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

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

Platform with **>275** patients treated and promising data generated

With **93%** response rate, **Viralym-M** received **RMAT & PRIME** from FDA and EMA

**Catalyst rich** development program with up to **9 pivotal or POC trials**

**Large Global Market Opportunity** for **Viralym-M** alone

**Manufacturing expertise** leading to **efficiencies of scale**

**Robust IP** and **patent portfolio** covering both products and processes

**Strong** existing **investor base**

**Experienced & proven** developmental, clinical, manufacturing and commercial **leadership team**

RMAT: Regenerative medicine advanced therapy; PRIME: PRIority MEdicine; POC: proof-of-concept

# Led by an Experienced Management Team with a Strong Operating and Scientific Foundation

## Leadership Team

**David Hallal**
*Chief Executive Officer*
CEO of ElevateBio
Former CEO Alexion
Amgen

elevatebio · ALEXION · AMGEN

**Vikas Sinha, MBA**
*President & Chief Financial Officer*
CFO of ElevateBio
Former CFO Alexion
Bayer

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**Ann Leen, Ph.D.**
*Chief Scientific Officer*
Co-Founder AlloVir
Professor, BCM CAGT

Baylor College of Medicine

**Agustin Melian, M.D.**
*Chief Medical Officer*
Former SVP Alexion
Merck

ALEXION · MERCK

**Ercem Atillasoy, M.D.**
*Chief Regulatory & Safety Officer*
Former VP Global Regulatory
Affairs & Clinical Safety, Merck

MERCK · NOVARTIS

**Jeroen van Beek, Ph.D.**
*Chief Commercial Officer*
Former CCO Tricida
Alexion, Pfizer

TRICIDA · ALEXION · Pfizer

**Dana Alexander**
*SVP of CMC Operations*
Former Head of Viral
Vectors Brammer Bio

brammer bio · ThermoFisher SCIENTIFIC

**Edward Miller, J.D.**
*General Counsel*
Former SVP Alexion
Boehringer Ingelheim

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allo vir

# High Risk Populations with T Cell Deficiencies are Vulnerable to Life-Threatening Viral Diseases Despite Current Treatment Options

## Viruses with No / Limited Treatments

- BK virus[1]
- Cytomegalovirus[2]
- Adenovirus[3]
- Epstein-Bar virus[4]
- Human Herpesvirus-6[5]
- JC Virus[6]
- Respiratory Syncytial Virus[7]
- Parainfluenza Virus[7]
- Human Metapneumovirus[8]
- Influenza Virus[7]
- SARS-CoV-2[8]
- Hepatitis B Virus[9]
- Human Herpesvirus-8[10]

## Uncontrolled Viral Diseases Cause End-Organ Damage and Mortality[1-3,10-13]

**Bladder**
Severe hemorrhagic cystitis
Urinary obstruction
Cystectomy

**Brain**
Seizure
Severe encephalitis
Memory defect
PML

**Kidneys**
Nephritis
Acute/chronic renal failure
End stage renal disease

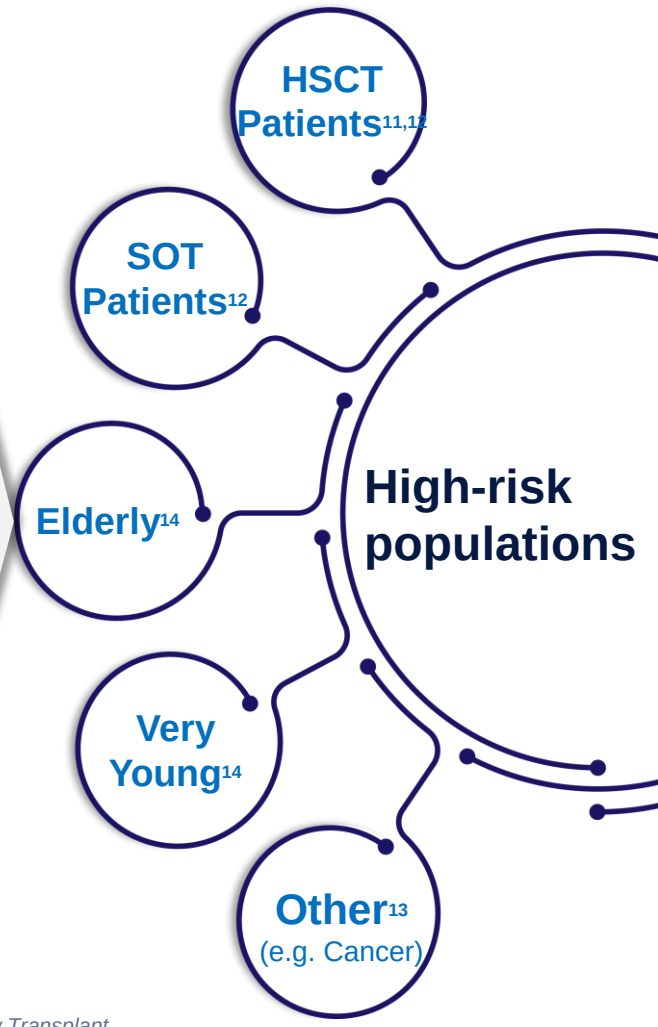
**Eyes**
Retinitis
Blindness

**Lungs**
Pneumonia
Bronchitis
Respiratory failure

**Liver**
Chronic hepatitis
Liver cirrhosis
HCC

**Small/Large Intestine**
Colitis
Ulceration / perforation
Intestinal bleeding

**Malignancy**
Kaposi sarcoma
Primary Effusion Lymphoma




PML: Progressive multifocal leukoencephalopathy; HCC: hepatocellular carcinoma

**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/s4109-018-0421-0. **4.** Leen AM, et al. *Blood.* 2009;114(19):4283-4292. 5. Perruccio K, et al. *Biol Blood Marrow Transplant.* 2018;24:2649-2557. **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.** Luppi M, et al. *New Engl J Med.* 2000;343:1378-1385. **11.** Kedia S, et al. *J Stem Cell Res Ther.* 2013;doi:10.4172/2157-7633.S3-002. 1**2.** Ison MG, Hirsch HH. *Clin Microbiol Rev.* 2019;32(4):1-33. **13.** Jose RJ, et al. *Medicine.* doi:10.1016/j.mpmed.2020.03.006. **14.** Simon AK, Hollander GA, McMichael A. *Proc Biol Sci*. 2015;282(1821):20143085.

# AlloVir Has Deep Pipeline of 5 Allogeneic, Off-the-Shelf VST Therapies Targeting 12 Viruses

| THERAPY CANDIDATE | TARGET INDICATION | TARGET POPULATION | PRECLINICAL | POC TRIAL (Phase 1b/2) | PIVOTAL TRIAL (Phase 3) |
|---|---|---|---|---|---|
| **Viralym-M (ALVR105)** Multi-VST | Treatment of Virus-Associated Hemorrhagic Cystitis | Allo-HSCT | | | |
| | Treatment of CMV | | | | |
| | Treatment of AdV | | | | |
| | Prevention of BKV, CMV, AdV, EBV, HHV-6 and JCV | | | | |
| | Treatment of BKV | Kidney Transplant | | | |
| | Treatment of CMV | Solid Organ Transplant | | | |
| **ALVR106** Multi-VST | Treatment of RSV, Influenza, PIV, and hMPV | Allo- / Auto-HSCT | | | |
| | | High-risk General Population | | | |
| **ALVR109** Single-VST | Treatment of COVID-19 | High-risk General Population | | | |
| **ALVR107** Single-VST | Treatment of HBV | Patients with Chronic HBV | | | |
| **ALVR108** Single-VST | Treatment of HHV-8 | Patients with KS, MCD or PEL | | | |

POC: Proof-of-concept; Allo-HSCT: Allogeneic HSCT; Auto-HSCT: Autologous HSCT; KT: Kidney Transplant; SOT: Solid Organ Transplant; KS: Kaposi Sarcoma; MCD: Multicentric Castleman Disease; PEL: Primary Effusion Lymphoma

# Key Investment Highlights

**INNOVATIVE ENGINE** for allogeneic, off-the-shelf, virus-specific T-cell immunotherapies

**5 VST THERAPY CANDIDATES** for **12** devastating, life-threatening viruses

**Viralym-M**: **LARGE MARKET OPPORTUNITY** in **RMAT / PRIME** Designations alone

**Viralym-M**: **3 PIVOTAL TRIALS** in 2020/2021

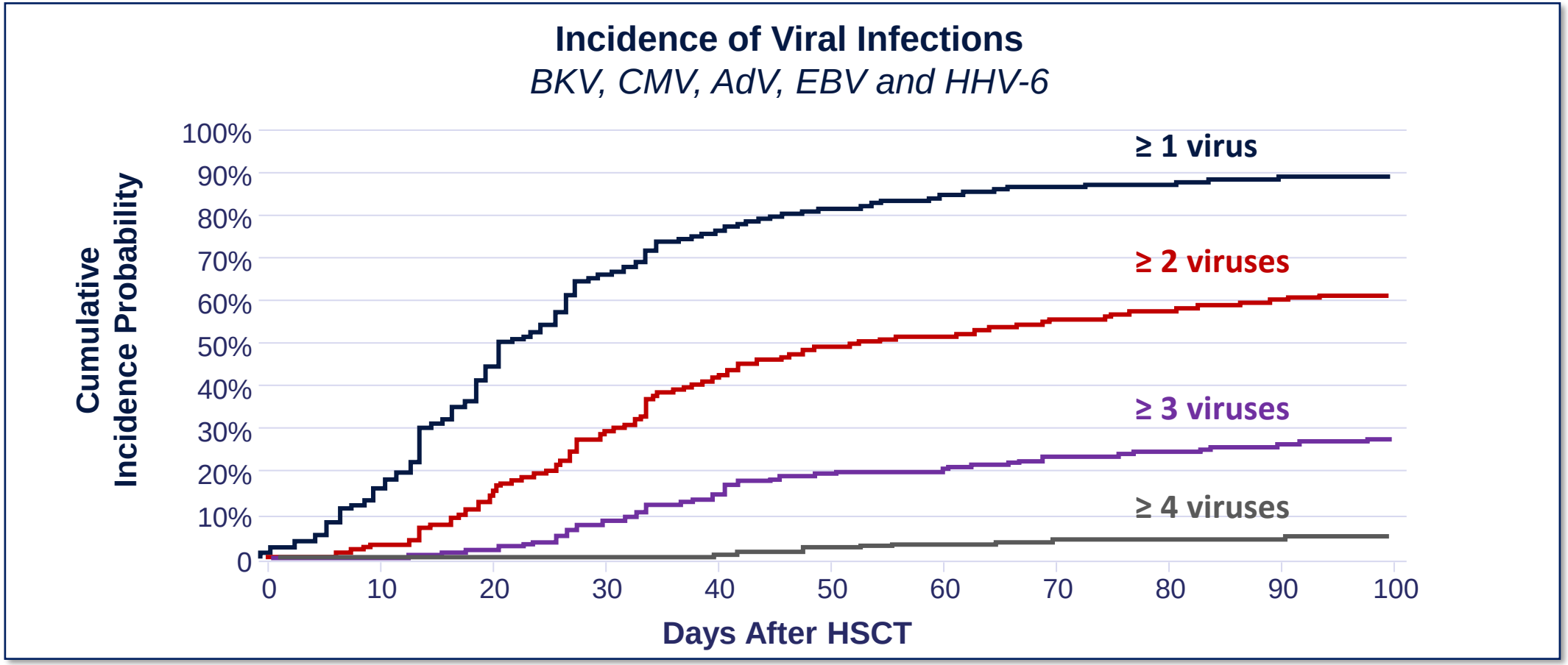
**Viralym-M**: POC trials for **PREVENTION** of all 5 viruses and **SOT** with initial data in 2021

**ALVR106 (MULTI-RESPIRATORY VSTs):** POC trial initiation in 2021

**ALVR109 (SARS-CoV-2 VSTs): ACCELERATED DEVELOPMENT** for treatment of COVID-19 with POC trial initiation in 2020 and initial data in 2021

# Transplant Patients and Viral Diseases

# Nearly Two-Thirds of Allogeneic HSCT Recipients Have More Than One dsDNA Viral Infection




**A 37% Increase of Non-Relapse Mortality for Every Log Increase in Viral Load from Day 1-100 in Allogeneic HSCT Patients**

CMV: Cytomegalovirus; AdV: Adenovirus; EBV: Epstein-Barr virus; HHV6: human herpesvirus 6.
Hill et al, *Blood* 2017.

