STATISTICAL ANALYSIS PLAN

Protocol Title:	Phase 2/3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of ALVR105 (Viralym-M) Compared to Placebo for the Prevention of AdV, BKV, CMV, EBV, HHV-6, and JCV Infection and/or Disease, in High-Risk Patients After Allogeneic Hematopoietic Cell Transplant
Protocol Number:	P-105-202
Protocol Version/Date:	V5.0 Amendment 4, 19 October 2021
Investigational Product:	ALVR105 (Viralym-M)
Sponsor:	AlloVir 1100 Winter Street Waltham, MA 02451 United States
SAP Version/Date:	V1.0/30 August 2022 (Phase 2)

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SIGNATURE PAGE

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We, the undersigned, have reviewed and approved this Statistical Analysis Plan:

Signature	**Date**
[redacted]	
[redacted]	

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AdV	Adenovirus
AE	Adverse Event
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
ATC	Anatomical Therapeutic Chemical
AUC	Area under the Curve
BKV	BK Virus
CBC	Complete Blood Count
CMV	Cytomegalovirus
CRF	Case Report Form
CRS	Cytokine Release Syndrome
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DSMB	Data Safety Monitoring Board
EBV	Epstein-Barr Virus
ECG	Electrocardiogram
ET	Early Termination Visit
GVHD	Graft Versus Host Disease
GGT	Gamma-glutamyl Transferase
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCT	Hematopoietic Cell Transplant
HHV-6	Human Herpesvirus 6
HLA	Human Leukocyte Antigen
ICF	Informed Consent Form
JCV	JC Virus
LFT	Liver Function Test
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute
OL	Open Label
PBMC	Peripheral Blood Mononuclear Cell
PT	Preferred Term
Q	Every
QoL	Quality of Life
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SoA	Schedule of Activities
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
TESAE	Treatment-Emergent Serious Adverse Event
WHO	World Health Organization

1 INTRODUCTION

The purpose of this Statistical Analysis Plan (SAP) is to provide a description of the statistical methods to be implemented for the analysis of data from the Phase 2 open label (OL) cohort of Protocol P-105-202. All the patients in the Phase 2 OL were enrolled, treated, and followed under Protocol Amendment 2 dated 7 April 2021. Data were collected under Protocol Amendment 2 Schedule of Activities (Appendix 2). The analysis will be based on Protocol Amendment 4 dated 19 October 2021. In addition, the clinically significant infections or episodes of end-organ disease were determined by the clinical investigators in Phase 2, [redacted]

The SAP will be finalized prior to Phase 2 database lock. Any deviations from the SAP after database lock will be documented in the final Clinical Study Report (CSR) for the Phase 2 OL cohort. [redacted].

2 STUDY OVERVIEW

2.1 Study Objectives

2.1.1 Primary Objective

The primary objective is to assess the efficacy of ALVR105 by the number of clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6, or JCV through Week 14 as determined by the clinical investigators.

2.1.2 Secondary Objectives

The key secondary objective is to assess the efficacy of ALVR105 by the number of clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6, or JCV through Week 26 as determined by the clinical investigators.

Other secondary objectives are as below:

- To assess the efficacy of ALVR105 by the number of clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, or HHV-6 due to each individual virus as determined by the clinical investigators through Week 14 and Week 26
- To assess the efficacy of ALVR105 in mean area under the curve (AUC) viral load for AdV, BKV, CMV, EBV, HHV-6, and JCV for each virus through Week 14 and Week 26

2.1.3 Exploratory Objectives

Exploratory objectives are as below:

- To determine the incidence and number of re-hospitalizations (following hospital discharge after HCT occurring after randomization) for AdV, BKV, CMV, EBV, HHV-6, or JCV infection or disease through Week 26
- To assess patient-reported quality of life (QoL) through Week 26

- To assess the efficacy of ALVR105 in the proportion of patients with undetectable AdV, BKV, CMV, EBV, HHV-6, or JCV viremia (defined as below the lower limit of quantification [LLOQ]) at Week 14
- To determine hospital length of stay (following initial hospital discharge) for AdV, BKV, CMV, EBV, HHV-6, or JCV infection or disease through Week 26
- To characterize virus specific T cells (VSTs) in patients who were administered ALVR105

2.1.4 Safety Objectives

The safety objectives are to characterize the safety and tolerability of ALVR105 when administered to patients at high-risk for AdV, BKV, CMV, EBV, HHV-6, or JCV following allogeneic HCT.

2.2 Study Design

2.2.1 Overview

This is a Phase 2/3, multicenter, randomized, double-blind, placebo-controlled trial to investigate the efficacy and safety of ALVR105 administered intravenously for the prevention of infection or disease due to AdV, BKV, CMV, EBV, HHV-6, or JCV in high-risk adult and pediatric patients after allogeneic HCT.

There are 2 parts to the study, a Phase 2 OL cohort [redacted] The first 25 to 35 patients (Phase 2 OL cohort) will receive ALVR105 for 14 weeks of OL dosing and will be followed for an additional 12 weeks. An assessment and optimization of study processes will be performed during the OL portion.

A review by the Data Safety Monitoring Board (DSMB) will be done when approximately 25 to 35 patients in the OL cohort have completed 30 days of treatment. At this time, an assessment of benefit, risk, and endorsement to proceed to Phase 3 will be undertaken. [redacted] Phase 2 OL patients already enrolled will continue in the open label cohort.

Once patients are assigned to ALVR105 in Phase 2, administration can begin as early as 15 days post-HCT as long as, in the Investigator's judgment, the patient has met the clinical engraftment criteria, and no later than 42 (+7) days post-HCT. AdV, BKV, CMV, EBV, HHV-6, and JCV viremia will be monitored as detailed in the Schedule of Activities (SoA) in the protocol.

Patients may receive all standard of care antiviral prophylaxis at their treating institutions including letermovir.

A summary of the Phase 2 OL cohort study design is shown in Figure 1.

