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

J.P. Morgan Healthcare Conference January 10, 2022

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## **AlloVir By the Numbers**







\*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. <sup>‡</sup> In millions. As of December 31, 2021. CONFIDENTIAL & PROPRIETARY © 2022

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



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## AlloVir's Therapies Aim to Treat or Prevent Life-Threatening Viral Diseases For Immunocompromised Patients<sup>1-13</sup>

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





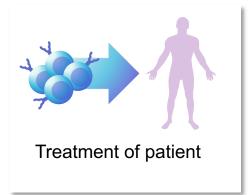
Carefully selected healthy seropositive donors



VST selective expansion using proprietary process



Cryopreservation and storage at global depots

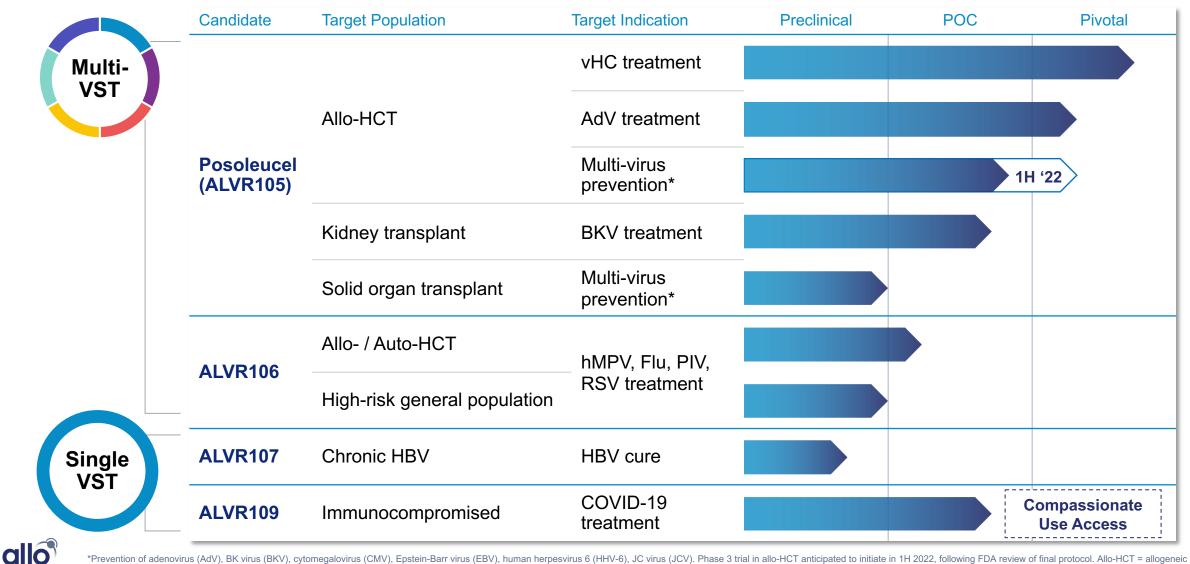


#### Key Advantages

- 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



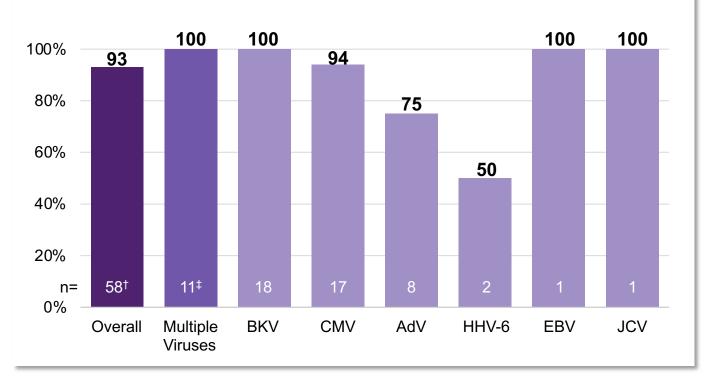
## **Our Pipeline Targets 12 Unique Viruses**



\*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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## Phase 2 CHARMS Study Demonstrated 93% Efficacy of Posoleucel in Treatment-Refractory Patients<sup>1,2</sup>