# Virus-Associated Hemorrhagic Cystitis in HSCT: A Devastating Disease with No Approved or Effective Treatment Options

## HC, a common manifestation in HSCT, caused by BKV, AdV and/or CMV

| HC Results in Severe Morbidity & Mortality[1-7] | | No Approved or Effective Therapies[1-7] |
|---|---|---|
| **Severe bleeding due to hematuria** |  | RBC or platelet transfusions<br>Bladder arteriole embolization and/or cystectomy |
| **Severe, prolonged and intractable pain** |  | Narcotics |
| **Life-disturbing urinary symptoms** |  | Continuous bladder irrigation |
| **Kidney dysfunction / failure** |  | Dialysis |
| **Increased mortality*** |  | |

*Treatment related mortality

**1.** Cesaro S, et al. *J Antimicrob Chemother.* 2018;73:12–21. **2.** Garguilo et al, *ecancer.* 2014; 8:420 doi: 10.3332/ecancer.2014.420. **3.** Silva LdeP, et al. *Haematologica.* 2009;95(7):1183-1190. **4.** Kloos RQ, et al. *Biol Blood Marrow Transplant.* 2013;19(8):1263-1266. **5.** Type B Briefing Package. **6.** Laskin BL, et al. *Clin Infect Dis.* 2019. doi: 10.1093/cid/ciz1194; **7.** Gilis L, et al. *Bone Marrow Transplantation.* 2014;49: 664–670.

# Cytomegalovirus and Adenovirus in HSCT: Cause Severe and Life-Threatening Consequences

## CMV

- Affects 65% of allogeneic HSCT patients[1]
- Potentially life-threatening consequences[2]
  - Pneumonia
  - Colitis
  - Retinitis
  - Encephalitis
  - Multi-organ failure/Death
- No FDA- or EMA-approved anti-viral agents[6]
- Off-label antiviral use associated with severe toxicities, including myelosuppression and nephrotoxicity
- Discontinuation of letermovir increased CMV infection (~18%) >100 days post HSCT[3]

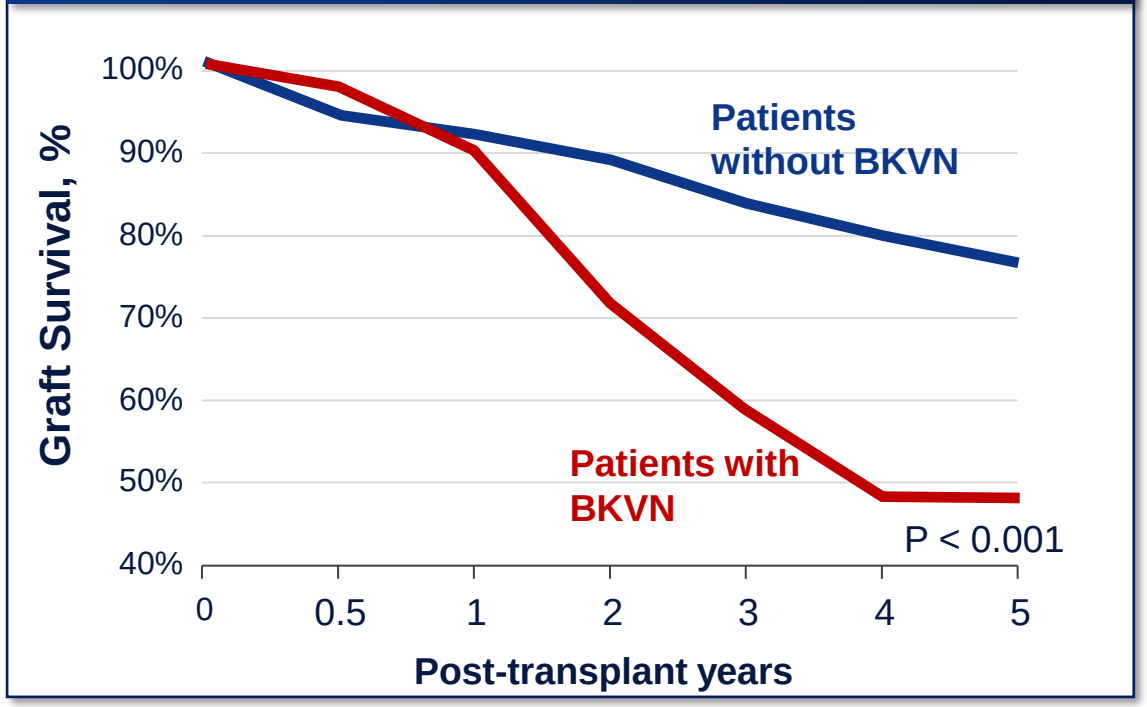
## AdV

- Occurs in 32% of pediatric and 6% of adult allogeneic HSCT patients[4]
- Potentially life-threatening consequences[5]
  - Pneumonia
  - Hemorrhagic enteritis or cystitis
  - Hepatitis
  - Multi-organ failure/Death
- No FDA-or EMA approved treatments
- Off-label antiviral use agent has demonstrated limited efficacy and severe toxicities including nephrotoxicity

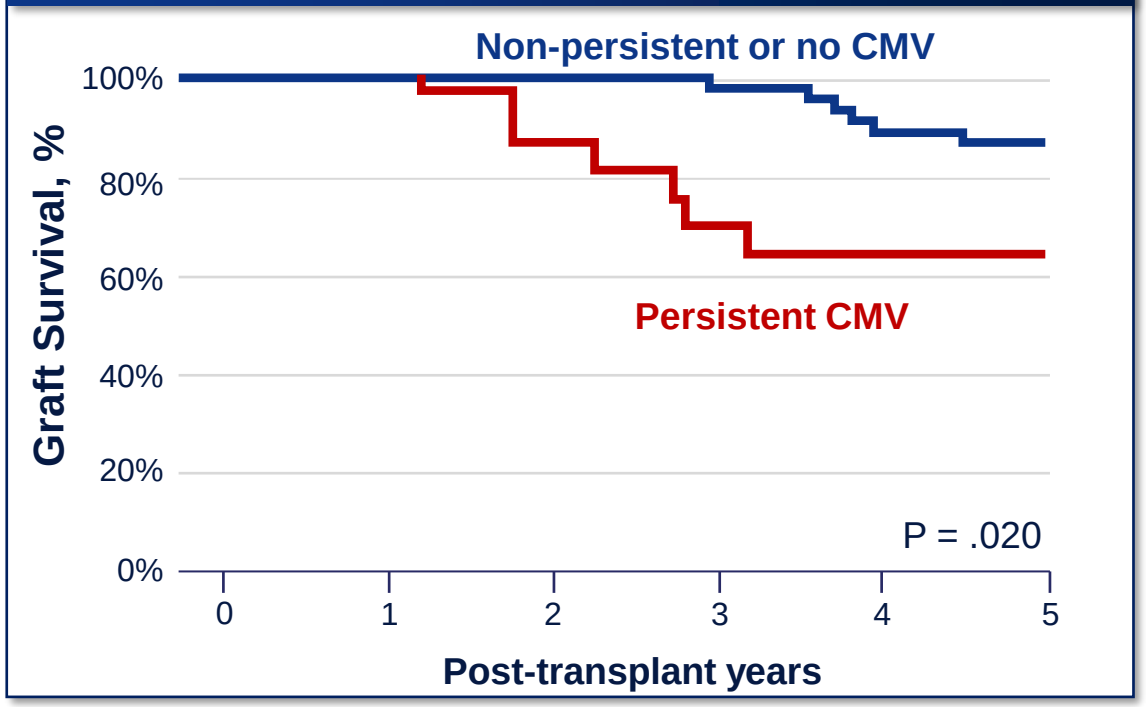
**1.** Hill J, et al. *Blood* 2017; **2.** Ljungman P, et al. *Clin Infect Dis.* 2017; **3.** Marty F, et al. *NEJM* 2017; **4.** Sedláček P, et al. *Biol Blood Marrow Transplant* 2018; **5.** Lion et al. *Clin Microbiol Rev* 2014 **6**. other than for CMV retinitis

# BKV in Kidney Transplant & CMV in SOT Patients: Lead to Decreased Graft Survival Despite Standard of Care[1,2]

## Worse Graft Survival in KT Patients with BKV Nephropathy[1]




## Worse Graft Survival in SOT Patients with Persistent CMV Infection[2]




BKVN: BKV Nephropathy

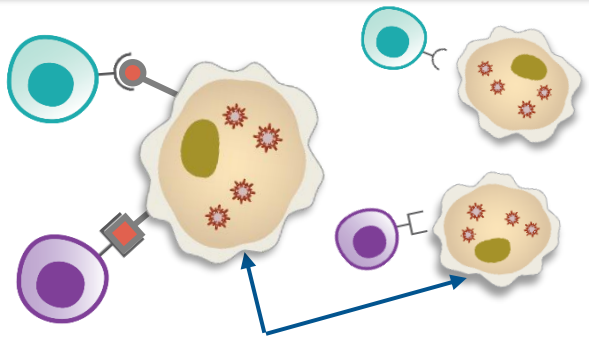
**1.** Vasudev B, et al. *Kidney International* 2005; **2.** Legendre C and Pascual C. *CID* 2008

# Our Solution

# Allogeneic, Off-the-Shelf Virus-Specific T-Cells

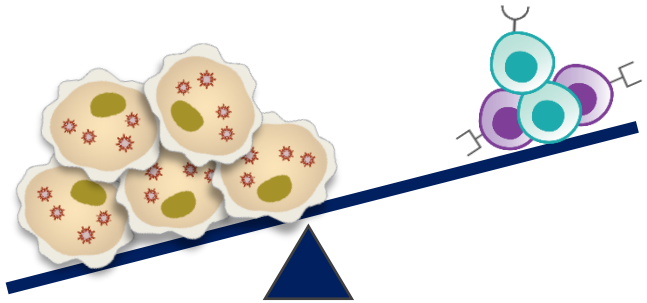
# Our Approach Utilizes the Adoptive Transfer of Off-the-Shelf VSTs to Restore Virus-specific Immunity[1-6]

**Patients with T-cell Deficiency are at High Risk for Devastating Viral Infections**

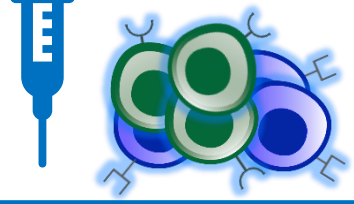



Treated with Current Care Options

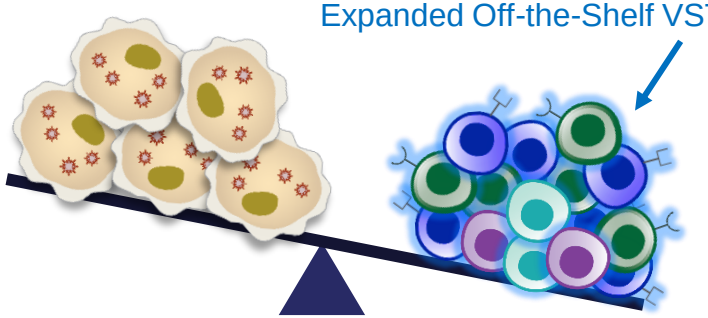
**Deficient T-cell Immunity Fails to Control Viral Infections, Resulting in Devastating Consequences**



**Treated with Off-the-Shelf VSTs**



**Restored T-cell Immunity with Expanded Off-the-Shelf VSTs Controls Viral Infections**




CD4+ T cells in patients | CD8+ T cells in patients | CD4+ Off-the-Shelf VSTs | CD8+ Off-the-Shelf VSTs

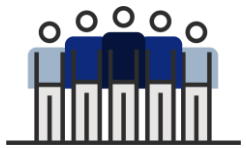
**1.** Swain, S., et al. *Nat Rev Immunol* 2012.; **2.** Muraro E, et al. *Front. Immunol.* 2017; **3.** Rosendahl HS et al. *Front Immunol.* 2014. **4.** Tzannou, *JCO* 2017; **5.** Vasileiou S et al. *Haematol* 2019. **6.** Type B Meeting Briefing Package.

