S. Food and Drug Administration (FDA) has agreed in principle with the company's plan to advance from this Phase 2 open-label study into a Phase 3 registrational trial. The company plans to initiate this study in the first half of 2022, following FDA review of the final protocol.

Posoleucel, the company's lead investigational product, is an allogeneic, off-the-shelf, virus-specific T cell (VST) therapy being evaluated for the prevention of six potentially life-threatening viruses that commonly impact allo-HCT patients – adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). Nearly 90% of all allo-HCT patients will reactivate at least one of these viruses following allo-HCT, and approximately two thirds of these patients reactivate multiple viruses. Based on an analysis of peer-reviewed published data and electronic medical record reviews, approximately 70% of high-risk allo-HCT patients develop clinically significant infection or end-organ disease from one or more of these viruses following allo-HCT. There are currently no effective preventive therapies that can target these multiple viruses simultaneously, resulting in significant and prolonged morbidity, hospitalization and premature death.

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“Viral infections frequently occur after allogeneic hematopoietic cell transplant and commonly lead to serious complications that can be life-threatening and negatively impact patient survival. Treatment is often complicated by adverse effects of antiviral medications that do not address the underlying issue – the immune-deficient state,” said Sanjeet Dadwal, M.D., Chief, Division of Infectious Diseases, and Professor of Medicine, City of Hope, and posoleucel study investigator. “Posoleucel has the potential to address the underlying immune deficit that leaves these patients vulnerable to viral infections and aims to work as a bridge to eventual immune reconstitution of the patient. The ability to prevent six serious viral infections or diseases in high-risk situations, such as soon after allo-HCT, would be a significant advancement, minimizing the downstream effects of these viral infections.”

“We are encouraged and excited by these positive data that support the potential for posoleucel to change the treatment paradigm for allogeneic hematopoietic cell transplant recipients, moving upstream to prevent viral infections or diseases before they occur,” said Diana Brainard, M.D., Chief Executive Officer, AlloVir. “Based on the strength of these data and the tremendous unmet medical need, we look forward to working with urgency with regulators and the transplant community to initiate a global Phase 3 multi-virus prevention study in the coming months which, in combination with our other posoleucel Phase 3 treatment studies for virus-associated hemorrhagic cystitis and adenovirus, present a critically important opportunity to better serve allo-HCT patients.”

Overview of the Multi-Virus Prevention Study Open-Label Preliminary Data

This two-part multicenter, randomized, double-blind, placebo-controlled study is evaluating the efficacy and safety of posoleucel for the prevention of six viral infections – AdV, BKV, CMV, EBV, HHV-6 and JCV. The Phase 2 open-label portion of this study is enrolling 25 high-risk allo-HCT patients. Patients receive up to seven biweekly posoleucel infusions and are tested for viremia by polymerase chain reaction (PCR) on a weekly basis against all six viruses over a period of 14 weeks. Following this dosing period, patients receive follow-up through Week 26.

At the time of the data cut-off for this preliminary analysis, 23 high-risk allo-HCT patients received at least a single dose of posoleucel, including 13 patients who had completed through Week 14, one patient who discontinued the study and nine patients whose evaluation for the primary endpoint is ongoing. Of these patients, 14 (61%) received cells from haploidentical donors, six (26%) from mismatched unrelated donors, two (9%) from matched unrelated donors with T cell depletion or with lymphopenia, and one (4%) from umbilical cord blood.

In this preliminary analysis, high-risk allo-HCT patients receiving posoleucel experienced no end-organ disease and had rates of clinically significant viral infections substantially lower than the expected rate estimated through an analysis of peer-reviewed published data and electronic medical record reviews.

The primary study endpoint is the number of new onset clinically significant infections or end-organ disease through Week 14. Among the 23 patients who received at least a single dose of posoleucel, only three of 138 possible clinically significant infections from these six common and life-threatening viruses were observed through 14 weeks. Three out of 23 patients experienced one clinically significant viral infection each. Specifically, two patients initiated preemptive CMV treatment with valganciclovir following withdrawal of letermovir, and one patient started rituximab for EBV in the setting of receiving high-dose steroids.

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Repeat posoleucel dosing has been generally well-tolerated, with no unanticipated safety signals. The observed rates and severity of graft versus host disease did not exceed those expected in this high-risk allo-HCT patient population. Two (9%) treatment-related serious adverse events were reported.

Virtual Investor Event Details

The company will host a virtual investor event on Monday, December 13, 2021, at 8:00 a.m. EST. 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 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. FDA has granted posoleucel Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of hemorrhagic cystitis (HC) caused by BKV in adults and children following allo-HCT, and 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 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 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

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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 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.

