

**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): January 10, 2022

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

Delaware
(State or other jurisdiction
of incorporation)

001-39409
(Commission
File Number)

83-1971007
(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 2.02. Results of Operations and Financial Condition.

On January 10, 2022, AlloVir, Inc. (the “Company”) posted the corporate presentation referred to in Item 7.01 of this Current Report on Form 8-K, which announced that its unaudited cash, cash equivalents and marketable securities totaled \$248.1 million as of December 31, 2021.

Item 7.01. Regulation FD Disclosure.

The Company is furnishing a corporate presentation, attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company intends to use from time to time in meetings with investors and others beginning on January 10, 2022. The corporate presentation will also be available in the investor relations section of the Company’s website at <http://allovir.com>.

The information in this Item 7.01 and Exhibit 99.1 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, 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	AlloVir, Inc. corporate presentation.
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: January 10, 2022

By: /s/ Edward Miller
Edward Miller
General Counsel



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

J.P. Morgan Healthcare Conference
January 10, 2022

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.

AlloVir By the Numbers



INVESTIGATIONAL
THERAPIES



TARGET
VIRUSES



POTENTIAL
INDICATIONS



PHASE 3
STUDIES



REGULATORY
DESIGNATIONS*

100+
EMPLOYEES

\$248.1
IN CASH, CASH EQUIVALENTS
& MARKETABLE SECURITIES[†]

69 CLINICAL
TRIAL SITES
ON 3 DIFFERENT CONTINENTS
ACROSS 5 CLINICAL STUDIES



*FDA Regenerative Medicine Advanced Therapy (RMAT) designation and Orphan Drug Designation (ODD) for virus-associated HC treatment, and RMAT for AdV treatment; EMA Priority Medicines (PRIME) designation for treatment of serious infections with AdV, BKV, CMV, EBV and HHV-6, and Orphan Medicinal Product (OMP) designation for treatment of viral diseases and infections in patients undergoing HCT.
[†] As of December 31, 2021.

AlloVir: A Leading Innovator in Allogeneic, Off-the-Shelf, Virus-Specific T Cell Immunotherapies

Clinically validated platform

93% overall response rate in Phase 2 CHARMS study

Expedited regulatory review pathways (RMAT, PRIME)

Rich pipeline

4 products targeting 12 viruses with both treatment and prevention potential

Posoleucel in 3 Phase 3 trials* and 1 ongoing proof-of-concept study by 1H 2022

Large unmet need and global opportunity

Currently focused on stem cell and solid organ transplant patients

Expanding to additional patient populations

Manufacturing at scale

Simple, non-gene-edited, scalable process with manufacturing redundancy

Off-the-shelf delivery for patient access within 48 hours



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

AlloVir's Therapies Aim to Treat or Prevent Life-Threatening Viral Diseases For Immunocompromised Patients¹⁻¹³

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/v111111049; 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.

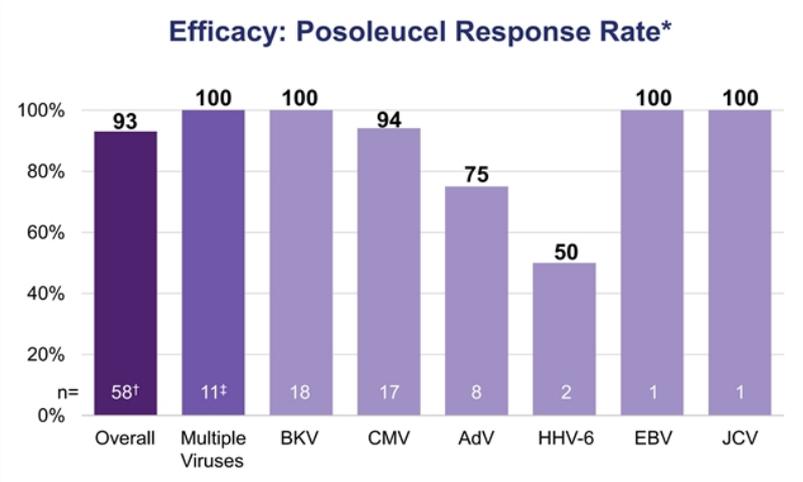
Our Patented and Highly Efficient Platform Delivers Rapid, Scalable, Off-the-Shelf VST Therapy