# Our Patented, Highly Efficient and Industrialized Platform Provides Key Advantages[1-5]

## Step 1
### VST Profiling / Antigen Selection & Donor Selection (Cytokin™*)

VST Profiling & Antigen Selection

**Cytokin™***



Carefully Selected Healthy Seropositive Donors

Proprietary VST profiling and antigen selection* process

CytokinTM* ensures broad patient coverage with a targeted number of carefully screened donor pool

## Step 2
### Rapid and Scalable Off-the-Shelf VST Manufacturing (14 ± 2 Days in Viralym-M)

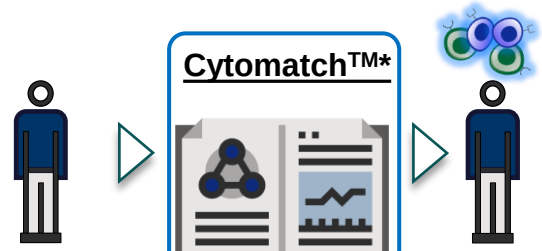
Selected Antigens + PBMCs from Donors → Selective Expansion of VSTs Using Proprietary Process → Mini-Banks of Cryopreserved VSTs

Patented expansion process designed to prevent antigen competition and preserve polyclonality of VSTs

One manufacturing run from a single donor can generate hundreds of doses of VSTs

VSTs have long-term stability and are available on demand as off-the-shelf therapy

## Step 3
### Cytomatch™* and Immediate Access to Our Allogeneic VST Therapies




Patient with Viral Infection → Cytomatch™* → Treatment of Patient

CytomatchTM* to rapidly select best-fit VSTs for patients

Immediate availability of off-the-shelf VSTs

Mini-banks ensure >95% patient coverage

*Patent pending
PBMCs: Peripheral Blood Mononuclear Cells

**1.** Tzannou I, et al. *Blood Adv.* 2019;3(17):2571–2580. **2.** Tzannou I, et al. *J Clin Oncol.* 2017 Nov 1;35(31):3547-3557. **3.** Vasileiou S, et al. *Haematologica.* 2019 Apr. **4.** Saglio et al. *Cytotherapy.* 2014 February; 16(2): 149–159. **5.** Type B Briefing Package.

# Viralym-M (ALVR105)

## The Potential to Transform the Lives of Transplant Patients by Dramatically Improving or Preventing Morbidity and Mortality

# Viralym-M: Our VST Therapy Designed to Target Viral Diseases That Result in Significant Morbidity and Mortality Post Allogeneic HSCT

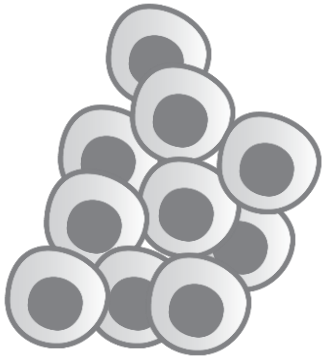
**12 Selected Antigens for Viralym-M**

- BKV: LT, VP1
- CMV: IE1, pp65
- AdV: Hexon, Penton
- EBV: EBNA1, LMP2, BZLF1
- HHV-6: U11, U14, U90

**Antigens Selected by Proprietary Virus Profiling and Antigen Selection Process**

+

**PBMCs**



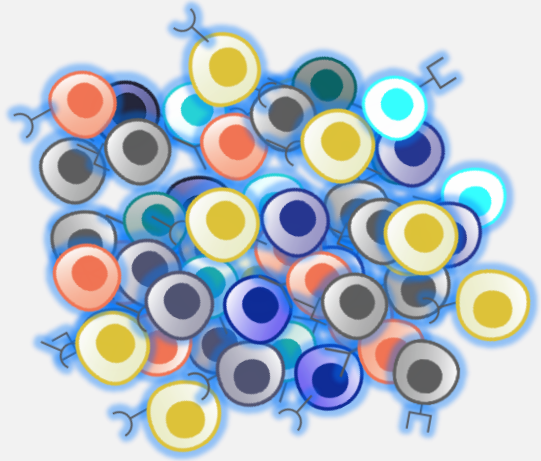
**PBMCs from Donors Identified by Proprietary Process**

**Stimulation & Expansion**

**Stimulation and Expansion of Polyclonal VSTs in One-step, High-yield Process**

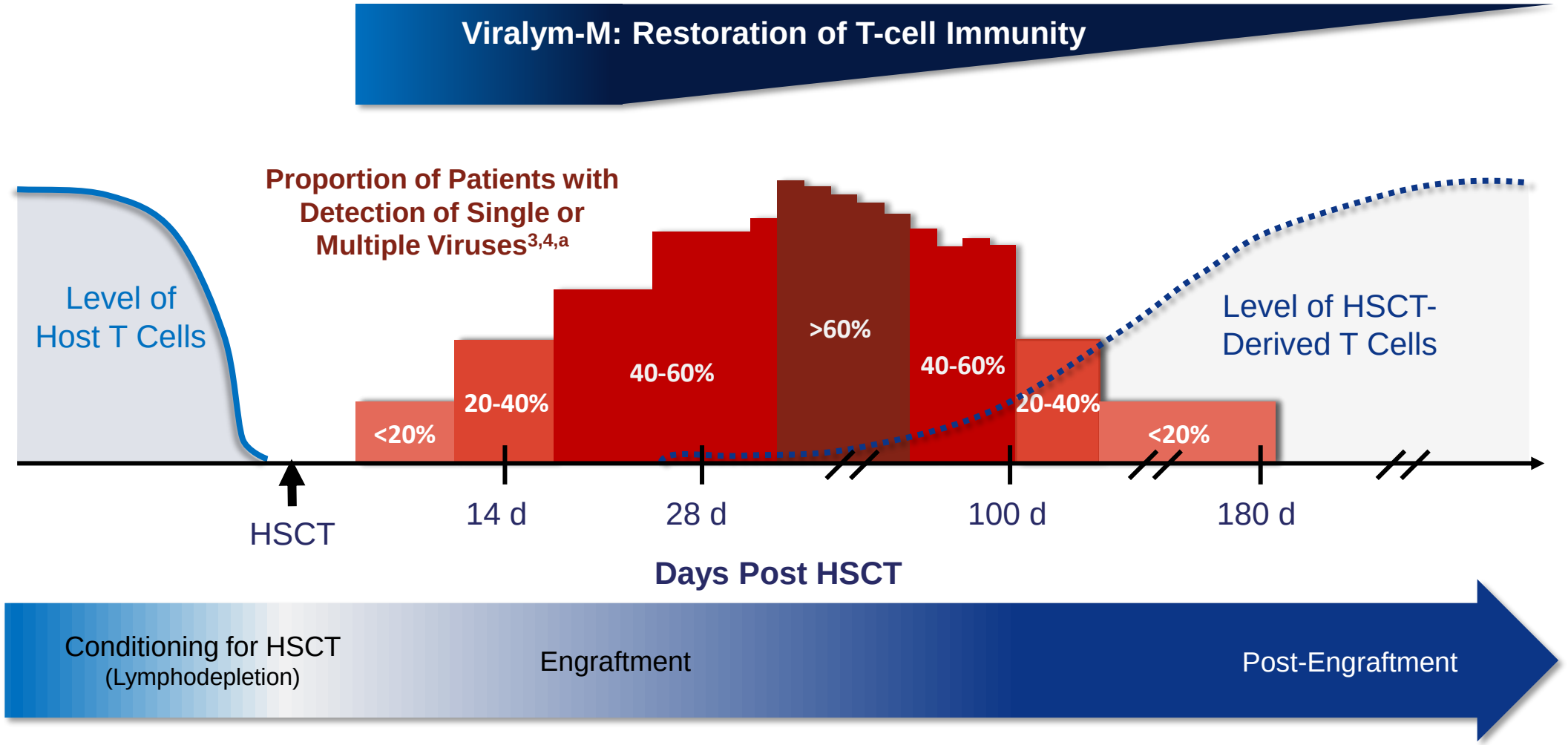
**Viralym-M (ALVR105)**

Multi-VST targeting BKV, CMV, AdV, EBV, and HHV-6



PBMCs: Peripheral Blood Mononuclear Cells

# Viralym-M 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, et al., as Hill et al. only measured out to 100 days.

**1.** Kedia et al., *J Stem Cell Res Ther* 2013. **2.** Ison, Hirsch. *Clin Microbiol Rev.* 2019. **3.** Hill et al, *Blood* 2017. **4.** Huang et al, *Biol Blood Marrow Trans* 2017. **5.** Stern L et al. *Front Immunol.* 2018;9:1-18. **6.** Hill CID 2018.

# Viralym-M Phase 2 Proof-of-Concept Study, CHARMS, Generated Promising Preliminary Disease Outcome and Safety Data

Phase 2, proof-of-concept, open label study to assess the safety and clinical effects of Viralym-M in allogeneic HSCT recipients with ≥1 treatment-refractory Infections

## Phase 2 POC CHARMS Trial Design (N=59*)

**Study endpoints**

- Safety
- Clinical endpoints
  - Viral loads
  - Clinical & virologic responses

**Population**

- Refractory BKV, CMV, AdV, EBV, HHV-6 and/or JCV
  - Failure of antiviral therapy; OR
  - Unable to tolerate standard antivirals

Follow-up

Viralym-M (ALVR105): 2 x $10^7$ VSTs/$m^2$

- If partial response, patients may receive up to 4 additional doses after 4 weeks at 2-week intervals

Day1
Single infusion

6 weeks
Assessment of clinical endpoints

12 months
End of study

*The CHARMS trial treated 58 unique patients. One patient was counted twice: enrolled twice, treated first for AdV and then for JCV. One patient with HHV-6 was not evaluable for response rate
GVHD: graft vs host disease.
**1.** Tzannou, JCO 2017; **2.** Type B Meeting Briefing Package.