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Media and Investor Contact:

Sonia Choi
AlloVir
schoi@allovir.com

Exhibit 99.2

AlloVir Virtual Investor Event

December 13, 2021

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Disclaimer

This presentation has been prepared by AlloVir, Inc. (“we,” “us,” “our,” “AlloVir” or the “Company”) and is made for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities. This presentation may contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the safety, efficacy and regulatory and clinical progress of our product candidates, including posoleucel. All such forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. The use of words such as, but not limited to, “may,” “might,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “future,” “potential,” or “continue,” and other similar words or expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. All statements other than statements of historical facts contained in this presentation, including statements regarding future results of operations and financial position, business strategy, current and prospective product candidates ongoing, and planned clinical trials and preclinical activities, including the initiation, timing, enrollment, progress and results of our preclinical and clinical studies and our research and development programs, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, including our ability to advance and successfully complete clinical studies, the timing and likelihood of success of our clinical trials, and the timing or likelihood of regulatory filings and approvals, expectations regarding market acceptance and size, plans for launch and commercialization, plans and objectives of management for future operations, and future results of anticipated product candidates, are forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

These statements are also subject to a number of material risks and uncertainties that are discussed in the section entitled "Risk Factors" in our quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2021, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. Neither we, nor our affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company’s own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and we make no representation as to the adequacy, fairness, accuracy or completeness of any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

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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	Rich pipeline	Manufacturing at scale	Large unmet need and global opportunity
93% overall response rate in Phase 2 study	4 products targeting 12 viruses with both treatment and prevention potential	Simple, non-gene-edited, scalable process with manufacturing redundancy	Currently focused on stem cell and solid organ transplant patients
Expedited regulatory review pathways (RMAT, PRIME)	Posoleucel in 3 Phase 3 trials* and 1 ongoing proof-of-concept study by 1H 2022	Off-the-shelf delivery for patient access within 48 hours	Expanding to additional patient populations

*Phase 3 trial for multi-virus prevention anticipated to initiate in 1H 2022, following FDA review of final protocol.
RMAT = Regenerative Medicine Advanced Therapy designation granted by the US Food and Drug Administration; PRIME = Priority Medicines designation granted by the European Medicines Agency.

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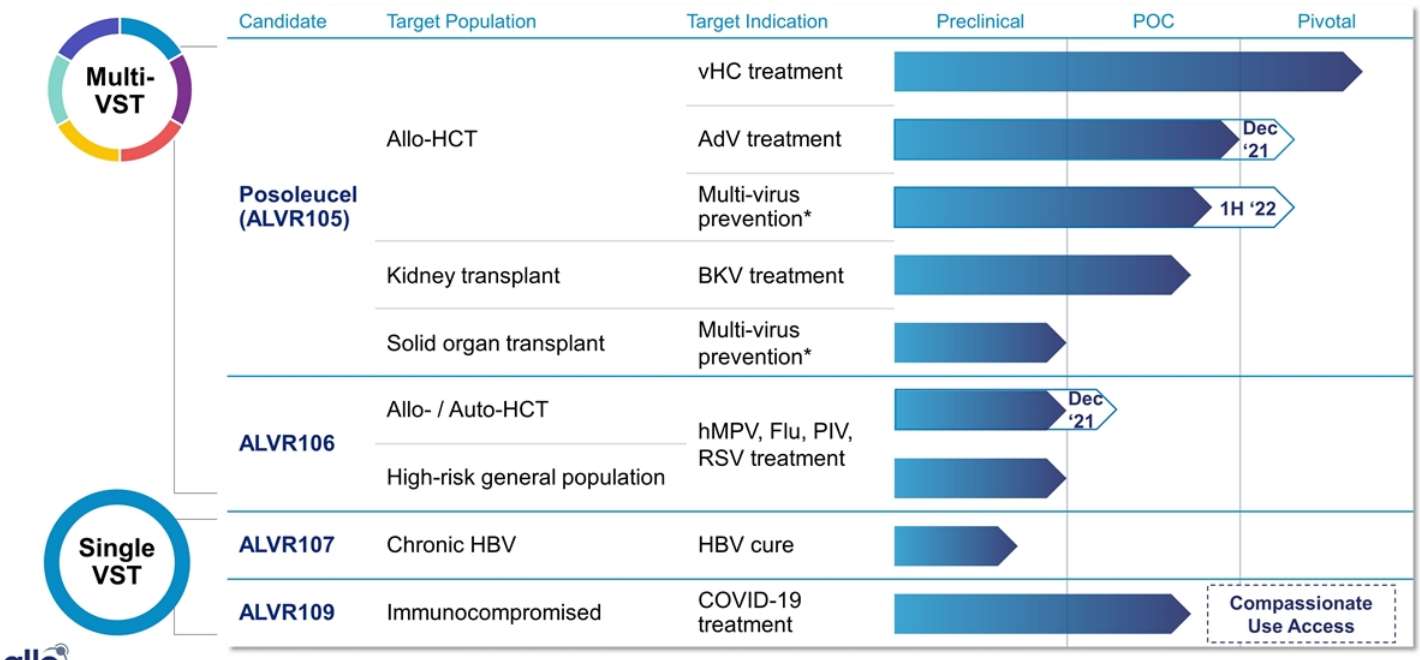
Our Pipeline Targets 12 Unique Viruses



*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.