Efficacy: Posoleucel Response Rate\*

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

#### Safety: Posoleucel Well Tolerated

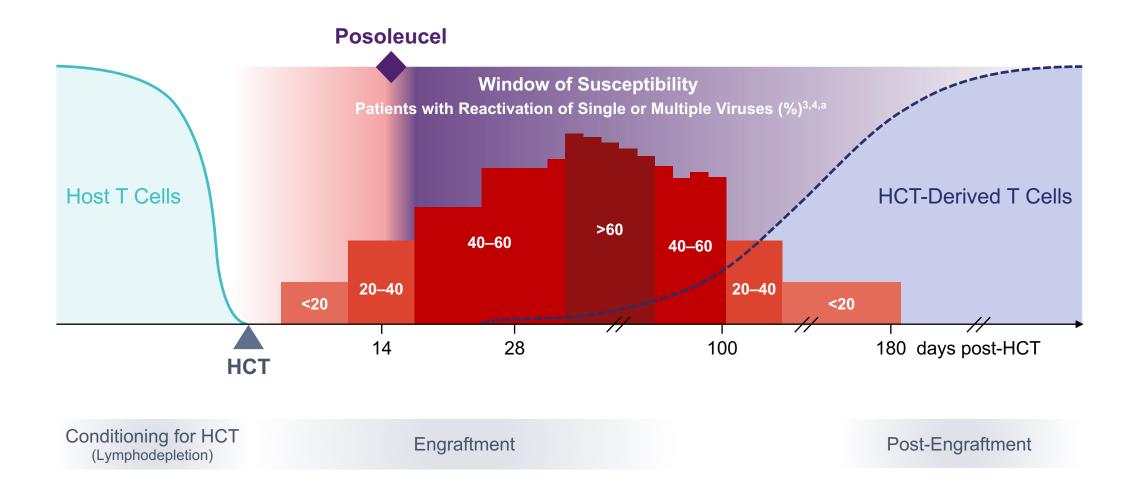
- Infusions were well tolerated
  - n=3 developed isolated fever within 24 hours of infusion; no immediate toxicities observed
- 14 cases of acute GVHD
  - n=8 had pre-existing GVHD
  - n=6 *de novo* GVHD; all had transient
    Grade I skin GVHD resolved with
    treatment
- No cytokine release syndrome



<sup>\*</sup>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.

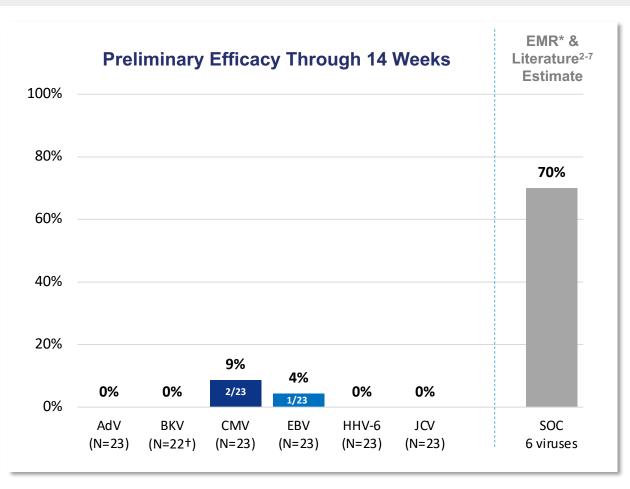
# Posoleucel is Designed to Treat and Prevent Viral Infections and Diseases Until the Patient's Own Immune System Recovers<sup>1-6</sup>





<sup>a</sup>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.

## Low Rates of Clinically Significant Infection and No End-Organ Disease Observed in Ongoing Open-Label Phase 2 Prevention Study<sup>1</sup>



#### **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-HCTs<sup>8-10</sup>
  - 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

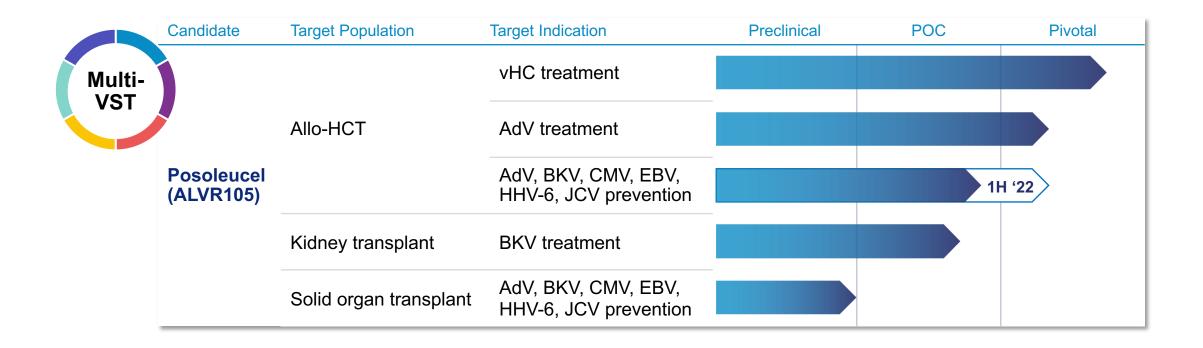
## Posoleucel achieved low rates of clinically significant infections across six devastating viruses through the Week 14 primary endpoint, and repeat dosing was generally well-tolerated<sup>‡</sup>