Key Advantages

- Rationally designed cell bank, facilitating availability of VSTs covering >95% of patients
- Our VST platform minimizes antigen competition, enabling retention of VST diversity and polyclonality
- Simple and robust manufacturing yields hundreds of VST doses from a single donor/production run
- Our VSTs have long-term stability, supporting on-demand, broad availability for patients

Phase 2 CHARMS Study Demonstrated 93% Efficacy of Posoleucel in Treatment-Refractory Patients^{1,2}



Safety: Posoleucel Well Tolerated

- Infusions were well tolerated
 - n=3 developed isolated fever within 24 hours of infusion; no immediate toxicities observed
- 14 cases of acute GVHD
 - n=8 had pre-existing GVHD
 - n=6 *de novo* GVHD; all had transient Grade I skin GVHD resolved with treatment
- No cytokine release syndrome

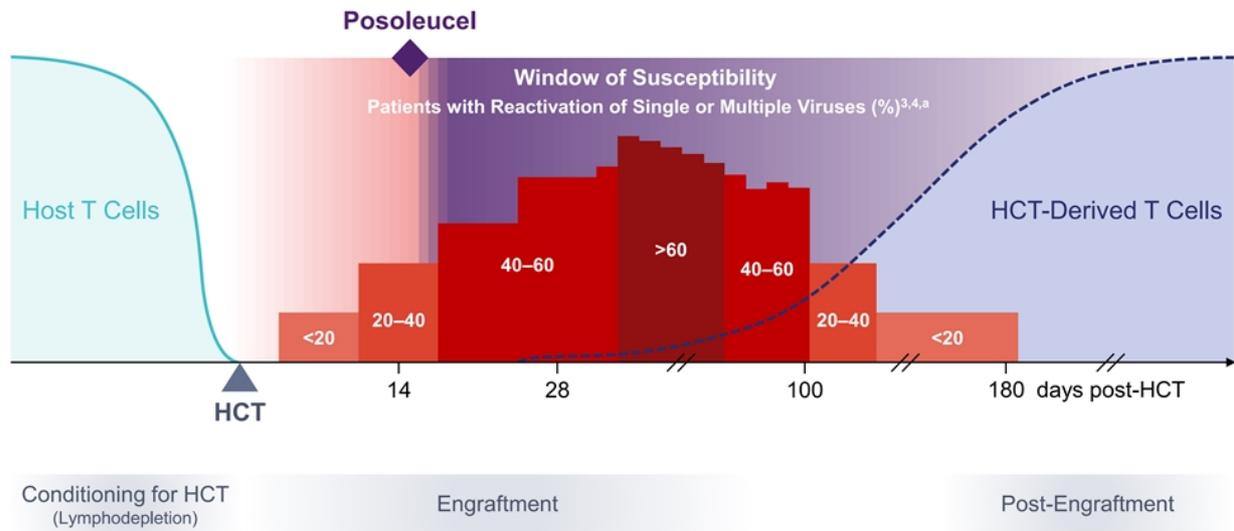
CR = Viral load return to normal range and resolution of clinical signs/symptoms
 PR = $\geq 50\%$ decrease in viral load and/or 50% improvement of clinical signs/symptoms



*Response rate / patient includes partial response (PR) or complete response (CR) by 6 weeks post-posoleucel infusion; [†]58/59 patients were evaluable for response rate; 1 patient with HHV-6 was not evaluable for response rate; [‡]11/11 patients had a response to ≥ 1 virus(es) and 19 of 23 viruses across the 11 patients responded to posoleucel.

1. Tzannou I, et al. *J Clin Oncol* 2017;35:3547-57; 2. Tzannou I, et al. *ASH* 2020. Accessed January 4, 2021. <https://ash.confex.com/ash/2020/webprogram/Paper143037.html>.