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AlloVir's Therapies Aim to Treat or Prevent Life-Threatening Viral Diseases For Immunocompromised Patients[1-13]

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**

GVHD = graft vs host disease; SOT = solid organ transplant. 1. Abudayyeh A, et al. *Am J Transplant.* 2016;16:1492-1502; 2. Camargo JF, Komarduri KV. *Hematol Oncol Stem Cell Ther.* 2017;10:233-238; 3. Cesaro S, et al. *Bone Marrow Transplant.* 2018;doi:10.1038/s41409-018-0421-0; 4. Leen AM, et al. *Blood.* 2009;114(19):4283-4292; 5. Perruccio K, et al. *Biol Blood Marrow Transplant.* 2018;24:2549-2557; 6. Saribas AS, et al. Future Virol. 2010;5(3):313-323. doi:10.2217/fvl.10.12; 7. Cho SY, et al. *Kor J Intern Med.* 2018;33:256-276; 8. Law N, Kumar D. *Drugs Aging.* 2017;34:743-754; 9. Gentile G, Antonelli G. *Viruses.* 2019;11:doi:10.3390/v11111049; 10. Kedia S, et al. *J Stem Cell Res Ther.* 2013;doi:10.4172/2157-7633.S3-002; 11. Ison MG, Hirsch HH. *Clin Microbiol Rev.* 2019;32(4):1-33; 12. Jose RJ, et al. *Medicine. 2020.* doi:10.1016/j.mpmed.2020.03.006; 13. Simon AK, Hollander GA, McMichael A. *Proc Biol Sci.* 2015;282(1821):20143085.

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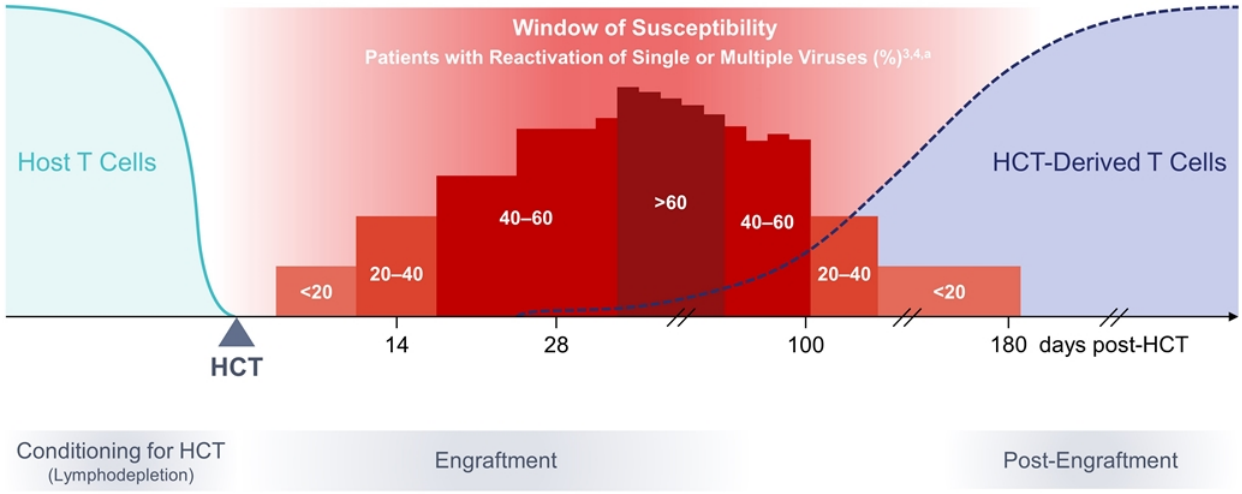
Following HCT, Patients are Susceptible to Life-Threatening Viral Infections[1-6]



[a]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.

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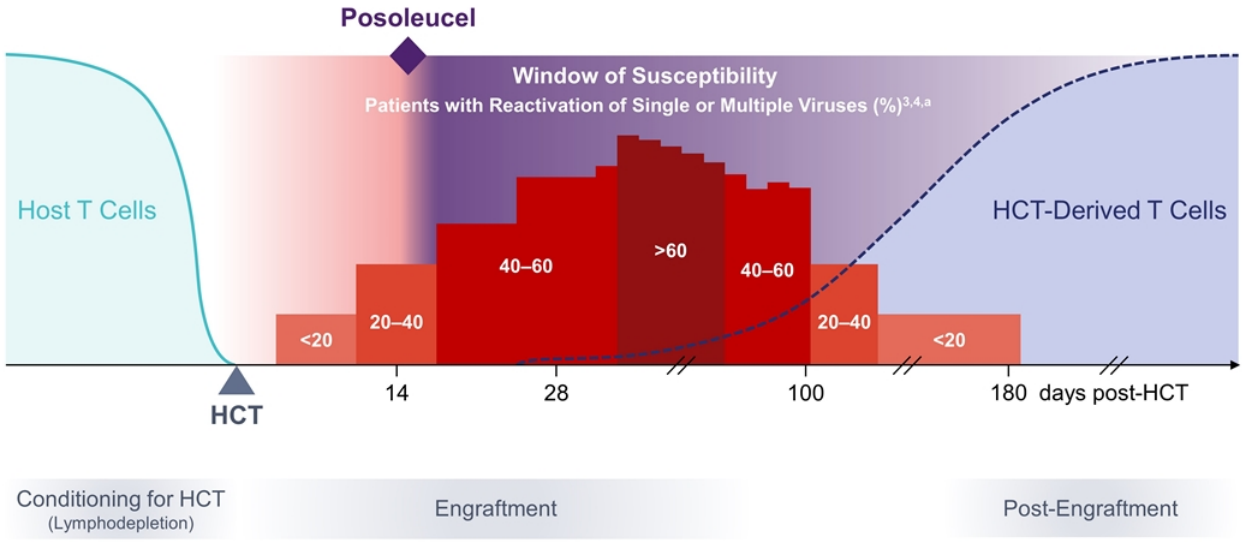
Posoleucel is Designed to Treat and Prevent Viral Infections and Diseases Until the Patient's Own Immune System Recovers[1-6]