\*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. <sup>†</sup>One patient excluded due to BKV hemorrhagic cystitis at baseline. <sup>‡</sup>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. <sup>1</sup>. Dadwal S et al. Abstract 1760. Presented at ASH 2021; 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. Mojtaba et al. *Biol Blood Marrow Transplant.* 2019; 6. El-Zimaity 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.

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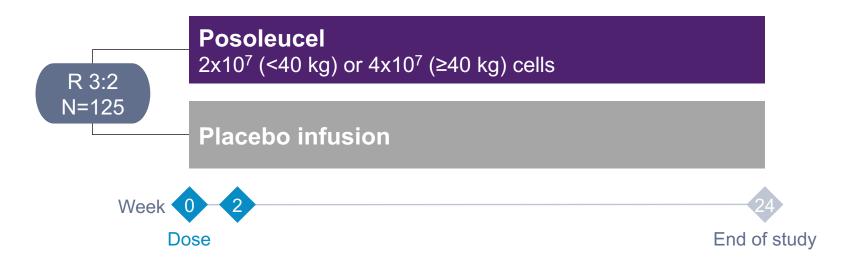
## Our Lead Candidate Posoleucel, a Multi-VST for Treatment and Prevention, Is a Pipeline in a Product



Three ongoing Phase 3 studies of posoleucel are anticipated by 1H 2022



## 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

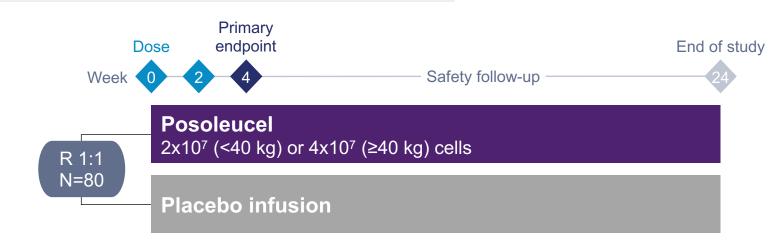
ClinicalTrials.gov NCT04390113

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- 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 ≥10,000 copies/mL, OR
  - 2 consecutive, rising AdV viremia ≥1,000 copies/mL and lymphopenia or T-cell depletion
- Primary endpoint: reduction in viral load

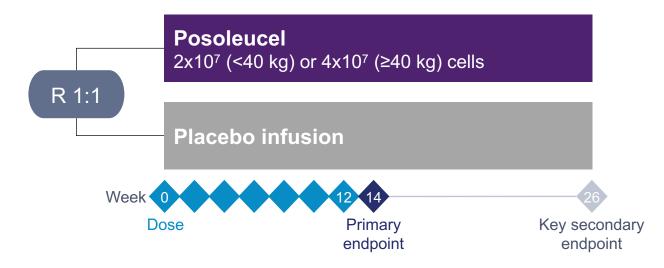
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ClinicalTrials.gov NCT05179057

• Patients with disease progression can enter optional 24-week cross-over period after Week 4

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

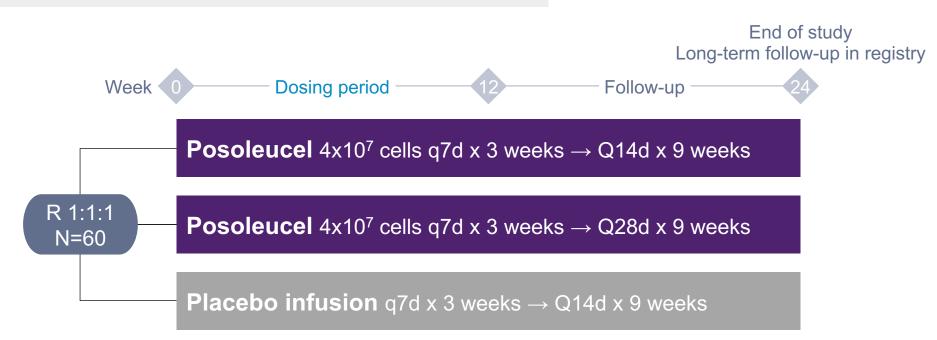
### Phase 3 Registrational Multi-Virus Prevention Trial Anticipated to **Start in 1H 2022**