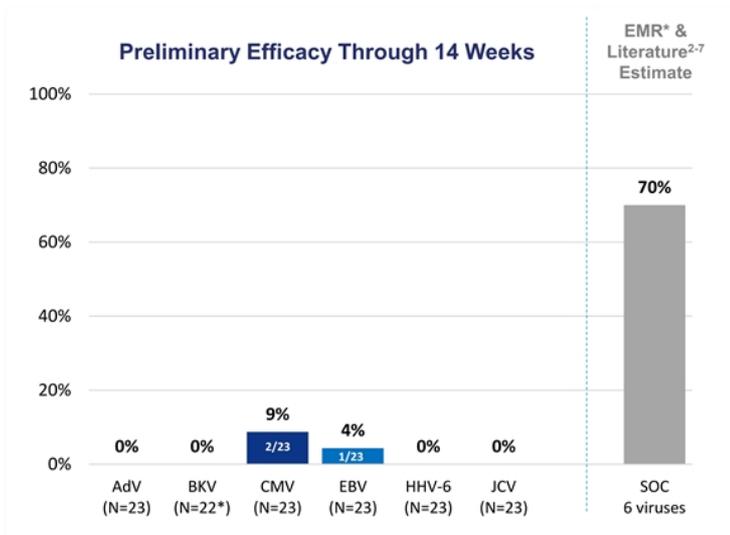
Posoleucel is Designed to Treat and Prevent Viral Infections and Diseases Until the Patient's Own Immune System Recovers¹⁻⁶



^aPost 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.

Low Rates of Clinically Significant Infection and No End-Organ Disease Observed in Ongoing Open-Label Phase 2 Prevention Study¹



Preliminary Safety

- No unexpected treatment-emergent adverse events or serious adverse events
- 6 cases (26%) of acute GVHD (grades II and III)
 - Consistent with 35-50% grade II-IV GVHD reported in high risk allo-HCTs⁸⁻¹⁰
 - No association between reported GVHD and number of HLA matches for posoleucel
 - No association between reported GVHD and number of posoleucel doses
- No cytokine release syndrome

Posoleucel achieved low rates of clinically significant infections across six devastating viruses through the Week 14 primary endpoint, and repeat dosing was generally well-tolerated[‡]

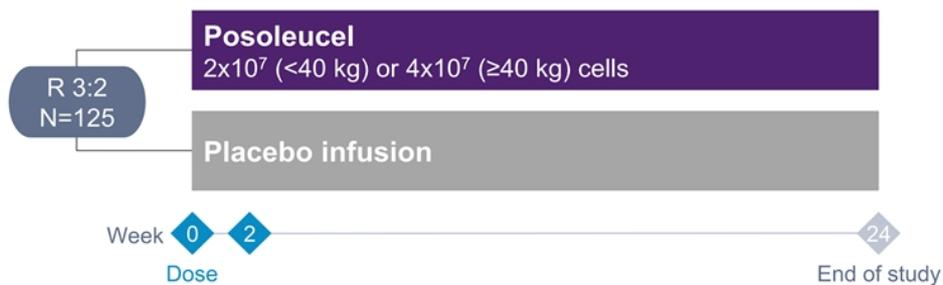


*Electronic medical records analysis of >1,400 patients identified between Jan 2018 and Apr 2021 through use of ganciclovir, valganciclovir, foscarnet, cidofovir or rituximab or ICD-10 code for viral disease where available.

[‡]Based on analysis of 23 patients who received at least one dose of posoleucel in the ongoing study, including those who completed, discontinued or are continuing posoleucel.

1. Dadwal S et al. Abstract 1760. Presented at ASH 2021; 2. Siade et al. *Transpl Infect Dis*. 2017; 3. Mohly et al. *British Journal of Haematology* 2019; 4. Salamonowicz-Bodzioch et al. *Ann Hematol*. 2021; 5. Mojtaba et al. *Biol Blood Marrow Transplant*. 2019; 6. El-Zimally et al. *Blood* 2014; 7. Gargiulo et al. *eCancer* 2014; 8. Malki et al. *Blood Adv*. 2021; 9. Saliba RM, et al. Abstract 31. Presented at: TCT 2020; 10. Chen et al., *Bone Marrow Transplant*. 2017.