# Viralym-M was Generally Well Tolerated in CHARMS Trial (N=59*)[1-2]

**Infusions were well tolerated**

- Three patients developed an isolated fever within 24 hours of infusion, no immediate toxicities were observed

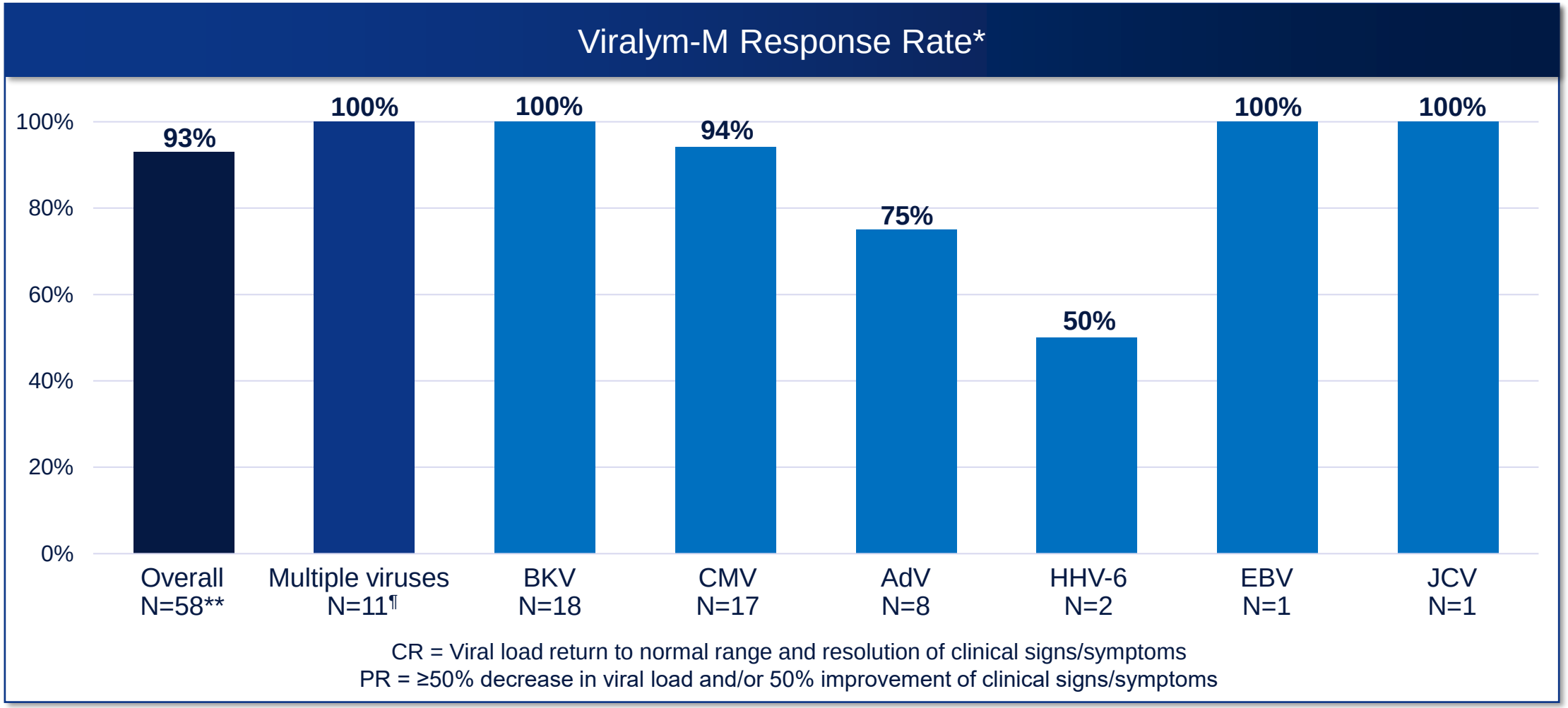
**There were 14 cases of acute GVHD**

- 8 patients with pre-existing GVHD
- 6 patients with *de novo* GVHD; All had transient Grade I skin GVHD resolved with treatment

- **No patients developed cytokine release syndrome**

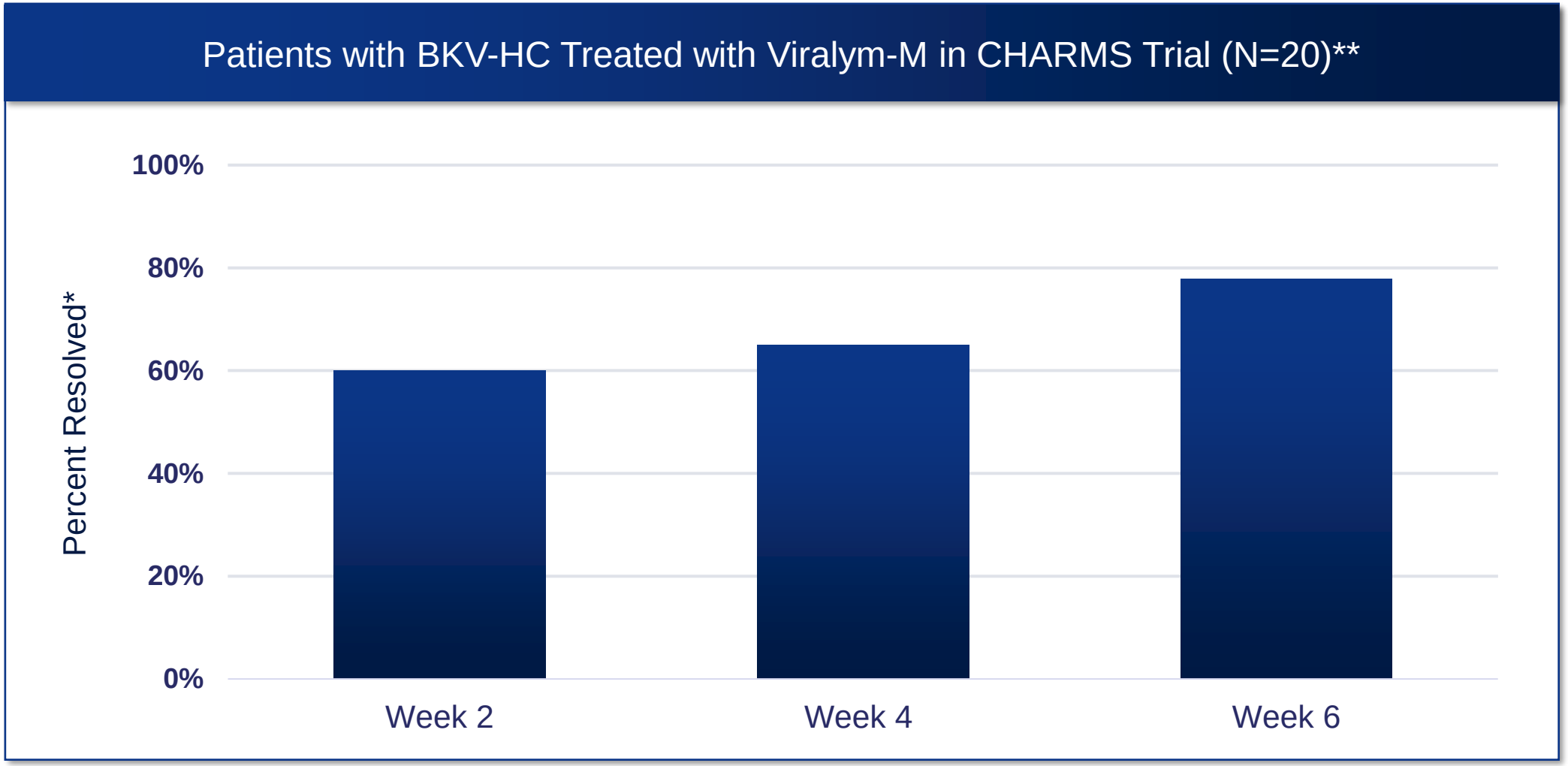
*The CHARMS study treated 59 patients (one patient was counted twice: enrolled twice, treated first for AdV and then for JCV)
GI: gastrointestinal; GVHD: graft versus host disease
**1.** Tzannou, JCO 2017; **2.** Type B Meeting Briefing Package.

# 93% of Patients Achieved a Clinical Response by 6 Weeks Post Viralym-M Treatment[1,2]



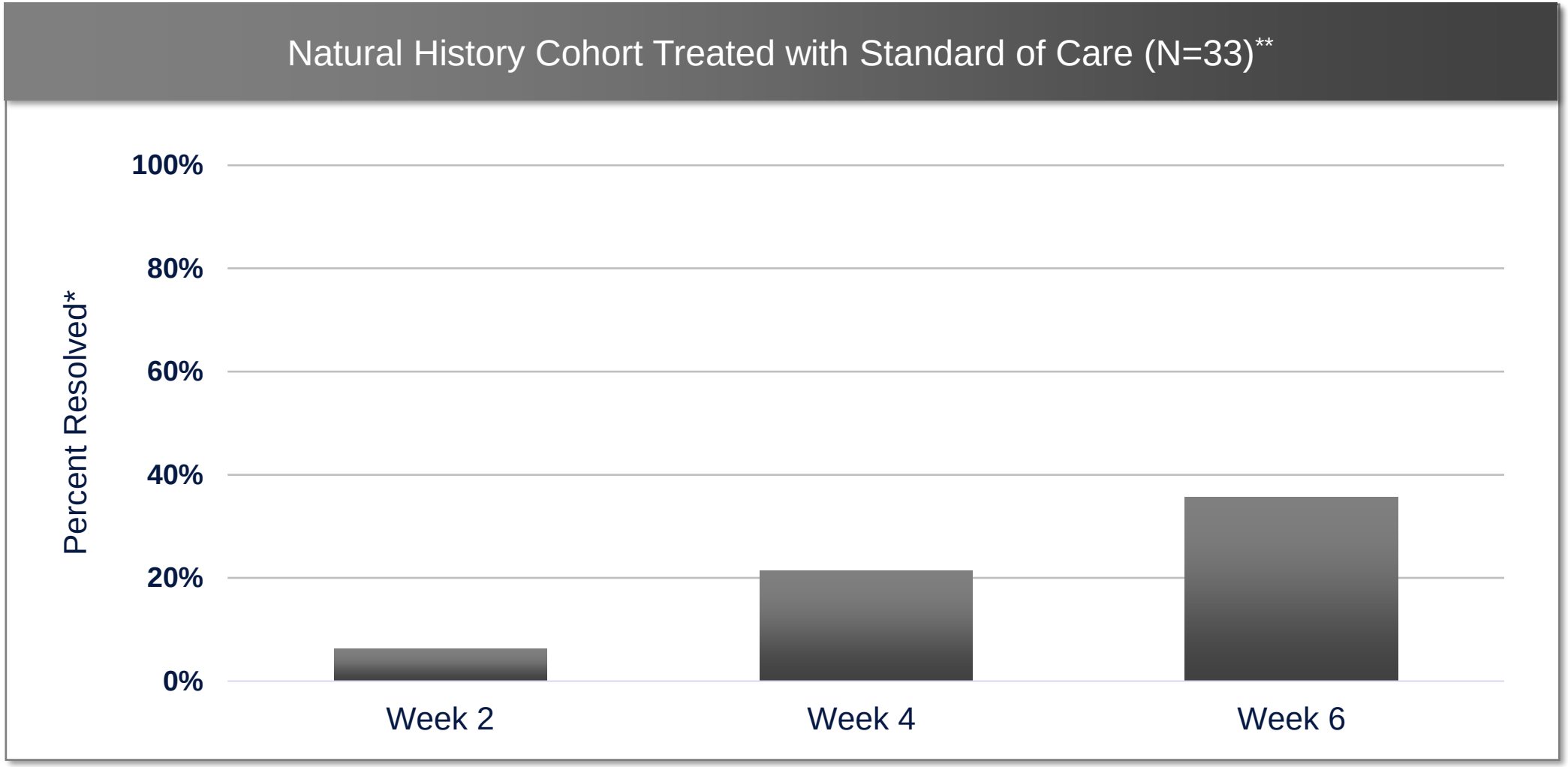

*Response rate / patient includes PR or CR by 6 weeks post Viralym-M infusion
**58/59 patients were evaluable for response rate. One patient with HHV-6 was not evaluable for response rate.
¶ 11/11 patients had a response to ≥1 virus(es) and 19 of 23 viruses across the 11 patients responded to Viralym-M.
**1.** Tzannou, JCO 2017; **2.** Type B Meeting Briefing Package.