- 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

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



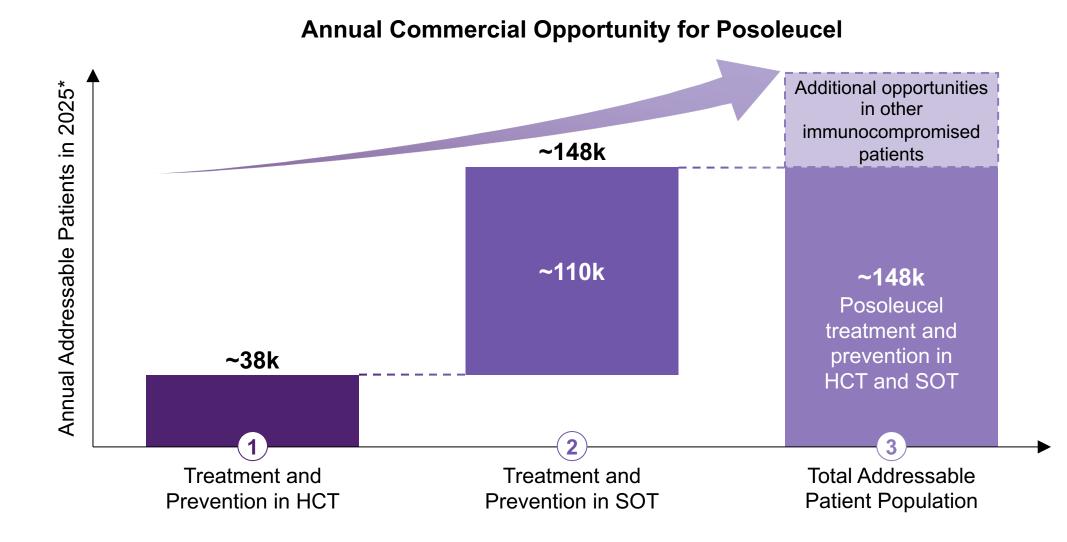
- Phase 2, multicenter, randomized, double-blind, placebo-controlled, multiple dosing interval, 2-period study
- Key eligibility criteria: adults with kidney transplant ≥28 days prior to enrollment, stratified by BK viral load
- Primary endpoint: safety and tolerability through Week 24
- Key secondary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

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ClinicalTrials.gov NCT04605484

#### Next Milestone: Presentation of preliminary data in 1H 2022

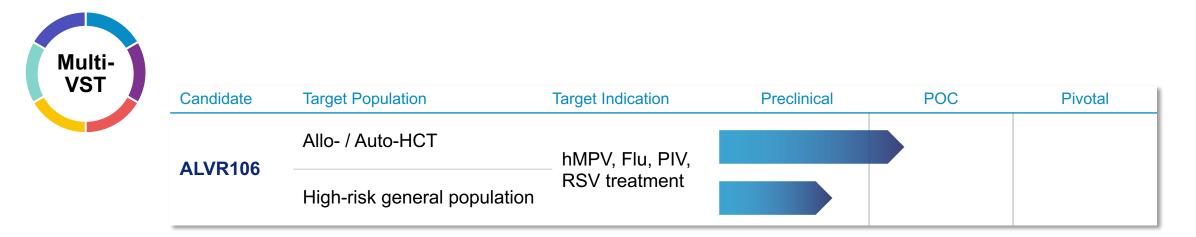
### Posoleucel: Large Addressable Patient Population for the Treatment and Prevention of Devastating Viral Diseases



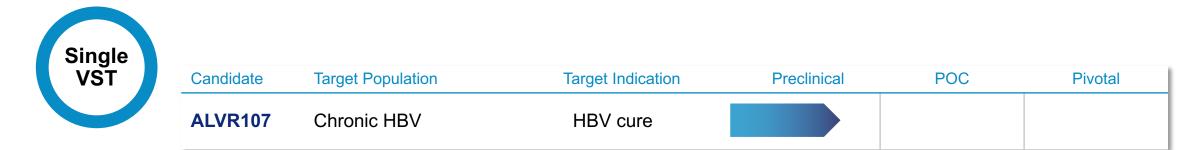
Projected addressable patient population in 2025 for posoleucel indications in target markets in NA, EU, LATAM and A/P. Source: AlloVir analysis.

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## **Extending Our Platform to Respiratory Viruses and Hepatitis B**



#### Next Milestone: Continued enrollment in the U.S.



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