[a]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.

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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

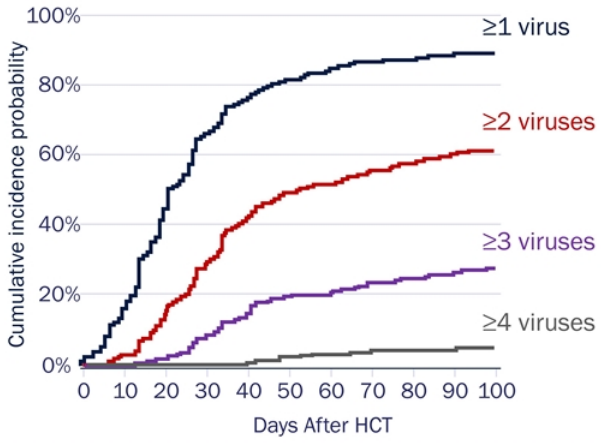
Results from an Open-Label Cohort of a Phase 2 Trial

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

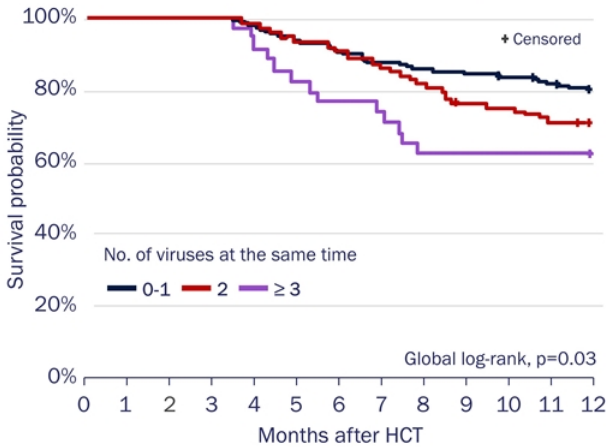
[1]City of Hope National Medical Center, Duarte, CA; [2]Stony Brook Cancer Center, Stony Brook, NY; [3]Children's Mercy Hospital, Kansas City, MO; [4]AlloVir, Cambridge, MA; [5]Glacier Bio, North Bend, WA; [6]Fred Hutchinson Cancer Research Center, Seattle, WA

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

Incidence of AdV, BKV, CMV, EBV, or HHV-6 infection[1] (N=404)



Overall survival, number of viruses at the same time[1] (N=358)



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

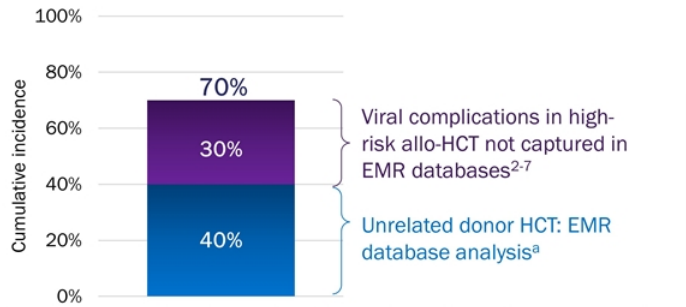
AdV: adenovirus; CMV: cytomegalovirus; EBV: Epstein-Barr virus; HHV-6: human herpesvirus 6.