# Virus-Associated Hemorrhagic Cystitis: Rapid Resolution was Achieved in Patients Treated with Viralym-M




BKV-HC: BKV-associated hemorrhagic cystitis
*Resolution of BKV-HC: Grade 1 (microscopic hematuria; minimal increase in frequency, urgency, dysuria, or nocturia; new onset of incontinence) or 0 (no symptoms)
**Based on 20 patients, including pediatric and adult patients, with data available for HC grading retrospectively assessed by 3 independent physicians using NCI CTCAE v4
Source: Type B Briefing Package

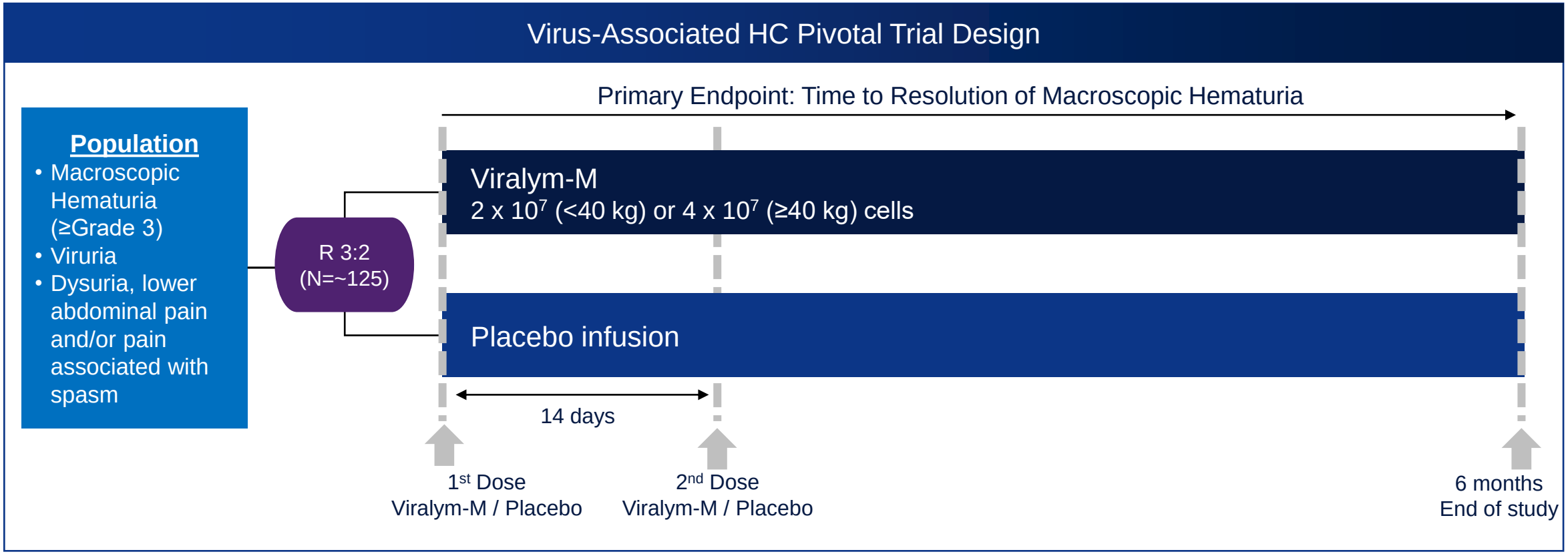
# Virus-Associated Hemorrhagic Cystitis: Prolonged Symptomatic Disease Observed in Patients Treated with SOC




BKV-HC: BKV-associated hemorrhagic cystitis; SOC: standard of care
*Resolution of BKV-HC: Grade 1 (microscopic hematuria; minimal increase in frequency, urgency, dysuria, or nocturia; new onset of incontinence) or 0 (no symptoms)
**In a retrospective study conducted at Baylor College of Medicine, out of the 33 pediatric allogeneic HSCT patients with an average of Grade 3 BK-HC receiving current standard of care, unpublished
Source: Type B Briefing Package

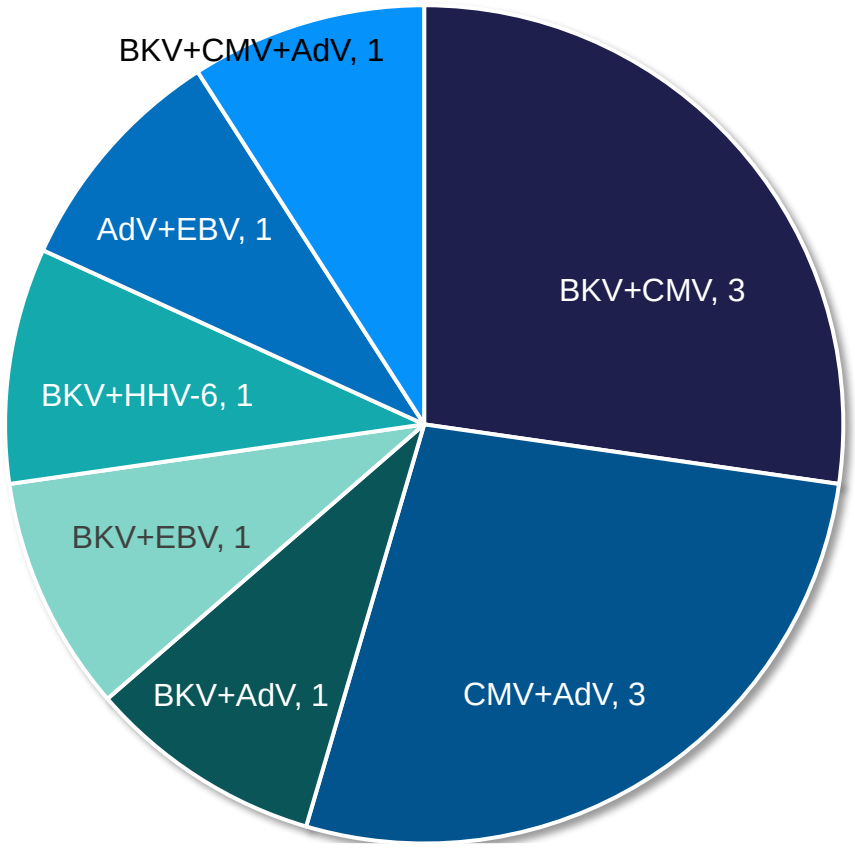
# Virus-Associated Hemorrhagic Cystitis: Viralym-M Registration Study Will Be Initiated in Q4 2020

Phase 3, multicenter, double-blind, placebo-controlled study to assess the safety and efficacy of Viralym-M compared to placebo for the treatment of patients with virus-associated hemorrhagic cystitis (HC) following allogeneic HSCT



# Multiple-viruses: Viralym-M Achieved 100% Response in Patients with ≥2 Viruses

## 11 Patients with 23 Viral Infections

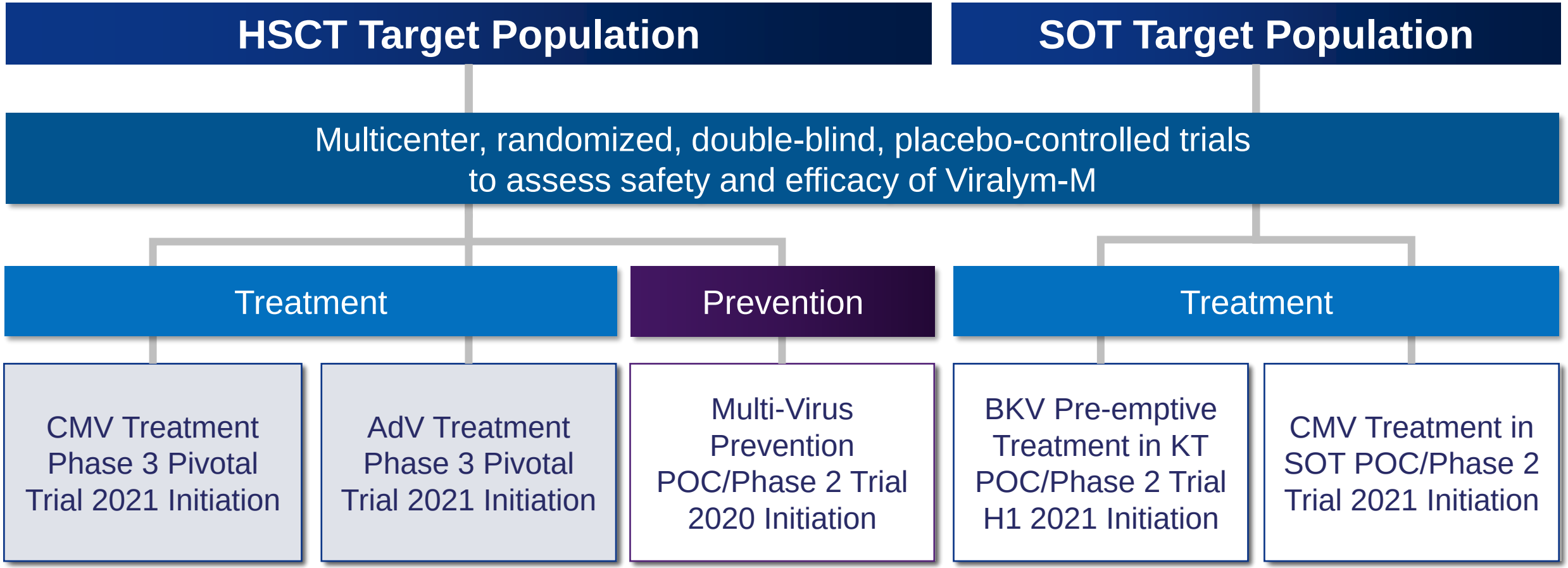



**11/11 (100%) patients** in CHARMS trial had a response to ≥1 virus(es)

- 19 of 23 viruses across the 11 patients responded to Viralym-M

**1.** Tzannou, JCO 2017; **2.** Type B Meeting Briefing Package.

# Viralym-M:
# 2 Additional Pivotal and 3 POC Trials Planned in 2020/2021




HSCT: Hematopoietic stem cell transplantation; SOT: solid organ transplant; KT: kidney transplant

# Viralym-M: Large Addressable Patient Population for the Treatment and Prevention of Devastating Viral Diseases

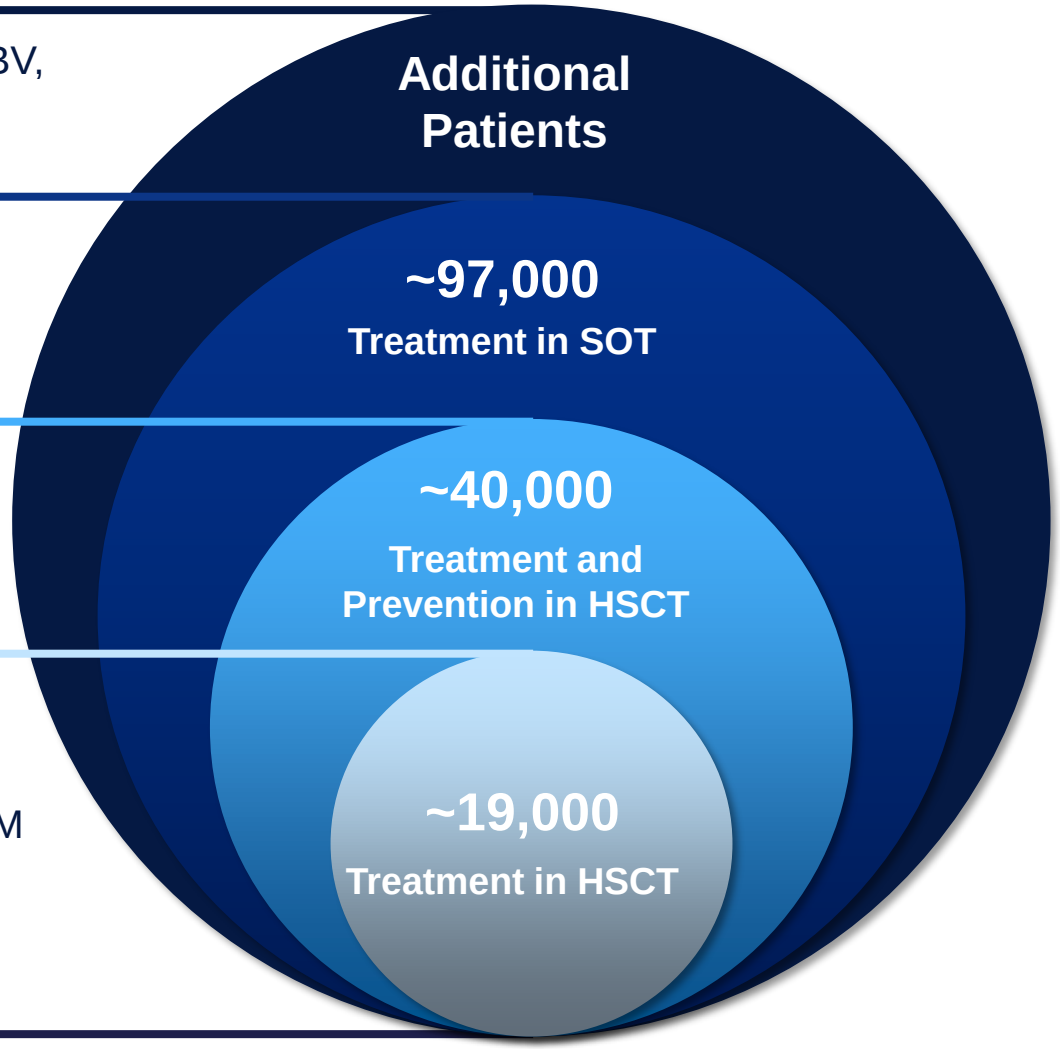
## Estimated Annual Addressable Patients in 2025