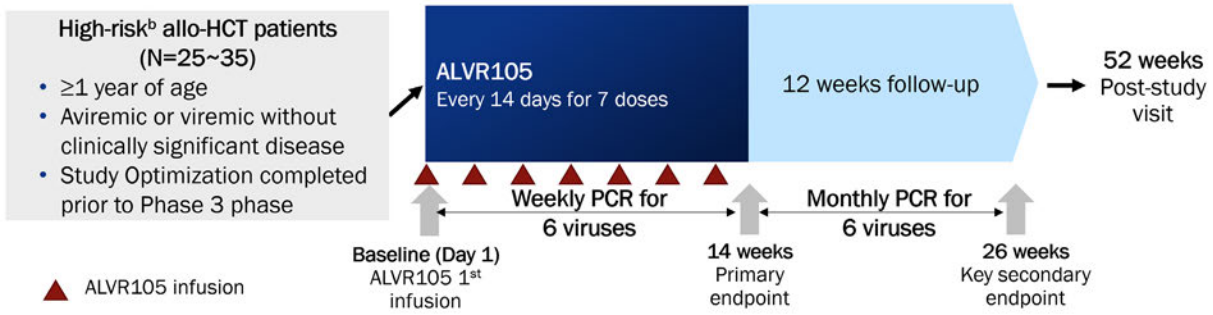
2.2.2 Study Drug

ALVR105 is a third-party, allogeneic, "off-the-shelf," VST product with specificity for BKV, AdV, CMV, EBV, and HHV-6 (with additional cross-reactive specificity for JCV) that is cryopreserved and ready for immediate use.

2.2.3 Sample Size Determination

The first 25 to 35 patients (Phase 2 OL cohort) will receive ALVR105 for 14 weeks of OL dosing, after which they will be followed for an additional 12 weeks. A review by the DSMB will be done when approximately 25 to 35 patients in the OL cohort have completed 30 days of treatment. At this time, an assessment of benefit, risk, and endorsement to proceed to Phase 3 will be undertaken. [redacted].

Figure 1. Study Flow Chart for Phase 2 OL Cohort



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.

2.3 Study Endpoints

2.3.1 Primary Efficacy Endpoint

The primary endpoint is the number of clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6, or JCV through Week 14.

2.3.2 Secondary Efficacy Endpoints

The key secondary endpoint is the number of clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6, or JCV through Week 26.

The other secondary endpoints include:

- Clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6, or JCV from each individual virus through Week 14 and Week 26 (6 endpoints each at Week 14 and Week 26)
- Mean viral load for AdV, BKV, CMV, EBV, HHV-6, and JCV for each individual virus through Week 14 and Week 26, obtained as AUC/number of days (6 endpoints each at Week 14 and Week 26)

2.3.3 Exploratory Efficacy Endpoints

The exploratory efficacy endpoints are:

- Proportion of patients with re-hospitalizations (defined as any hospitalization following hospital discharge from HCT or from any subsequent hospitalization before randomization) for AdV, BKV, CMV, EBV, HHV-6, or JCV infection or disease through Week 26
- For patients with re-hospitalizations, number of re-hospitalizations (defined as any hospitalization following hospital discharge from HCT or from any subsequent hospitalization before randomization) for AdV, BKV, CMV, EBV, HHV-6, or JCV infection or disease through Week 26
- Change in QoL, EQ-5D-5L, EQ-5D-Y, and EQ-5D-Y Proxy Version 1, through Week 26
- Undetectable AdV, BKV, CMV, EBV, HHV-6, or JCV viremia (defined as below the LLOQ for each virus) at Week 14
- Number of hospital days related to clinically significant AdV, BKV, CMV, EBV, HHV-6, or JCV infection or disease through Week 26
- Monitoring of anti-AdV, BKV, CMV, EBV, HHV-6, or JCV-specific T cell populations

Since the hospitalization and re-hospitalization data are not collected in the Phase 2 cohort, these endpoints will not be analyzed in this SAP. The anti-viral specific T cell data will not be analyzed in this SAP but reported separately.

2.3.4 Safety Endpoints

The safety endpoints include:

- Severity and incidence of acute graft versus host disease (aGVHD)
- Severity and incidence of chronic GVHD
- Severity and incidence of cytokine release syndrome
- Severity and incidence of graft failure
- Severity and incidence of clinically significant cytopenias
- Severity and incidence of renal dysfunction
- Effect on measures of engraftment
- Overall and non-relapse-related mortality

Data for effect on measures of engraftment were not collected in Phase 2 and will not be analyzed in this SAP. Safety assessments also include adverse events (AEs), vital signs, 12-lead electrocardiograms (ECGs), physical examination findings, and clinical laboratory evaluations (hematology, chemistry, and urinalysis).

3 STATISTICAL METHODOLOGY

3.1 General Considerations

3.1.1 Study Day

Study day will be calculated from the date of first dose of study drug, as actual visit date – first dose date + 1. The day of the first dose of study drug will be Day 1, and the day immediately before and after Day 1 will be Day -1 and Day 2.

3.1.2 Analysis Visits

Subject visits might not occur on protocol-specified days. Therefore, for the purpose of analysis, all scheduled, unscheduled, and early termination visits will be assigned to analysis visits according to the analysis windows (Appendix 1) based on study days. If there is more than 1 assessment in an analysis window, the assessment closest to the target day will be used in the analysis. If there are 2 assessments in a window equidistant from the target day, the later assessment will be used in the analysis.

3.1.3 Definition of Baseline

Baseline is defined as the last non-missing measurement prior to the first dose of study treatment. This can be on Day 1 as long as the measurement is taken prior to the first dose.

3.1.4 Summary Statistics

Summary statistics will be presented. Unless otherwise stated, continuous variables will be summarized using the number of non-missing observations, arithmetic mean, standard deviation, median, minimum, and maximum values as descriptive statistics. Categorical variables will be summarized using the frequency count and the percentage of patients in each category as descriptive statistics.