1. Hill et al, *Blood* 2017;

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[1])

Estimated incidence of clinically significant viral infection or disease



[a]>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)

Conservative estimate

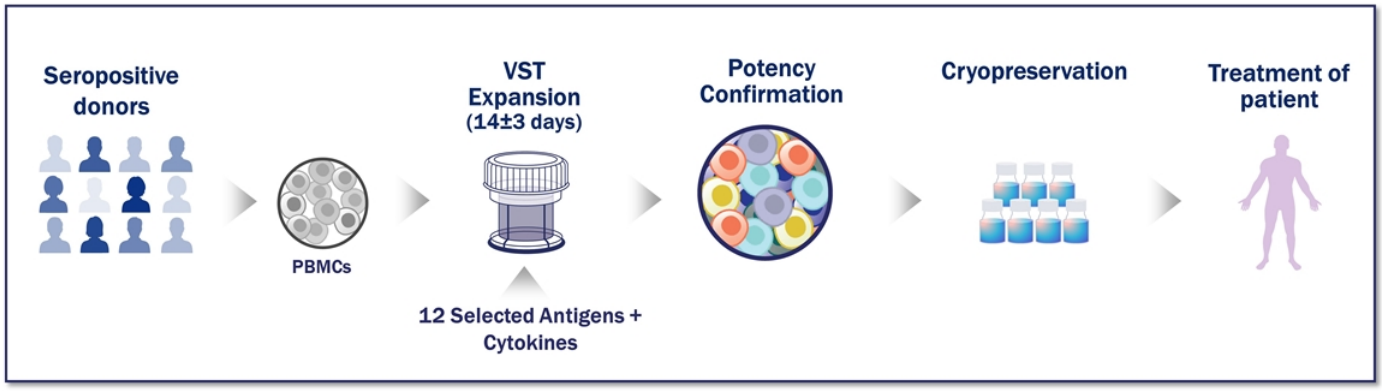
- Not all viral infections or diseases captured
- EMR database does not include patients with haploidentical HCTs

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

1. CIBMTR 2020 summary report; 2. Slade et al. *Transpl Infect Dis*. 2017; 3. Mohty et al. *British Journal of Haematology* 2019; 4. Salamonowicz-Bodzioch et al. *Ann Hematol*. 2021; 5. Chang et al. *J Blood Med*. 2019; 6. El-Zimaity et al. *Blood* 2004; 7. Gargiulo et al. *eCancer* 2014

Posoleucel (ALVR105)

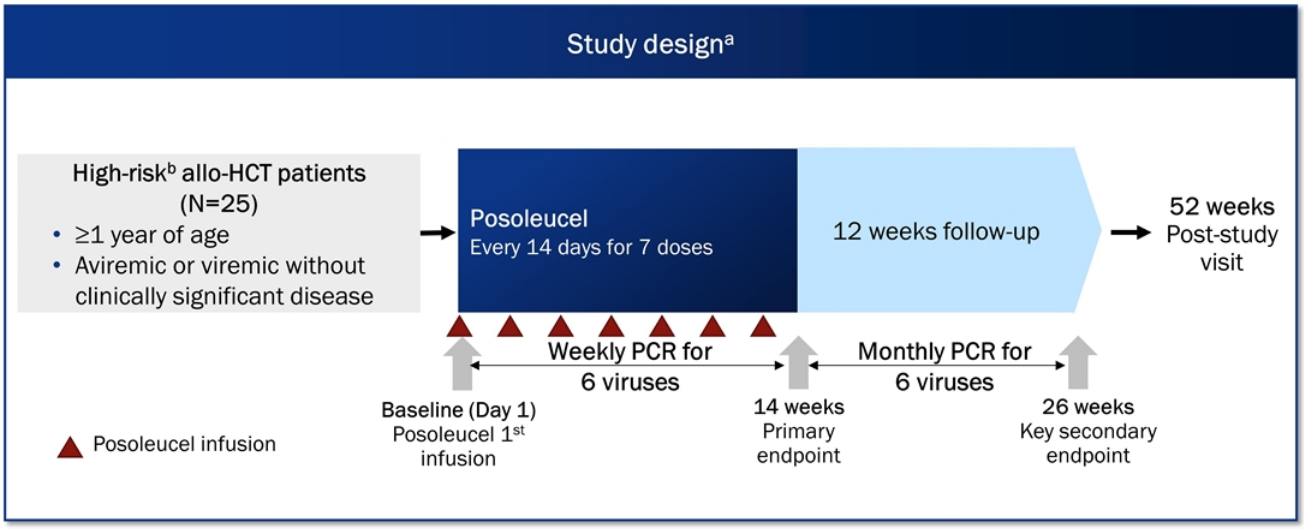
- Allogeneic, off-the-shelf, multivirus-specific T-cell (VST) therapy targeting AdV, BKV, CMV, EBV, HHV-6, and JCV[a]
- 93% response rate in Phase 2 CHARMS study[1]



[a]JCV activity based on homology with BKV

1. Tzannou et al. *Blood* 2020

Phase 2 Multi-Virus Prevention Open-Label Study Design



[a]NCT04693637
[b]High-risk allo-HCT defined as: umbilical cord donor, haploidentical donor, MMRD, MUD, MMUD, recipient of T-cell depletion (ex vivo, alemtuzumab, ATG), persistent lymphopenia <180/mm^3

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[a] AND Initiation of preemptive antiviral therapy
End-organ disease	Signs or symptoms of organ damage from AdV, BKV, CMV, EBV, HHV-6, or JCV

[a]Defined as two consecutive results of >1,000 copies/mL with the second result being higher than the first and drawn at least 48 hours after the first