Registrational Trial for the Treatment of Virus-Associated Hemorrhagic Cystitis is Ongoing



- Phase 3, multicenter, double-blind, placebo-controlled
- Key eligibility criteria: patients with vHC following allogeneic HCT
 - Macroscopic hematuria (Grade ≥3)
 - Viruria
 - Dysuria, lower abdominal pain and/or pain associated with spasm
- Primary endpoint: time to resolution of macroscopic hematuria through Week 24

Next Milestone: Enrollment expected to complete in 1H 2023

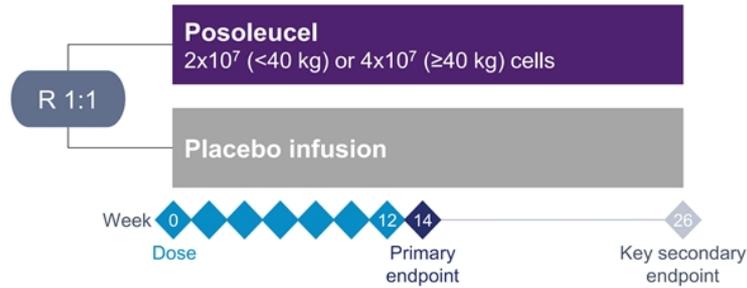
Second Phase 3 Posoleucel Trial Has Been Initiated for Adenovirus Treatment



- Phase 3, randomized, double-blind, placebo-controlled
- Key eligibility criteria: patients with adenovirus reactivation following allogeneic HCT:
 - AdV viremia $\geq 10,000$ copies/mL, OR
 - 2 consecutive, rising AdV viremia $\geq 1,000$ copies/mL and lymphopenia or T-cell depletion
- Primary endpoint: reduction in viral load
- Patients with disease progression can enter optional 24-week cross-over period after Week 4

Next Milestone: Continued enrollment in U.S. and Europe

Phase 3 Registrational Multi-Virus Prevention Trial Anticipated to Start in 1H 2022



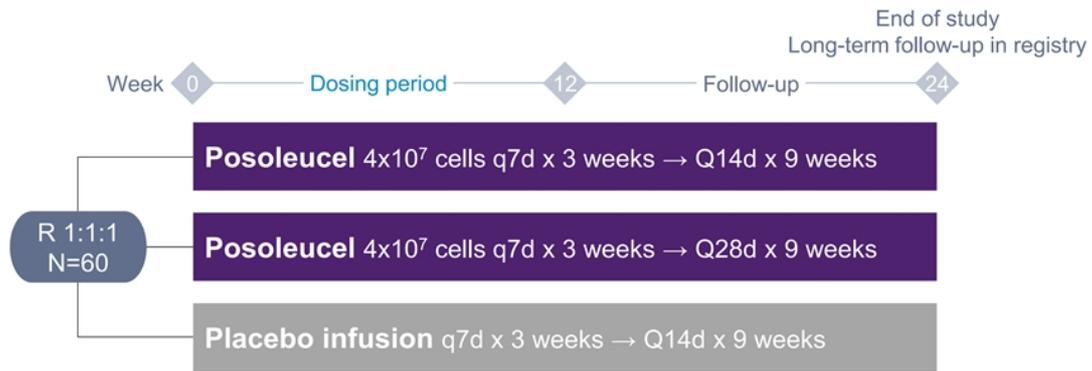
- Phase 3, multicenter, randomized, double-blind, placebo-controlled
- Key eligibility criteria: high-risk* allo-HCT recipients, including matched unrelated donor
 - Age ≥ 1 year
 - Aviremic or viremic without clinically significant disease
- Primary endpoint: reduction in clinically significant viral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