3.1.5 Handling of Dropouts and Missing Data

In general, data will be analyzed and presented as observed and will not be imputed for the analysis of efficacy and safety, unless otherwise specified.

In case the start and end dates for adverse events and concomitant medications/procedures are missing or incomplete, the missing component(s) will be assumed as the most conservative value possible. For example, AEs with missing start dates, but with stop dates either overlapping into the treatment period or missing, will be counted as treatment-emergent, taking the worst-case approach. When partial dates are present in the data, both a partial start date and/or a partial stop date will be evaluated to determine whether it can be conclusively established that the AE started prior to the start of study treatment or ended prior to the start of study treatment. If the above cannot be conclusively established based on the partial and/or present dates, then the AE will be considered as treatment-emergent. Actual data values as they appear in the original case report forms (CRFs) will be presented in the data listings.

3.2 Analysis Populations

3.2.1 Enrolled Population

The Enrolled Population will include all patients who signed the Informed Consent Form (ICF).

3.2.2 Safety Population

The Safety Population will include all patients who received ALVR105. All efficacy and safety analyses will be based on the Safety Population.

3.3 Patient Data and Study Conduct

3.3.1 Patient Disposition

Patient disposition information will be summarized using the Enrolled Population. The numbers and percentages of patients who were screened, screen failure along with the reasons of screen failure, not dosed, dosed, completed study drug, discontinued study drug early along with the reasons for early discontinuation of study drug, completed the study, and discontinued the study early along with the reasons for early discontinuation of study, received a Week 52 follow-up call will be summarized.

The numbers and percentages of patients in Safety Population with reason for exclusion will also be summarized.

By-patient listings will also be provided for patient disposition, screen failures, patients who were enrolled but not dosed, and reason for exclusion from analysis population.

3.3.2 Protocol Deviations

The numbers and percentages of patients with protocol deviations by deviation category will be summarized on Safety Population. All protocol deviations will be determined prior to database lock and listed by patient.

3.3.3 Demographic and Baseline Characteristics

Demographic (age, sex, race, and ethnicity) and baseline characteristics (height, weight, BMI, and childbearing potential at baseline) will be summarized with descriptive statistics or counts and percentages of patients as appropriate for safety population.

The following disease characteristics will also be summarized using frequencies and percentages: diagnosis, donor type, HLA alleles from the study patient, the allogeneic HCT donor(s), and the VST donor(s) as well as the number of shared alleles among these individuals, pre-conditioning therapy received, CMV serostatus at baseline of donor and recipient, letermovir use at Baseline, presence of Baseline viremia (based on central lab) and level of conditioning (myeloablative, reduced intensity, and non-myeloablative). A by-patient listing will be provided.

3.3.4 Medical History

Medical history will be coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA). The numbers and percentages of patients with

medical history by system organ class and preferred term will be summarized for safety population.

A by-patient listing of medical history will be provided.

3.3.5 Prior and Concomitant Medications

Concomitant medications will be coded to anatomical therapeutic chemical (ATC) class and preferred term using the WHODrug Dictionary. All medications taken prior to the first dose of study treatment will be considered as prior medications. The medications taken prior to the first dose of study treatment and were ongoing or started on or after the first dose of study treatment will be considered as concomitant medications.

The numbers and percentages of patients taking prior and concomitant medications by ATC class and preferred term will be summarized based on the Safety Population.

A by-patient listing will be provided for prior and concomitant medications.

3.3.6 Study Drug Exposure and Compliance

Study drug duration, number of doses, and total dosing will be summarized based on Safety Population.

The length of exposure to study drug will be calculated as the number of days from the first dose of study drug to the last dose of study drug plus 14 days, regardless if the patient missed one or more doses of study drug. Length of exposure will be summarized using descriptive statistics for the safety population.

A by-patient listing will be provided for study drug exposure.

Overall compliance will be calculated as:

*(Sum of total vials administrated)/ (total vials planned)*100*

The number and percentage of patients will be summarized for the Safety Population for the following categories: 0- <70% and >= 70%.

3.4 Efficacy Analyses

This section describes the analysis to be conducted on the primary, secondary and exploratory efficacy endpoints. The efficacy analyses for the Phase 2 OL cohort will be performed using the Safety Population.

3.4.1 Primary Efficacy Endpoint

The primary endpoint is the number of clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6, or JCV through Week 14.

Clinically significant infections/episodes will be considered as a failure of prevention, thus, in calculating the value of this endpoint for a patient, each virus will be counted at most once, even if there are multiple infections/episodes for a given virus. Therefore, each patient could experience as many as 6 infections, one for each of the targeted viruses. In addition, a new onset is defined as a new clinically significant infection/episode that is not present at Baseline. Patients will be excluded from a particular virus of interest endpoint if they demonstrated clinically

significant infection with that virus at Baseline. Clinically significant infections include viremia requiring treatment and/or episodes of end-organ disease.

The number of clinically significant infections or episodes will be summarized using descriptive statistics.

3.4.2 Secondary Efficacy Endpoints

The key secondary endpoint is the number of clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6, or JCV through Week 26. The definition of clinically significant infections or episodes is the same as for the primary endpoint. The summary statistics will be provided by each individual virus at Week 14 and 26, respectively.

Similar analysis will be performed for the clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6 or JCV, from each individual virus through Week 14 and Week 26 (i.e., 6 endpoints each at Week 14 and Week 26).

The mean viral load for each AdV, BKV, CMV, EBV, HHV-6, and JCV virus, obtained as AUC/number of days at Week 14 and Week 26, will be summarized by descriptive statistics in the original and log10 scales. For each virus, the viral load and change from baseline over time will also be summarized in the original and log10 scales.

By-patient listings will be provided for the clinically significant infections or episodes of end-organ disease per patient due to AdV, BKV, CMV, EBV, HHV-6, or JCV.

3.4.3 Exploratory Efficacy Endpoints

The exploratory efficacy endpoints are listed in Section 2.3.3.