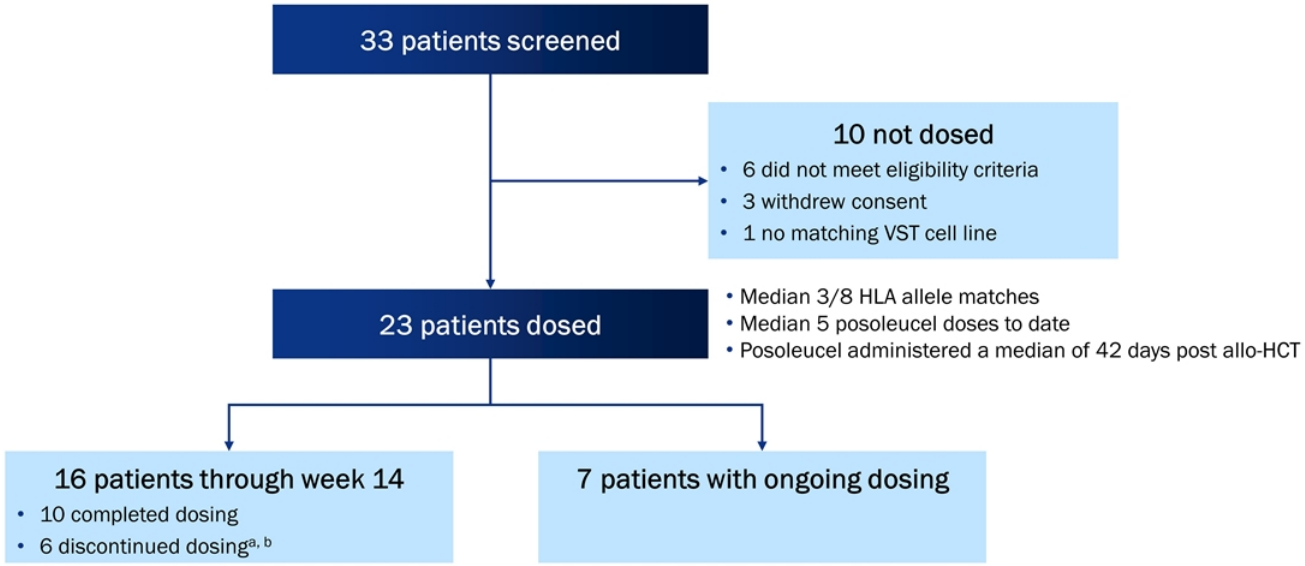
Baseline Demographics

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

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

[a]Multiple myeloma and adrenoleukodystrophy
[b]Matched unrelated transplant recipients included if also met another high-risk criterion: T cell depletion or persistent lymphopenia
[c]1 AdV, 7 BKV, 2 EBV and/or 4 HHV-6 viremia(s) detected in 10 patients

Patient Disposition



[a]4 patients due to AEs assessed not related to posoleucel; 1 patient due to AEs assessed as possibly related to posoleucel; 1 patient withdrew consent
[b]Median (range) posoleucel doses: 3 (1-6)

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[1-3]
  - No association between reported GVHD and number of HLA matches for posoleucel
  - No association between reported GVHD and number of posoleucel doses

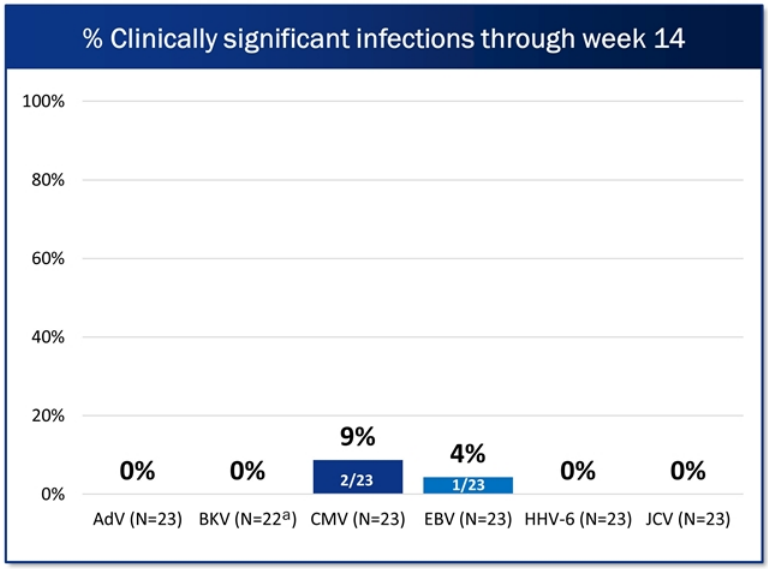
Events	N=23
Common adverse events (AEs)	
Diarrhea	7 (30%)
Weight decrease	5 (22%)
SAEs	11 (48%)
Treatment-related SAE	2 (9%)[a]
Deaths	1 (4%)[b]
Posoleucel DC due to TEAEs	3 (13%)[c]
Adverse events of interest	
Acute GVHD II-IV	6 (26%)
Grade II	2 (9%)
Grade III	4 (17%)
Grade IV	0 (0%)
Cytokine release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

[a]1 patient with infusion reaction; 1 patient with acute GVHD
[b]Relapse of primary malignancy ~2 months after the 7th dose of posoleucel
[c]2 patients assessed as not related to posoleucel; 1 patient assessed as possibly related to posoleucel
[d]Tolerated subsequent posoleucel doses with pre-medication (diphenhydramine).