Additional opportunities with EBV, HHV-6 & JCV in transplant and immunocompromised patients

Expansion beyond HSCT patients to SOT patients

Prevention of multi-virus infections with Viralym-M will transform HSCT landscape

Projected addressable patient population in 2025 for Viralym-M indications in target markets in NA, EU, LATAM and A/P



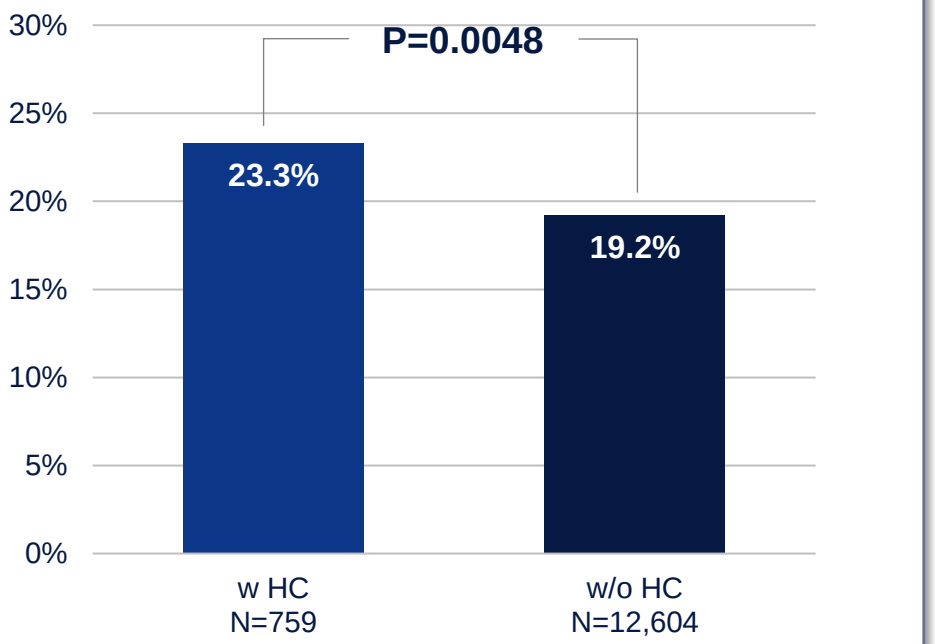

- **Focused commercial infrastructure targeting high-volume transplant centers globally**
  - In US and EU5, 80% of allogeneic HSCT performed in top 70 / 185 and 129 / 411 stem cell transplant centers, respectively
  - Top 100 / 240 transplant centers in US perform 80% of kidney transplants
- **We believe that many of these transplant centers will also have participated in our pivotal and POC trials**

*Projected addressable patient population in 2025 for Viralym-M indications in target markets in NA, EU, LATAM and A/P
Source: AlloVir analysis and estimates based on annual growth rate assumption

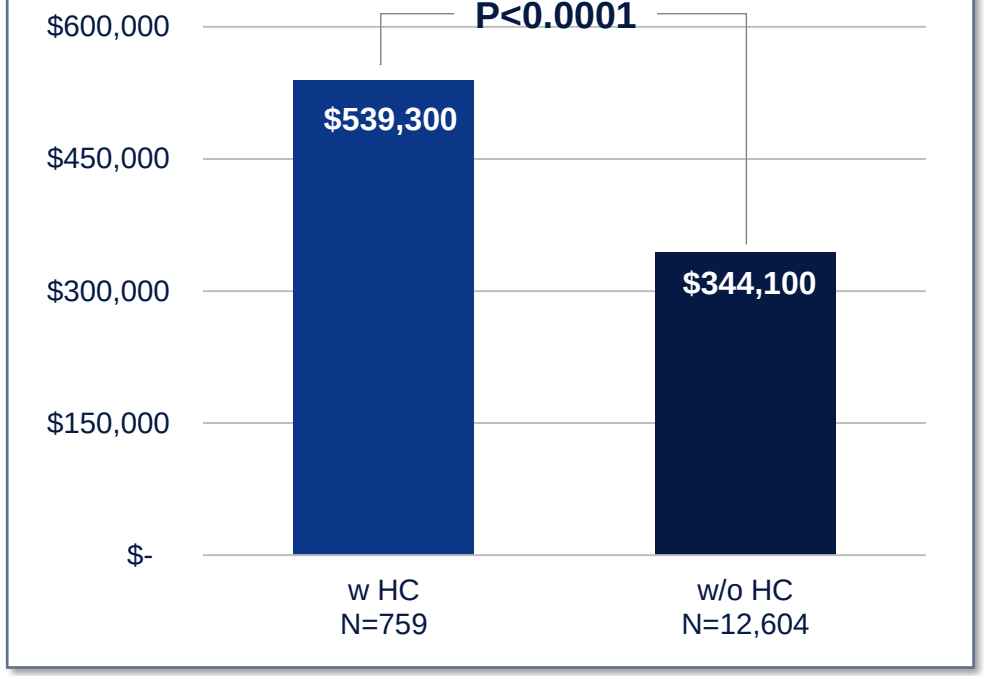
# HSCT Recipients with Virus-Associated HC Have Significantly Higher Mortality and Incur Greater Healthcare Reimbursements

## Real-world claims analysis confirms high clinical and economic burden of virus-associated hemorrhagic cystitis (HC)

### 1-yr All-Cause Mortality Rate for Allogeneic HSCT Recipients




### Mean Total Reimbursements for Allogeneic HSCT Recipients




All reimbursed amounts in the insurance claims up to 1-year post-transplant were reported. Reimbursement amounts include inpatient services and admission summaries, outpatient services, and outpatient pharmaceutical dispensed claims
Source: Real-world claims data analysis

# Viralym-M: Ph3 Ready, Multi-Virus Specific T-Cell Therapy with 93% RR in Ph2 and Demonstrated Safety Profile

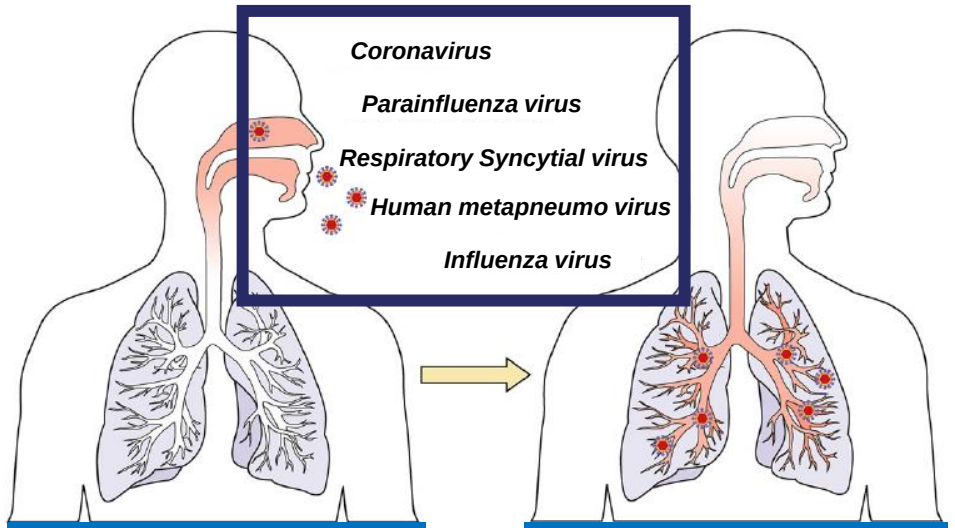
- Multi-virus T cell therapy specific for 12 viral antigens from BK virus, Cytomegalovirus, Adenovirus, Epstein-Barr virus, and Human Herpesvirus 6
- 93% RR in Ph2 Study in drug refractory patients; POC achieved for 5 viral infections
- Partially HLA-matched, to mediate extensive antiviral coverage, with mini-banks that each accommodate >95% of allogeneic HSCT patients
- Type B meeting with FDA and Scientific Advice Meeting with EMA completed and planned move into Phase 3 registrational study
- Designated Regenerative Medicine Advanced Therapy (RMAT) by the FDA and PRIority MEdicine (PRIME) by the EMA; ODD in EU for treatment of all 5 viruses in HSCT
- Completed technology transfer and scale-up to CDMO

RR: Response Rate; ODD: Orphan Drug Designation; CDMO: Contract development and manufacturing organization.

# Extending Our Platform to Tackle Major Public Health Needs

# Devastating Consequences of Respiratory Virus Infections and Disease

## Consequences to High-Risk Patients with URTI and LRTI




| | Upper Respiratory Tract Infection (URTI) | Lower Respiratory Tract Infection (LRTI) |
|---|---|---|
| **Potential Consequences** | • Progression from URTI to LRTI<br>• Lost productivity<br>• Fatigue | • ER visits<br>• Pneumonia<br>• Hospitalization<br>• Respiratory failure<br>• Death |

Ison M and Hirsch H. *CMR* 2019.

# Respiratory Virus Infections & Diseases in High-Risk Populations: Substantial Unmet Need for Treatment and Prevention

## Devastating Consequences of Respiratory Infections/ Disease

- **High-risk populations**
  - **SARS-CoV2: >14,000,000** confirmed cases of COVID-19 & **>600,000** deaths worldwide as of July 20, 2020[1]
  - **RSV**: **~ 66,000 – 199,000 deaths** each year[2]
  - **PIV**: **7%** of pediatric and up to **11.5%** of adult hospitalization for RTIs[3]
  - **hMPV**: **50%** of infected elderly patients developed LRTI, which led to **50**% mortality[4]
  - **Influenza**: High mortality rates in patients ≥ 75 yrs and < 5 yrs[5]
- **Transplant population**[6-8]
  - RTIs due to RSV, influenza, PIV and hMPV, detected in **up to 40%** of allogeneic HSCT patients
  - **~50%** progress to **LRTI with 20-45% mortality rate**
  - Respiratory viruses can infect all types of SOT patients

## No or Limited Care Options Available[6]

- **SARS-CoV-2**: Investigational approaches in development / no vaccines currently available
- **PIV and hMPV**: No FDA-/EMA-approved treatment or vaccines
- **RSV**: Ribavirin / pavilizumab for children / no vaccines available
  - Logistical challenge to administer, toxicity, and development of resistance
- **Influenza**: neuraminidase inhibitors & vaccines
  - Drug resistance common in immunocompromised patients
  - Partially effective vaccine in high-risk populations

RTI: Respiratory tract infection; LRTI: Lower tract respiratory infection

**1.** WHO; **2.** Paes BA, et al. *Can Respir J*. 2011;18(2):e10-e19; **3.** Branche AR, et al. *Semin Respir Crit Care Med*. 2016;37(4):538-554. **4.** Shafagati N, Williams J. *F1000Res*. 2018;7:135. Published 2018 Feb 1 **5.** Clayville LR. *P T*. 2011;36(10):659-684; **6.** Ison M and Hirsch H. *CMR* 2019. **7.** Versluys AB, Boelens JJ. *Front Microbiol*. 2018;9:2795. **8.** Piñana J, Montoro J, Aznar C, et al. *J Infect*. 2020;80(3):333-341. doi:10.1016/j.jinf.2019.12.022.