Next Milestones: Study initiation in 1H 2022; final Phase 2 data presentation in 2H 2022



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

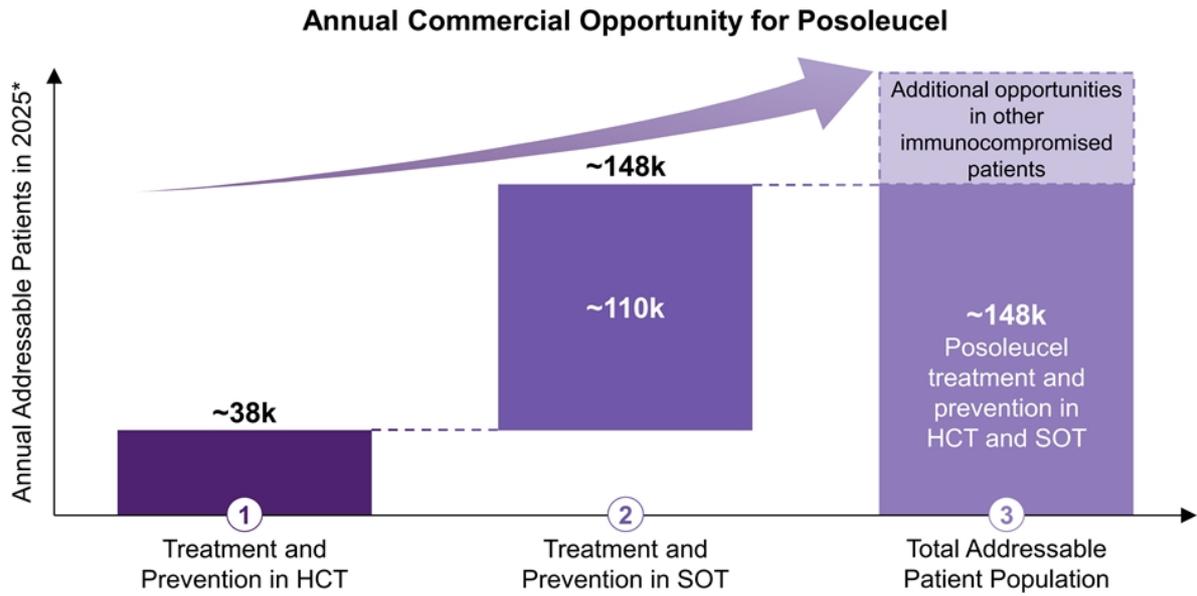
Phase 2 Trial for BK Virus Treatment in Kidney Transplant Recipients Expanding to Higher Viral Load Patients



- 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
- Primary endpoint: safety and tolerability through Week 24
- Key secondary endpoint: reduction in BK viremia

Next Milestone: Presentation of preliminary data in 1H 2022

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



*Projected addressable patient population in 2025 for posoleucel indications in target markets in NA, EU, LATAM and A/P. Source: AlloVir analysis.

Extending Our Platform to Respiratory Viruses and Hepatitis B



Candidate	Target Population	Target Indication	Preclinical	POC	Pivotal
ALVR106	Allo- / Auto-HCT	hMPV, Flu, PIV, RSV treatment			
	High-risk general population				

Next Milestone: Continued enrollment in the U.S.



Candidate	Target Population	Target Indication	Preclinical	POC	Pivotal
ALVR107	Chronic HBV	HBV cure			

Next Milestone: Initiation of POC study by end of 2022

Key Investment Highlights in 2022

Versatile engine for allogeneic, off-the-shelf, virus-specific T cell therapies targeting 12 life-threatening viruses with no or limited treatments

Lead product, posoleucel, with 3 Phase 3 studies in 3 distinct indications expected this year

Initial proof-of-concept data for posoleucel in solid organ transplant patients

Rich pipeline advancing 2 additional VST therapies

RMAT, PRIME and Orphan Drug Designations to support regulatory pathway

Experienced management team that has developed 10+ blockbuster therapies for rare diseases and viral infections