1. Malki et al. *Blood Adv*. 2021. 2. Saliba RM, et al. Abstract 31. Presented at: TCT 2020. 3. Chen et al., *Bone Marrow Transplant*. 2017.

Preliminary Results: Primary Endpoint (Week 14)

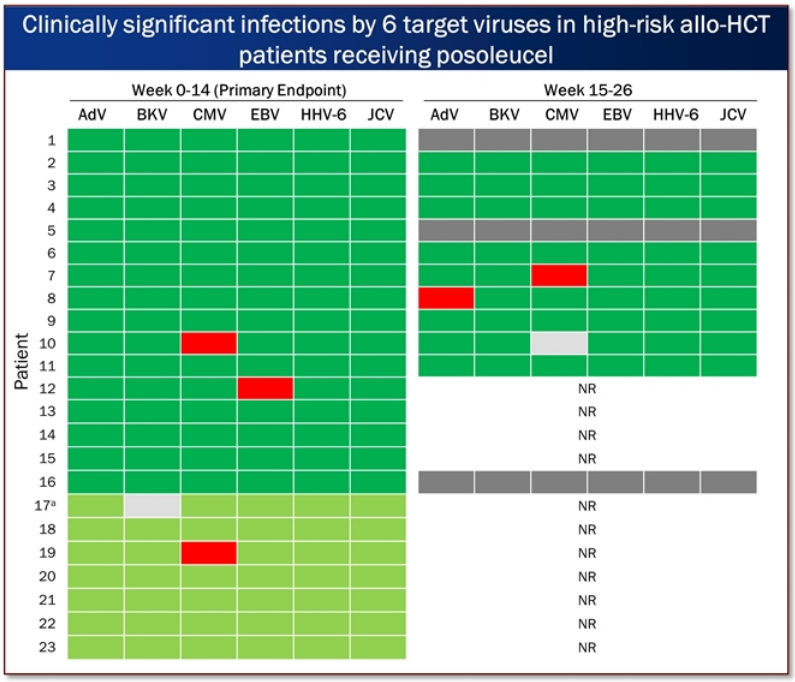
- 3 clinically significant infections
  - 2 patients started on pre-emptive valganciclovir for CMV post letermovir withdrawal
  - 1 patient started on rituximab for EBV in the setting of high-dose steroids
- No end-organ disease[a]



[a]One patient excluded due to BKV hemorrhagic cystitis at baseline

Preliminary Results: Secondary Endpoint (Week 26)

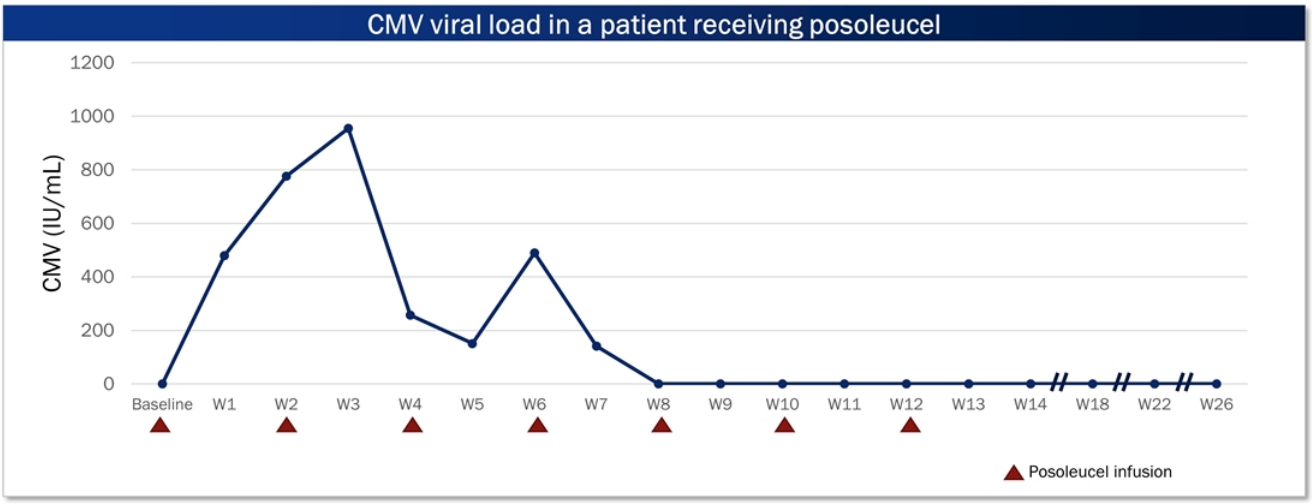
- 2 additional clinically significant infections
  - 1 patient started on pre-emptive valganciclovir for CMV post letermovir withdrawal
  - 1 patient started cidofovir for AdV in the setting of high-dose steroids
- No end-organ disease