# ALVR106 & ALVR109

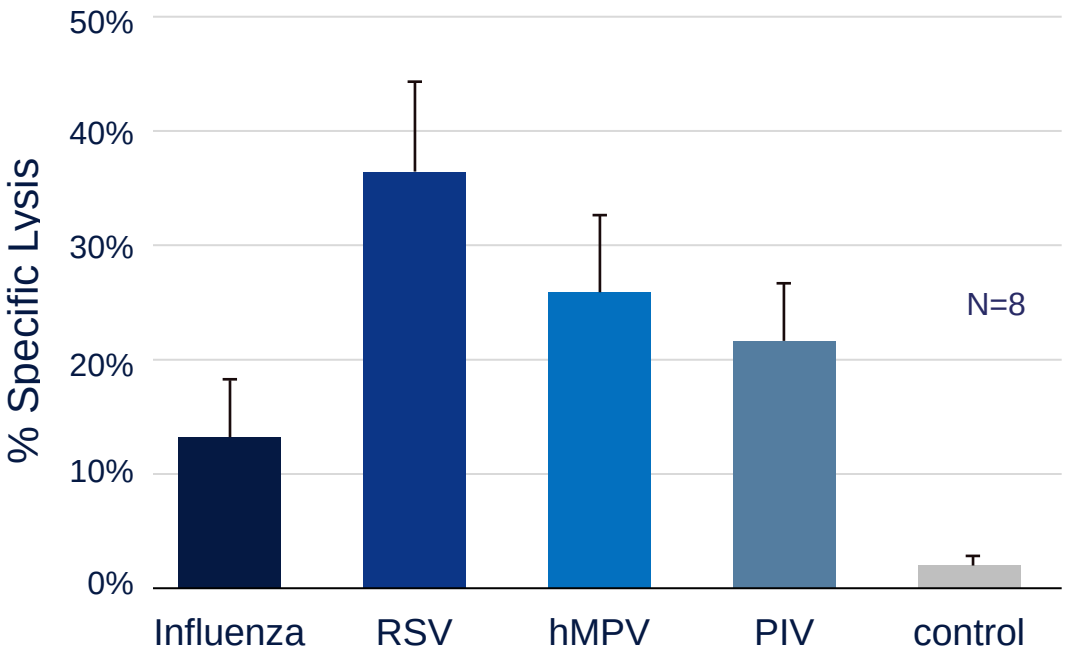
## VST Therapies for Respiratory Viruses such as RSV, Influenza, PIV, hMPV and SARS-CoV-2

allo vir

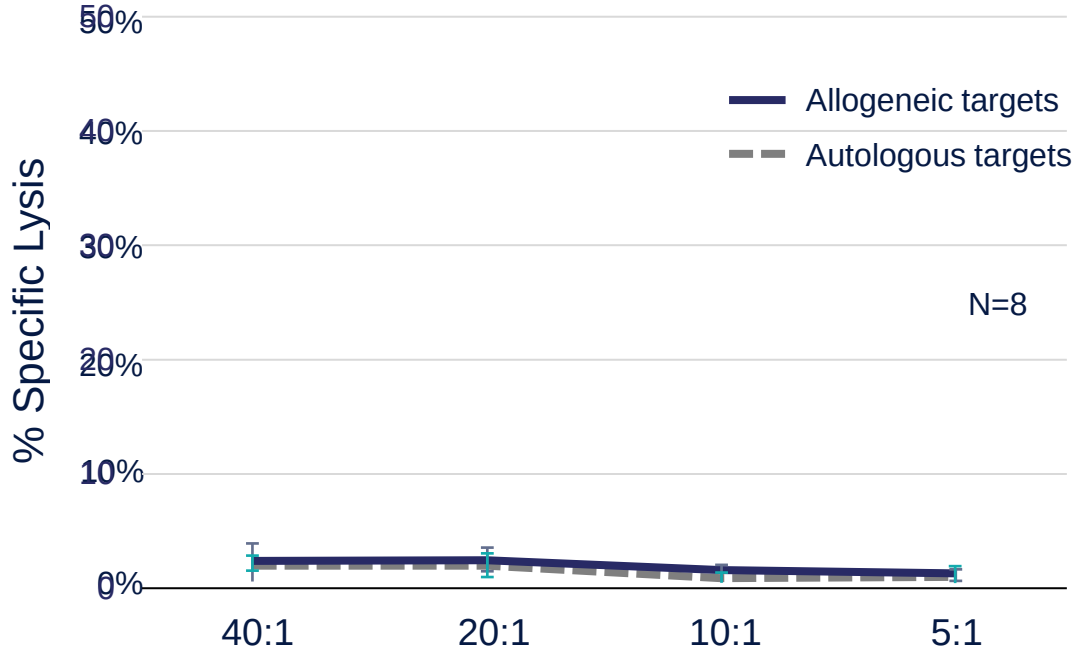
# ALVR106, Multi-Respiratory Virus T-Cell Therapy Candidate Specific for RSV, Influenza, PIV, and hMPV, in High-Risk Patients with T Cell Deficiencies

## ALVR106 has selective antiviral activity against target viruses while leaving non-virus infected targets intact

### Cytolytic Activity of ALVR106 against Target Viruses




### No / Minimal Activity of ALVR106 against Non-Infected Targets




Vasileiou S et al. *Haematologica* 2020.

# ALVR106 POC Basket Study Targeting RSV, Influenza, PIV, and hMPV to be Initiated in 2021; IND anticipated to file before year end

**Multicenter, randomized, double-blind, placebo-controlled trial**

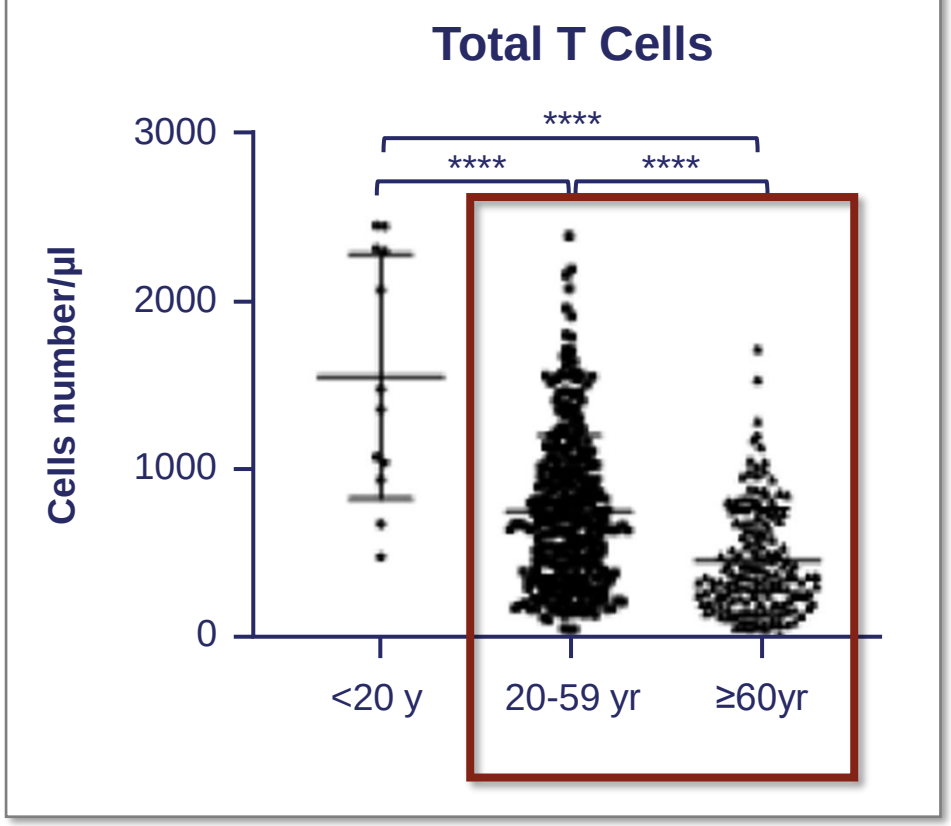
| PART A (URTI) | PART B (URTI) | PART C (LRTI) | PART D (EXPANSION) |
|---|---|---|---|
| Dose escalation cohort to assess safety and select optimal dose<br>• High risk auto- / allo- HSCT patients | Efficacy expansion cohort to assess safety and efficacy of the optimized dose<br>• High risk auto- / allo- HSCT patients | Dose escalation cohort to assess safety and select optimal dose<br>• High risk auto- / allo- HSCT patients | Efficacy expansion cohort(s) to assess safety and efficacy in additional populations<br>• Immunocompromised cancer patients;<br>• The elderly; and/or<br>• The very young |

**Pre-IND meeting with FDA completed**

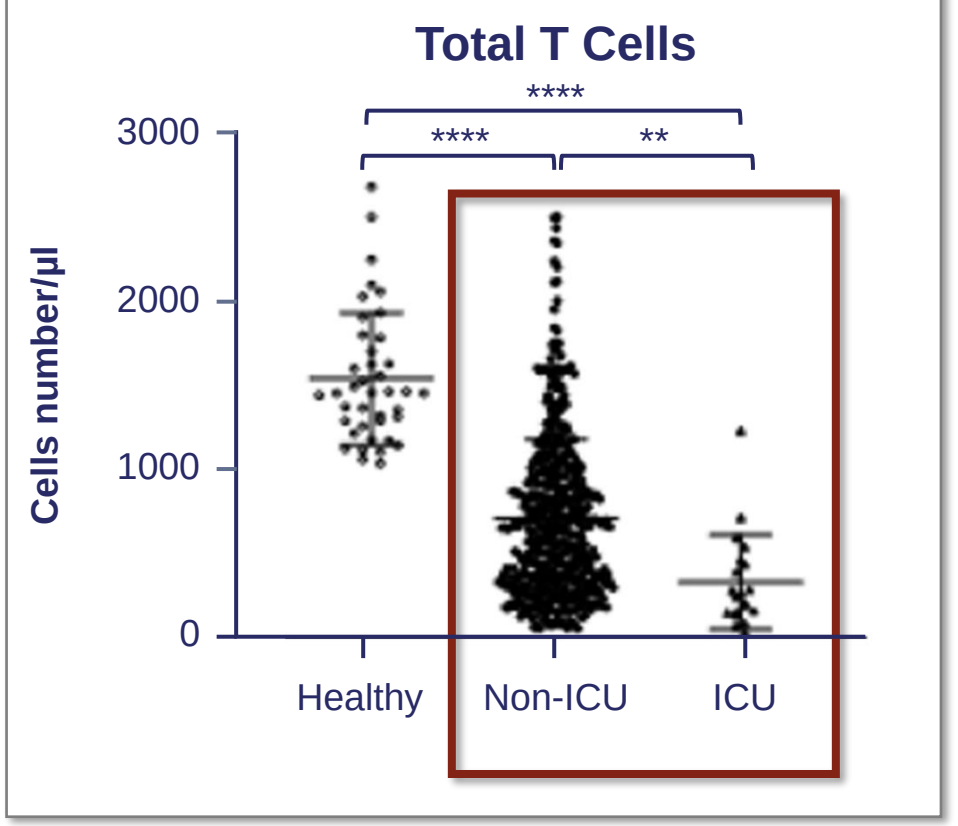
POC: Proof of Concept; URTI: upper respiratory tract infection; LRTI: lower respiratory tract infection