The observed and change from baseline in QoL assessments will be summarized through Week 26. Listings will be provided for the QoL assessments.

Since most of the patients are undetectable, the number and percentage of patients with detectable viremia (i.e., >=LLOQ) will be summarized at Week 14 as well as by visit and at any visit.

By-patient listing will be provided for AdV, BKV, CMV, EBV, HHV-6, and/or JCV viremia and QoL measures.

Subgroup analyses may be conducted for the efficacy endpoints by type (class I or II), the number of HLA matches, and letermovir treatment at Baseline.

3.5 Safety Analyses

Safety data will be summarized based on the Safety Population. Categorical endpoints will be summarized using the number and percentage of patients within each category. Continuous endpoints will be summarized descriptively with summary statistics (number of non-missing observations, arithmetic mean, standard deviation, median, minimum, and maximum).

3.5.1 Adverse Events (AEs)

All AEs will be coded to system organ class and preferred term using MedDRA. Treatment emergent adverse events (TEAEs) are defined as an AE with onset or worsening on or after the first dose of study treatment through the end of study (i.e., Week 26).

An overall summary of AEs will be provided with the number and percentage of patients who experienced at least 1 AE or TEAE in the following categories:

- Any TEAEs
- Any TEAEs by severity
- Any treatment-related TEAEs
- Any AEs of special interest (AESIs)
- Any treatment-emergent AESI (TEAESIs)
- Any treatment-related TEAESIs
- Any serious AEs (SAEs)
- Any treatment-emergent serious AEs (TESAEs)
- Any treatment-related TESAEs
- Any TEAEs leading to discontinuation of study treatment
- Any TEAEs leading to discontinuation of study
- Any AEs leading to death

The numbers and percentages of patients will also be presented by system organ class (SOC) and preferred term (PT) for each of the TEAE categories in the summary. Patients with multiple AEs will be counted only once per SOC and PT. The number and percentage of patients with TEAEs will be tabulated by PT and by the highest CTCAE Grade.

Listings will be presented specifically for any AEs, deaths, SAEs, and TEAEs leading to discontinuation of study treatment and study.

3.5.2 AEs of Special Interest

Adverse events of special interest (AESI) include infusion-related AEs, GVHD, and cytokine release syndrome (CRS). These AESIs will be reviewed by the DSMB as per the DSMB Charter. Criteria for acute and chronic GVHD and CRS can be found in Protocol Appendix 5 and 6, respectively. The number and percentage of patients who had the AESIs will be summarized:

- Severity and incidence of acute GVHD
- Severity and incidence of chronic GVHD
- Severity and incidence of CRS
- Severity and incidence of infusion-related AEs
- Severity and incidence of graft failure

Subgroup analyses may be conducted for the severity and incidence of acute GVHD by HLA type and the number of HLA matching.

3.5.3 Clinical Laboratory Tests

Laboratory assessments comprise safety laboratory tests (hematology, clinical chemistry and routine urinalysis), pregnancy test and other screening tests.

Descriptive statistics will be provided for safety laboratory test results and changes from baseline. A shift table, presenting the 2-way frequency tabulation for baseline and the worst post-baseline value according to the v5.0 NCI CTCAE grade, will be provided for safety laboratory tests.

Listings will be presented for all laboratory data and all test values outside the normal range will be flagged.

3.5.4 Vital Signs

Descriptive statistics will be provided for vital signs (including blood pressures, pulse rate, respiratory rate, oximetry, and body temperature), body weights, and BMIs by visit. Changes from baseline will also be summarized.

All vital sign data will be listed by patient.

3.5.5 Electrocardiograms

Electrocardiogram (ECG) measurements include heart rate (bpm) and measures PR (msec), QRS (msec), and QTc (msec) (corrected using Bazett's method, QTcB). Descriptive statistics will be provided for PR, QRS, and QTcB and the changes from baseline.

All ECG parameters and the Investigator interpretation of findings including details of any abnormalities will be listed by patient.

3.5.6 Physical Examinations

All abnormal physical examination findings, including details of any abnormalities will be listed by patient.

3.6 Data Safety Monitoring Board

An independent Data Safety Monitoring Board (DSMB) will be convened for this study to routinely monitor patient safety and evaluate pre-specified interim analyses to stop the study early. The DSMB will receive summary reports of all SAEs including unexpected SAEs. A DSMB charter, detailing all aspects of the DSMB's composition, scope of review, and procedures will be provided in a separate document. An unblinded statistician will be assigned to the DSMB. This statistician will not be involved in any aspects of study conduct outside of the DSMB, and their role will be defined in the DSMB charter.

A review by the DSMB will be done when approximately 25 to 35 patients in the OL cohort have completed 30 days of treatment. At this time, an assessment of benefit, risk, and endorsement to proceed to Phase 3 will be undertaken. [redacted]

Appendix 1 Analysis Visit Windows

Table 1. Analysis Visit Windows for Quality of Life Data

Nominal Visit	Nominal Study Day	Visit Window Study Day	
		Lower Limit	Upper Limit
Day 1/Baseline	1	1	1
Week 4	29	2	43
Week 8	57	44	71
Week 12	85	72	92
Week 14	99	93	113
Week 18	127	114	141
Week 22	155	142	169
Week 26	183	>169	

Table 2. Analysis Visit Windows for Viral Load Data

Nominal Visit	Nominal Study Day	Visit Window Study Day	
		Lower Limit	Upper Limit
Day 1/Baseline	1	1	1
Week 1	8	2	11
Week 2	15	12	18
Week 3	22	19	25
Week 4	29	26	32
Week 5	36	33	39
Week 6	43	40	46
Week 7	50	47	53
Week 8	57	54	60
Week 9	64	61	67
Week 10	71	68	74
Week 11	78	75	81
Week 12	85	82	88
Week 13	92	89	95
Week 14	99	96	127
Week 22	155	128	169
Week 26	183	>169	