[a]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 1st posoleucel dose
- No pre-emptive therapy during study
- Completed all 7 posoleucel doses



Biomarker Summary

- Preliminary assessment of T cell activity by IFNγ 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

- 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

- 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

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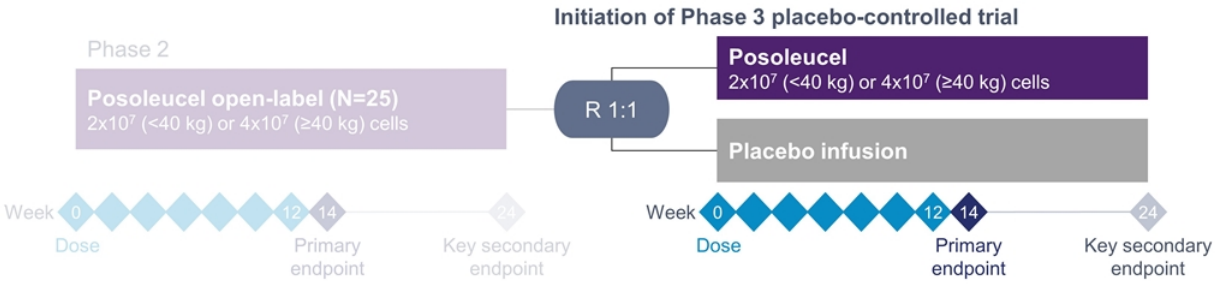
Ongoing Posoleucel Trial for Multi-Virus Prevention Anticipated to Progress to Phase 3 Registrational Study in 1H 2022



- 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

*High-risk all-HCT defined as haploidentical donor, umbilical cord blood, mismatched unrelated donor, matched unrelated donor, mismatched related donor, recipient of T cell depletion, persistent lymphopenia <180/mm^3.
ClinicalTrials.gov NCT04693637.

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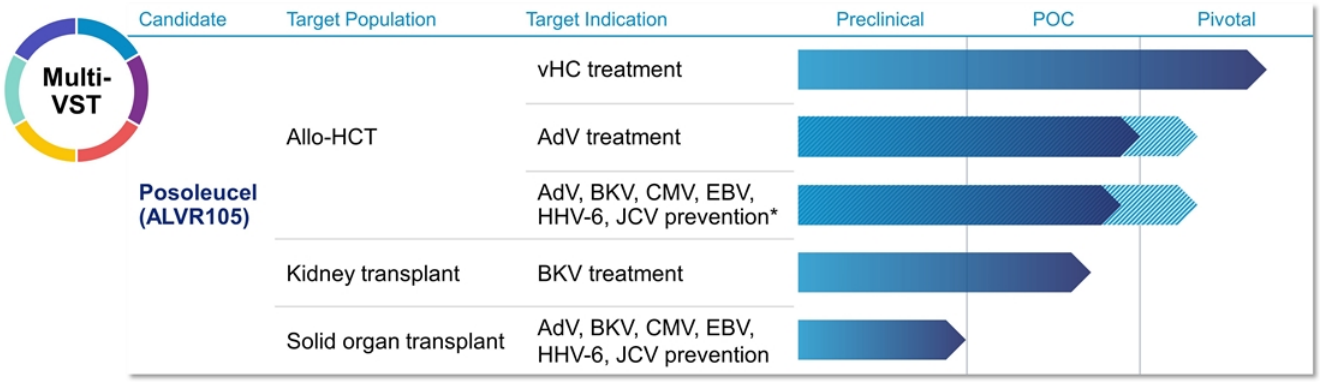
Three Ongoing Phase 3 Studies of Posoleucel Anticipated By 1H 2022



*Phase 3 trial for multi-virus prevention in allo-HCT anticipated to initiate in 1H 2022, following FDA review of final protocol.

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

	Recent Milestones	Remaining 2021 Catalysts	Future Activities
Posoleucel	✓ Pivotal trial initiation in vHC ✓ FDA orphan drug designation for vHC treatment ✓ POC trial initiation in multi-virus prevention and initial data ✓ POC trial initiation in BKV in kidney transplant ✓ **Abstract submission for early data from BKV in kidney transplant trial**	• **Pivotal trial initiation for AdV**	• Phase 3 trial initiation for multi-virus prevention in HCT patients • POC trial initiation for multi-virus prevention in SOT patients
ALVR106	✓ IND clearance by FDA for POC trial in multiple respiratory viruses	• **POC trial initiation for multiple respiratory viruses**	
ALVR107	✓ *In vitro*, preclinical, IND-enabling studies		• POC trial initiation for HBV cure
ALVR109	✓ Initial data for SARS-CoV-2		• Compassionate use access

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Q&A

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