# High-Risk COVID-19 Patients Have Significant T-Cell Deficiencies

## T-cell Deficiencies in COVID-19 Patients of Different Ages (N=522)



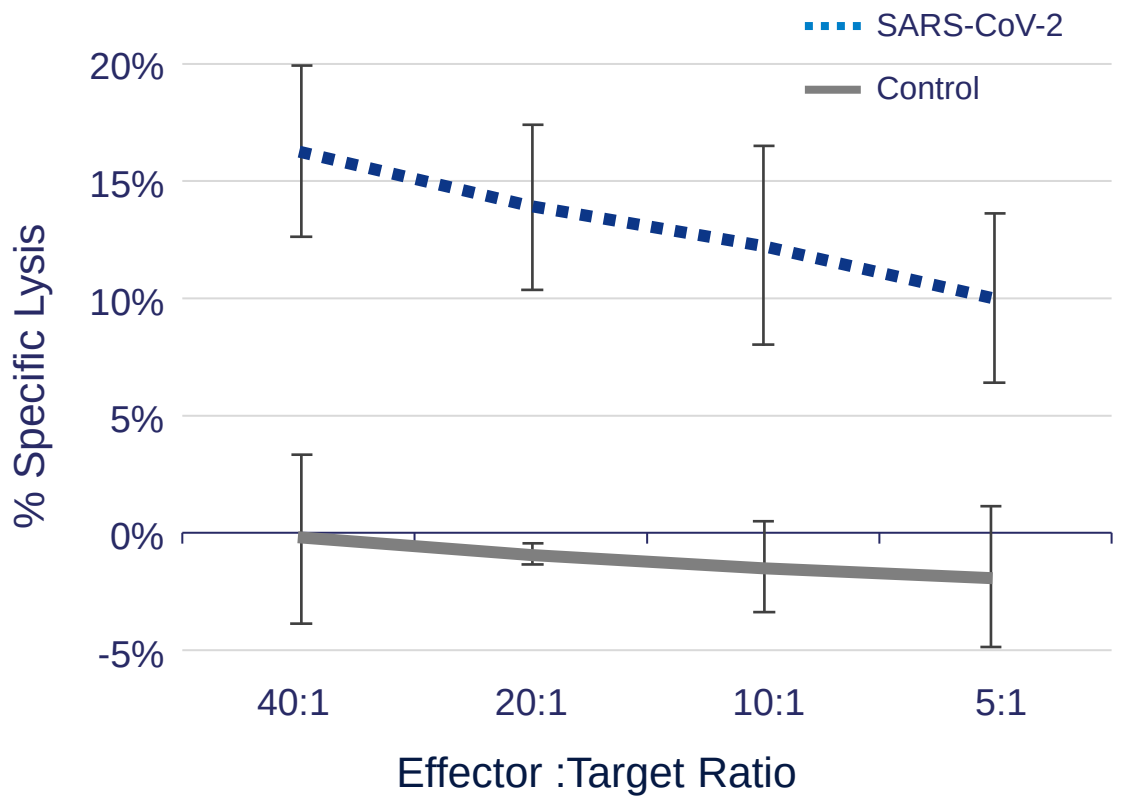

## T-cell Deficiencies in Different COVID-19 Patient Groups (N=522)



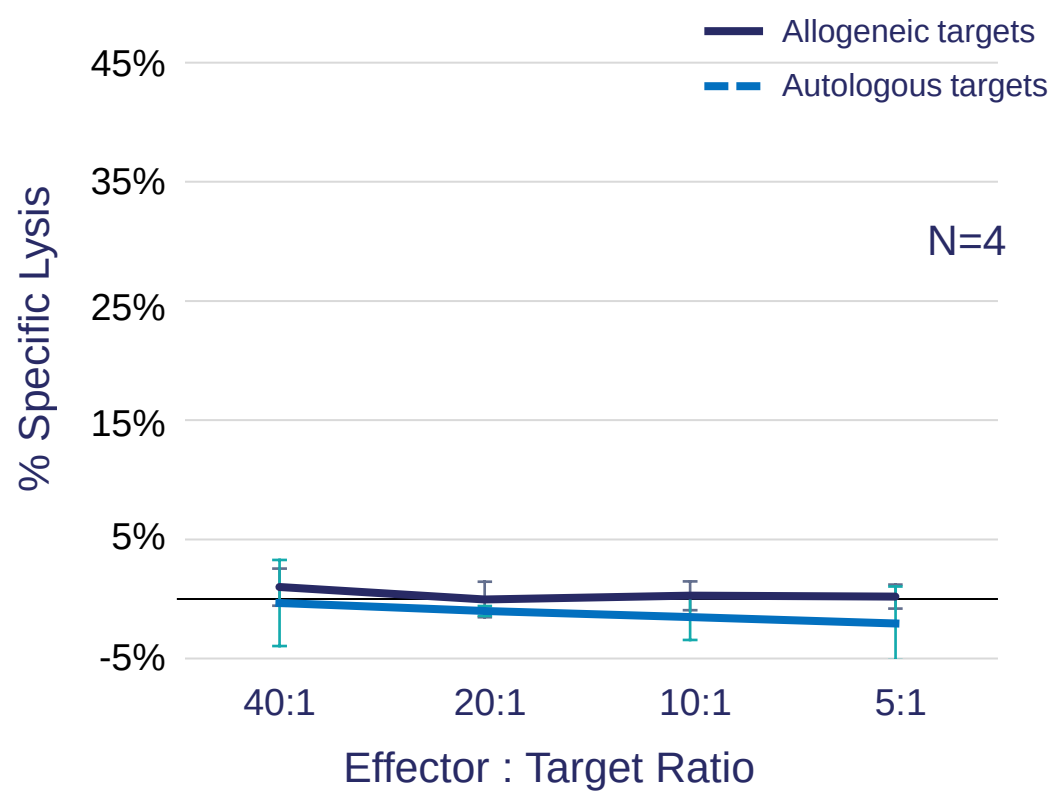

**p<0.01, ***p<0.001, ****p<0.0001
Diao B, et al. *Front Immunol* 2020.

# ALVR109 Has Demonstrated Selective Cytolytic Activity against SARS-CoV-2 While Leaving Non-Virus Infected Targets Intact

## Cytolytic Activity of ALVR109 against SARS-CoV-2

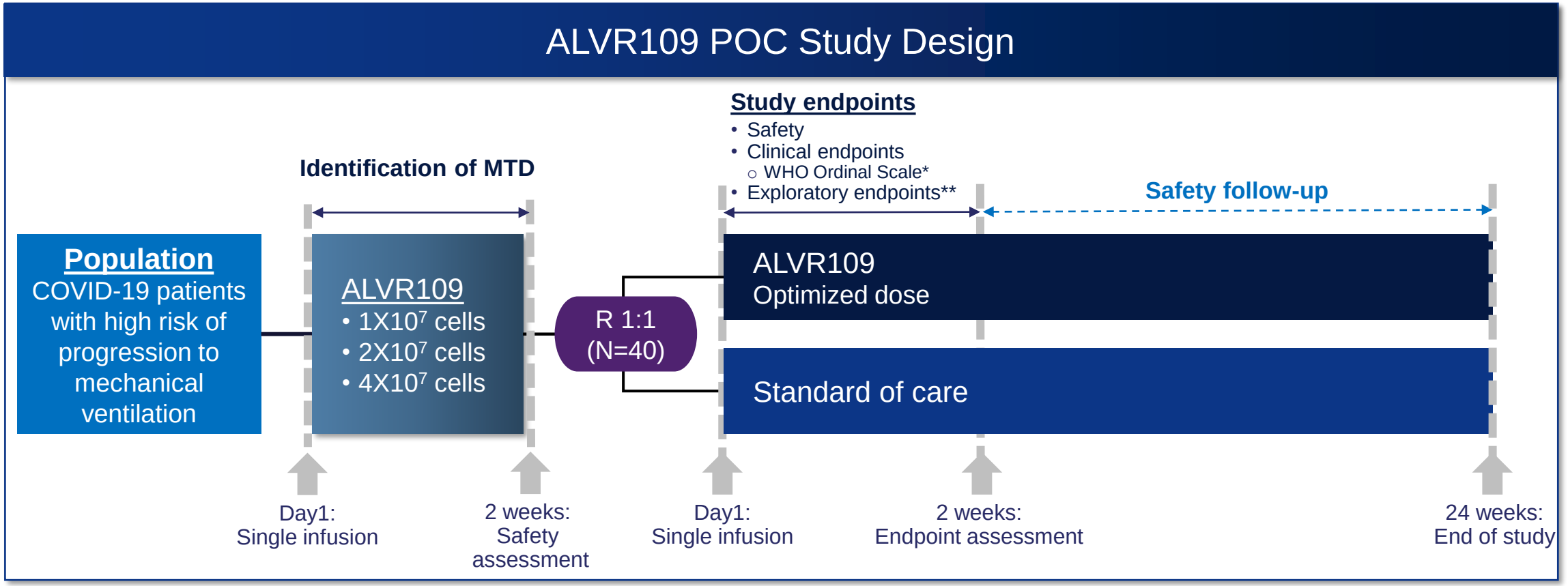



## No / Minimal Activity of ALVR109 against Non-Infected Targets




Source: ASH abstract: "Using Allogeneic, Off-the-Shelf, SARS-CoV-2-specific T Cells to Treat High Risk Patients with COVID-19"

# ALVR109 POC Trial Initiated with Top Line Data Expected in 2021




MTD: Maximum tolerated dose
*Including analyses of hospitalization, O2 requirements, need for mechanical ventilation and survival
**Including Expansion/persistence and in vivo effects of infused T cells assessed by a range of T cell measures, endogenous immune reconstitution/antibody induction, extended safety of T cell infusion to day 28 and 42 post-infusion, etc.
Clinical Trials.gov NCT04390113

# Advancing Towards Commercialization

# BaseCamp is a Premium Global Cell and Gene Therapy R&D and Manufacturing Company Dedicated to Its Affiliated Companies

elevatebio base camp

- R&D for immunotherapy, regenerative medicine and gene therapy
- Process development
- GMP manufacturing of viral vectors
- GMP manufacturing of immune cells
- Regulatory and quality support
- Innovation and process consulting

# AlloVir Has Achieved Meaningful Milestones in Off-the-Shelf VST Manufacturing Leveraging BaseCamp

## Successful Completion of Technology Transfer and Scale-Up from Baylor to CDMO

- Completed technology transfer of manufacturing process to our CDMO
  - Successful engineering runs and potency assay to support multiple clinical trials
- Robust manufacturing process industrialized with CDMO GMP facility
- Quality control and computer system validation per FDA requirement have been completed

## Capacity Expansion and Redundancy of Manufacturing Sites Has Commenced

- An external cGMP CDMO is currently manufacturing Viralym-M and ALVR106
- An academic cGMP facility is manufacturing ALVR109
- On track to add ElevateBio BaseCamp to our manufacturing network in 2021

# Conclusion

# Robust Set of Potential Value Enhancing Catalysts Ahead

## 2020

- **Viralym-M:**
  - Pivotal Trial Initiation in Virus-Associated HC
  - POC Trial Initiation in Multi-Virus Prevention
- **ALVR109:**
  - POC Trial Initiated for SARS-CoV-2

## 2021

- **Viralym-M:**
  - POC Trial Initiation in BKV in Kidney Transplant
  - Pivotal Trial Initiation for CMV
  - Pivotal Trial Initiation for AdV
  - POC Trial Initiation in CMV for Solid Organ Transplants
  - **POC Initial Data in Multi-Virus Prevention**
  - **POC Interim Data in BKV in Kidney Transplant**
- **ALVR109:**
  - **POC Top Line Data for SARS-CoV-2**
- **ALVR106:**
  - **POC Trial Initiation for Multiple Respiratory Viruses**

# Key Investment Highlights

**INNOVATIVE ENGINE** for allogeneic, off-the-shelf, virus-specific T-cell immunotherapies

**5 VST THERAPY CANDIDATES** for **12** devastating, life-threatening viruses

**Viralym-M**: **LARGE MARKET OPPORTUNITY** in **RMAT / PRIME** Designations alone

**Viralym-M**: **3 PIVOTAL TRIALS** in 2020/2021

**Viralym-M**: POC trials for **PREVENTION** of all 5 viruses and **SOT** with initial data in 2021

**ALVR106 (MULTI-RESPIRATORY VSTs):** POC trial initiation in 2021

**ALVR109 (SARS-CoV-2 VSTs): ACCELERATED DEVELOPMENT** for treatment of COVID-19 with POC trial initiation in 2020 and initial data in 2021