Table 3. Analysis Visit Windows for Vital Sign Data

Nominal Visit	Nominal Study Day	Visit Window Study Day	
		Lower Limit	Upper Limit
Day 1/Baseline	1	1	1
Week 2	15	2	22
Week 4	29	23	36
Week 6	43	37	50
Week 8	57	51	64
Week 10	71	65	78
Week 12	85	79	92
Week 14	99	93	113

Week 18	127	114	141
Week 22	155	142	169
Week 26	183	>169	

Table 4. Analysis Visit Windows for ECG, Clinical Labs, and Physical Exam Data

Nominal Visit	Nominal Study Day	Visit Window Study Day	
		Lower Limit	Upper Limit
Day 1/Baseline	1	1	1
Week 2	15	2	22
Week 4	29	23	36
Week 6	43	37	50
Week 8	57	51	64
Week 10	71	65	78
Week 12	85	79	92
Week 14	99	93	141
Week 26	183	>141	

Appendix 2 Schedule of Activities

Table 5. Schedule of Activities: Pre-screening Period and Screening Period (All Cohorts)

	Pre-screening Visit[a]	Pre-screening Period[a]	Screening Visit[b]	Screening Period[b]
Study Week	NA	Weekly Visits	Up to 6 weeks before Study Drug Administration	Weekly after Screening Visit until Study Drug Administration
Study Day	NA	NA	May be from Day -42 to Study Drug Administration Day	May be from Day -42 to Study Drug Administration Day
Visit Window (Days)	NA	±3	NA	±3
Study Procedures				
Informed consent/assent[c]	X		X	
I/E criteria	X[d]		X	
Demographics			X	
Medical history[d]			X	
Documentation of HLA typing[e]			X	
Prior and concomitant medications including conditioning regimen for HCT			X	X
Adverse events[f]			X	X
Complete physical examination			X	
Weight and height[g]			X	
Vital signs[h]			X	
12-lead ECG			X	
Clinical labs[i]			X	
Pregnancy test[j]			X	
Testing for HIV, HCV, HBV[k]			X	
BKV, AdV, CMV, JCV, EBV, and HHV-6 viral load[l]	X	X	X	X[m]

Abbreviations: AdV = adenovirus; ALT = alanine aminotransferase; AST = aspartate aminotransferase; β-HCG = beta human chorionic gonadotropin; BKV = BK virus; CBC = complete blood count; CMV = cytomegalovirus; EBV = Epstein-Barr virus; ECG = electrocardiogram; GGT = gamma- glutamyltransferase; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HHV-6 = human herpesvirus 6; HLA = human leukocyte antigen; I/E = inclusion and exclusion; JCV = JC virus; LFT = liver function test; NA = not applicable; PBMCs = peripheral blood mononuclear cells

Note: Visits may be done via a home health visit as agreed with the Sponsor. Please see the Study Manual for more information.

[a] Adult patients and pediatric patients ≥12 years old may participate in an optional pre-screening period that may begin up to 4 weeks prior to administration of conditioning for HCT and continue until there is a decision on whether to screen for the study. Viremia testing during pre-screening will begin after HCT and will continue weekly, if possible. Pre- screening is not required for eligibility.

[b] The Screening Visit could occur any time between the day of HCT and up to 42 (+7) days post-HCT. When this visit occurs during this time period may vary by patient depending upon when the decision is made to participate in the study.

[c] Prior to conducting any study-related activities, written informed consent/assent to participate in the study must be provided by the patient and/or patient's guardian. The ICF for the pre-screening period is separate from the ICF that is signed at Screening Visit for study participation.

[d] To include CMV sero status of both patient and HCT donor.

[e] The HLA type of the patient and their HCT cell donor(s) will be obtained from the medical record.

[f] Adverse events will be monitored and documented from signing of the ICF for study participation until study participation is complete.

[g] Height and weight will be measured at screening. At later assessments during the Treatment Period, only weight will be assessed.

[h] Includes body temperature, blood pressure, heart rate, O2 saturation, and respiration rate and will be measured after resting for 5 minutes.

[i] Clinical laboratory assessments collected as part of standard of care may be used to fulfill these requirements. CBC must include differential and LFTs must include alkaline phosphatase, bilirubin (total and direct), GGT, AST, and ALT. Urinalysis must be performed. Laboratory safety evaluations (hematology, chemistry, and urinalysis) specified in the protocol will be performed prior to study therapy initiation. These samples will be sent to the appropriate central laboratory(ies) following the procedure(s) described in the study manual(s).

[j] For female patients, at Screening a β-HCG blood test will be performed. A urine pregnancy test will also be performed at the site prior to study therapy initiation (SoA for Treatment Period, Table 6).

[k] Serum will be screened for HIV, HBV, and HCV antibodies with reflex nucleic acid testing of plasma. Medical records of previous testing in the last 3-6 months may be used.

[l] Viral loads of BKV, AdV, CMV, JCV, and HHV-6 in plasma and of EBV in PCMBs will be measured weekly for adult patients and pediatric patients ≥ 12 years old after allogenic HCT conditioning during pre-screening period and screening period until treatment assignment, if possible. Pediatric patients < 12 years old will have only one blood draw during the Screening visit and will not have weekly blood draws during the screening period. Viral load testing should NOT be done on day of HCT during pre-screening. The results of the repeat analyses from the screening period must be available at the time of treatment assignment, unless the timing of the Screening Visit is 1 week or less before treatment administration. Results of central laboratory testing for viral load will be used for the purpose of determining eligibility/inclusion.

[m] Adult patients and pediatric patients ≥ 12 years old only.

Table 6. Schedule of Activities: Treatment - Period 1 for Patients ≥12 Years of Age (Week 1 to 14, All Cohorts)

		Treatment Period														
Time Period	**Treatment Assignment**	**Study Drug Administration Day**	**Wk 1**	**Wk 2**	**Wk 3**	**Wk 4**	**Wk 5**	**Wk 6**	**Wk 7**	**Wk 8**	**Wk 9**	**Wk 10**	**Wk 11**	**Wk 12**	**Wk 13**	**Wk 14**
Study Day		**1[a]**	**8**	**14**	**21**	**28**	**35**	**42**	**49**	**56**	**63**	**70**	**77**	**84**	**91**	**98**
Visit Window (Days)		**NA[b]**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±3**
Study Procedures																
Review of I/E criteria		X														
Prior & concomitant medications as well as conditioning regimen for HCT		X		X		X		X		X		X		X		X
Adverse events[c]		X		X		X		X		X		X		X		X
Physical examination[d]		X		X		X		X		X		X		X		X
Weight		X				X				X				X		X
Vital signs[e]		X		X		X		X		X		X		X		X
12-lead ECG[f]		X		X		X		X		X		X		X		X
Clinical labs[g]		X		X		X		X		X		X		X		X
Pregnancy test[h]		X		X		X		X		X		X		X		
BKV, AdV, CMV, JCV, and HHV-6 viral load[i]		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
EBV PCMBs[i]		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Treatment Assignment[j]	X															

		Treatment Period														
Time Period	**Treatment Assignment**	**Study Drug Administration Day**	**Wk 1**	**Wk 2**	**Wk 3**	**Wk 4**	**Wk 5**	**Wk 6**	**Wk 7**	**Wk 8**	**Wk 9**	**Wk 10**	**Wk 11**	**Wk 12**	**Wk 13**	**Wk 14**
Study Day		**1[a]**	**8**	**14**	**21**	**28**	**35**	**42**	**49**	**56**	**63**	**70**	**77**	**84**	**91**	**98**
Visit Window (Days)		**NA[b]**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±3**
Study Procedures																
Virus-Specific T Cell Assessment[k]		X				X		X			X			X		X
Study treatment administration[l]		X		X		X		X		X		X		X		
Post infusion monitoring[m]		X		X		X		X		X		X		X		
Infection assessment[n]		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Quality of Life (FACT- BMT, EQ- 5D-5L, EQ-5D-Y, EQ-5D-Y Proxy Version 1)[o]		X				X				X				X		X

Abbreviations: AdV = adenovirus; ALT = alanine aminotransferase; AST = aspartate aminotransferase; ; β-HCG = beta human chorionic gonadotropin; BKV = BK virus; CBC = complete blood count; CMV = cytomegalovirus; EBV = Epstein-Barr virus; ECG = electrocardiogram; ET = Early Termination Visit; GGT = gamma-glutamyl transferase; GVHD = graft versus host disease; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HHV-6 = human herpesvirus 6; I/E = inclusion and exclusion; IVIG = intravenous immunoglobulin; JCV = JC virus; LFT = liver function test; NA = not applicable; PBMC = peripheral blood mononuclear cell; SoA = Schedule of Activities; VST = virus-specific T cell; Wk = week

Note: Visits may be done via a home health visit as agreed with the Sponsor. Please see the Study Manual for more information.

[a] Unless noted otherwise, Day 1 procedures must be performed within 72 hours prior to study treatment administration.

[b] Dosing day may be up to +7 days with Sponsor approval.

[c] Adverse event monitoring should include the collection of all adverse events through the treatment period in all patients, including those who have discontinued study treatment but are continuing in the study. For patients who have discontinued, only drug-related SAEs and SAEs leading to death will be collected until Week 26.

[d] After treatment assignment, a targeted physical exam may be performed if a patient has any complaints. Post-HCT, the skin should be examined, even if the patient has no complaint, for evidence of rash/acute skin GVHD.

[e] Includes body temperature, blood pressure, heart rate, O_2 saturation, and respiration rate and will be measured after resting for 5 minutes. After treatment assignment, vital signs should be performed during and after infusions and if targeted physical examination is performed.

[f] Performed within 1 hour after study treatment administration and at the end of study or early termination visit, which are listed in the SoA for the Short-term Follow-up period (Table 8).

[g] Clinical laboratory assessments collected as part of standard of care may be used to fulfill these requirements. CBC must include differential and LFTs must include alkaline phosphatase, bilirubin (direct and indirect); GGT, AST, and ALT. Urinalysis must be performed. Laboratory safety evaluations (hematology, chemistry, and urinalysis) specified in the protocol will be performed prior to study drug initiation. These samples will be sent to the appropriate central laboratory(ies) following the procedure(s) described in the study manual(s).

[h] For female patients, a urine pregnancy test will be performed at the site prior to study therapy initiation. If the urine pregnancy test result is negative, the patient will be eligible for treatment assignment and the remainder of the Day 1 testing/procedures will be performed. If the urine pregnancy result is positive, the patient must not be assigned to treatment and should reflex to a β-HCG blood test before screen failing. A urine pregnancy test will be performed prior to each treatment for female patients who are of childbearing potential.

[i] Viral loads of AdV, BKV, CMV, JCV, and HHV-6 in plasma and of EBV in PCMBs will be measured. Additional post-infusion samples may be collected, as clinically indicated. If patient develops any clinically significant infection of AdV, BKV, CMV, EBV, HHV-6, or JCV at any point during the study periods, infection assessments should be followed prior to initiating standard of care therapy.

[j] Patients in Cohort OL will be assigned to ALVR105. Patients in Cohorts A and B will be randomized to either ALVR105 or placebo based upon the last viral load assessed and within 7 days of randomization. Treatment assignment will be about 2 to 3 days before Day 1.

[k] Patient peripheral blood mononuclear cells will be assessed for the presence of virus-reactive T cells using enzyme-linked immunospot.

[l] All patients will receive infusions of either ALVR105 or placebo. Patients will receive the same [redacted] dose for patients ≤40 kg or [redacted] dose for patients >40 kg for all infusions of ALVR105, administered at a dose interval of every 14 days (±3 days). Placebo infusions will be administered every other week in order to maintain the blind. As GVHD and CRS are a theoretical safety concern associated with administration of third-party allogeneic T cells, the incidence and severity of GVHD and CRS will be monitored during the study. No patients will be permitted to receive a subsequent infusion of ALVR105 if they develop new onset GVHD Grade >2 or worsening of GVHD (ie, relative to baseline GVHD at the time of enrollment into the study) at the proposed time for infusion of the next dose, or if they develop CRS Grade >2; if any patient develops GVHD or CRS, the Medical Monitor should be contacted immediately, and the patient treated per standard of care. If discontinued for CRS or GVHD these participants should be followed up to resolution of symptoms. Patients may resume treatment only with consultation and agreement between the Medical Monitor and the Investigator. If possible, IVIG and ALVR105 should not be administered on the same day.

[m] Patients will be monitored closely and must remain in the clinic for ≥1 hour after the end of each infusion. Vital signs, including body temperature, heart rate, O_2 saturation, respiration rate, and blood pressure, will be measured at the end of the infusion, and at 15, 30, 45, and 60 minutes after the end of the infusion. Patients must also remain on continuous pulse oximetry for ≥30 minutes after the end of the infusion. Post-infusion monitoring should be completed for all infusions of study treatment.

[n] The infection assessment will be performed for all patients who require either treatment for disease or initiation of preemptive therapy during both the primary study period and the follow-up period through Week 26. It is very important to ensure that all procedures, as outlined in the SoA, are performed immediately prior to the initiation of treatment of viral diseases or initiation of preemptive therapy (ie, on the day anti-viral therapy is initiated). Most importantly, a plasma

sample for AdV, BKV, CMV, HHV-6, and JCV and a PBMC sample for EBV for PCR testing at the central laboratory should be collected. Patients who develop viral infections will continue to be followed in the study and complete all remaining visits through Week 26.

º Assessment of quality of life (using FACT-BMT, EQ-5D-5L, EQ-5D-Y, EQ-5D-Y Proxy Version 1questionnaires, as age-appropriate) should be completed prior to any study procedures at this visit.

Table 7. Schedule of Activities: Treatment - Period 1 for Patients <12 Years of Age (Week 1 to 14, All Cohorts)

		Treatment Period														
Time Period	**Treatment Assignment**	**Study Drug Administration Day**	**Wk 1**	**Wk 2**	**Wk 3**	**Wk 4**	**Wk 5**	**Wk 6**	**Wk 7**	**Wk 8**	**Wk 9**	**Wk 10**	**Wk 11**	**Wk 12**	**Wk 13**	**Wk 14**
Study Day		**1[a]**	**8**	**14**	**21**	**28**	**35**	**42**	**49**	**56**	**63**	**70**	**77**	**84**	**91**	**98**
Visit Window (Days)		**NA[b]**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±3**
Study Procedures																
Review of I/E criteria		X														
Prior & concomitant medications as well as conditioning regimen for HCT		X		X		X		X		X		X		X		X
Adverse events[c]		X		X		X		X		X		X		X		X
Physical examination[d]		X		X		X		X		X		X		X		X
Weight		X				X				X				X		X
Vital signs[e]		X		X		X		X		X		X		X		X
12-lead ECG[f]		X		X		X		X		X		X		X		X
Clinical labs[g]		X		X		X		X		X		X		X		X
Pregnancy test[h]		X		X		X		X		X		X		X		
BKV, CMV, JCV, and HHV-6 viral load[i]		X		X		X		X		X		X		X	X	X
EBV PBMCs[i]		X		X		X		X		X		X		X	X	X
AdV viral load		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Treatment Assignment[j]	X															
Virus- Specific T Cell Assessment[k]		X				X		X			X			X		X
Study treatment administration[l]		X		X		X		X		X		X		X		

		Treatment Period														
Time Period	**Treatment Assignment**	**Study Drug Administration Day**	**Wk 1**	**Wk 2**	**Wk 3**	**Wk 4**	**Wk 5**	**Wk 6**	**Wk 7**	**Wk 8**	**Wk 9**	**Wk 10**	**Wk 11**	**Wk 12**	**Wk 13**	**Wk 14**
Study Day		**1[a]**	**8**	**14**	**21**	**28**	**35**	**42**	**49**	**56**	**63**	**70**	**77**	**84**	**91**	**98**
Visit Window (Days)		**NA[b]**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±5**	**±3**	**±3**
Study Procedures																
Post infusion monitoring[m]		X		X		X		X		X		X		X		
Infection assessment[n]		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Quality of Life (FACT- BMT, EQ-5D-5L, EQ-5D-Y, EQ-5D-Y Proxy Version 1)[o]		X				X				X				X		X

Abbreviations: AdV = adenovirus; ALT = alanine aminotransferase; AST = aspartate aminotransferase; ; β-HCG = beta human chorionic gonadotropin; BKV = BK virus; CBC = complete blood count; CMV = cytomegalovirus; EBV = Epstein-Barr virus; ECG = electrocardiogram; ET = Early Termination Visit; GGT = gamma-glutamyl transferase; GVHD = graft versus host disease; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HHV-6 = human herpesvirus 6; I/E = inclusion and exclusion; IVIG = intravenous immunoglobulin; JCV = JC virus; LFT = liver function test; NA = not applicable; PBMC = peripheral blood mononuclear cell; SoA = Schedule of Activities; VST = virus-specific T cell; Wk = week

Note: Visits may be done via a home health visit as agreed with the Sponsor. Please see the Study Manual for more information.

[a] Unless noted otherwise, Day 1 procedures must be performed within 72 hours prior to study treatment administration.

[b] Dosing day may be up to +7 days with Sponsor approval.

[c] Adverse event monitoring should include the collection of all adverse events through the treatment period in all patients, including those who have discontinued study treatment but are continuing in the study. For patients who have discontinued, only drug-related SAEs and SAEs leading to death will be collected until Week 26.

[d] After treatment assignment, a targeted physical exam may be performed if a patient has any complaints. Post-HCT, the skin should be examined, even if the patient has no complaint, for evidence of rash/acute skin GVHD.

[e] Includes body temperature, blood pressure, heart rate, O_2 saturation, and respiration rate and will be measured after resting for 5 minutes. After treatment assignment, vital signs should be performed during and after infusions and if targeted physical examination is performed.

[f] Performed within 1 hour after study treatment administration and at the end of study or early termination visit, which are listed in the SoA for the Short-term Follow-up period (Table 8).

[g] Clinical laboratory assessments collected as part of standard of care may be used to fulfill these requirements. CBC must include differential and LFTs must include alkaline phosphatase, bilirubin (direct and indirect); GGT, AST, and ALT. Urinalysis must be performed. Laboratory safety evaluations (hematology, chemistry, and urinalysis) specified in the protocol will be performed prior to study drug initiation. These samples will be sent to the appropriate central laboratory(ies) following the procedure(s) described in the study manual(s).

[h] For female patients who are of childbearing potential, a urine pregnancy test will be performed at the site prior to study therapy initiation. If the urine pregnancy test result is negative, the patient will be eligible for treatment assignment and the remainder of the Day 1 testing/procedures will be performed. If the urine pregnancy result is positive, the patient must not be assigned to treatment and should reflex to a β-HCG blood test before screen failing. A urine pregnancy test will be performed prior to each treatment for female patients who are of childbearing potential.

[i] Viral loads of AdV, BKV, CMV, JCV, and HHV-6 in plasma and of EBV in PCMBs will be measured. See the Laboratory Manual for more detailed information on volume of blood draws. Additional post-infusion samples may be collected, as clinically indicated. If patient develops any clinically significant infection of AdV, BKV, CMV, EBV, HHV-6, or JCV at any point during the study periods, infection assessments should be followed prior to initiating standard of care therapy (see Section 8.3).

[j] Patients in Cohort OL will be assigned to ALVR105. Patients in Cohorts A and B will be randomized to either ALVR105 or placebo based upon the last viral load assessed and within 7 days of randomization. Treatment assignment will be about 2 to 3 days before Day 1.

[k] Patient peripheral blood mononuclear cells will be assessed for the presence of virus-reactive T cells using enzyme-linked immunospot.

[l] All patients will receive infusions of either ALVR105 or placebo. Patients will receive the same [redacted] dose for patients ≤40 kg or [redacted] dose for patients >40 kg for all infusions of ALVR105, administered at a dose interval of every 14 days (±3 days). Placebo infusions will be administered every other week in order to maintain the blind. As GVHD and CRS are a theoretical safety concern associated with administration of third-party allogeneic T cells, the incidence and severity of GVHD and CRS will be monitored during the study. No patients will be permitted to receive a subsequent infusion of ALVR105 if they develop new onset GVHD Grade >2 or worsening of GVHD (ie, relative to baseline GVHD at the time of enrollment into the study) at the proposed time for infusion of the next dose, or if they develop CRS Grade >2; if any patient develops GVHD or CRS, the Medical Monitor should be contacted immediately, and the patient treated per standard of care. If discontinued for CRS or GVHD these participants should be followed up to resolution of symptoms. Patients may resume treatment only with consultation and agreement between the Medical Monitor and the Investigator. If possible, IVIG and ALVR105 should not be administered on the same day.

[m] Patients will be monitored closely and must remain in the clinic for ≥1 hour after the end of each infusion. Vital signs, including body temperature, heart rate, O_2 saturation, respiration rate, and blood pressure, will be measured at the end of the infusion, and at 15, 30, 45, and 60 minutes after the end of the infusion. Patients must also remain on continuous pulse oximetry for ≥30 minutes after the end of the infusion. Post-infusion monitoring should be completed for all infusions of study treatment.

[n] The infection assessment will be performed for all patients who require either treatment for disease or initiation of preemptive therapy during both the primary study period and the follow-up period through Week 26. It is very important to ensure that all procedures, as outlined in the SoA, are performed immediately prior to the initiation of treatment of viral diseases or initiation of preemptive therapy (ie, on the day anti-viral therapy is initiated). Most importantly, a plasma sample for AdV, BKV, CMV, HHV-6, and JCV and a PBMC sample for EBV for PCR testing at the central laboratory should be collected. Patients who develop viral infections will continue to be followed in the study and complete all remaining visits through Week 26.

[o] Assessment of quality of life (using FACT-BMT, EQ-5D-5L, EQ-5D-Y, EQ-5D-Y Proxy Version 1questionnaires, as age-appropriate) should be completed prior to any study procedures at this visit.

Table 8. Schedule of Activities: Short-Term Follow-Up - Period 2, All Ages (Weeks 18 to 26, All Cohorts)

Study Week	Week 18	Week 22	Week 26/ET[a]
Study Day	**126**	**154**	**182**
Visit Window (Days)	**±3**	**±3**	**±3**
Study Procedures			
Prior & concomitant medications	X	X	X
Adverse events[b]	X	X	X
Weight			X
Vital signs	X	X	X
12-lead ECG			X
Clinical Labs			X
BKV, AdV, CMV, JCV, and HHV-6 viral load[c]		X	X
EBV PCMBs[c]		X	
Virus-Specific T Cell assessment[d]	X	X	X
Infection assessment[e]	X	X	X
Quality of Life (FACT-BMT and EQ-5D-5L, EQ-5D-Y, EQ-5D-Y Proxy Version 1)[f]	X	X	X

Abbreviations: AdV = adenovirus; ALT = alanine aminotransferase; AST = aspartate aminotransferase; BKV = BK virus; CBC = complete blood count; CMV = cytomegalovirus; EBV = Epstein-Barr virus; ECG = electrocardiogram; ET = Early Termination Visit; GVHD = graft versus host disease; HHV-6 = human herpesvirus 6; JCV = JC virus; LFT = liver function test; PBMCs = peripheral blood mononuclear cells

Note: Visits may be done via a home health visit as agreed with the Sponsor. Please see the Study Manual for more information.

[a] The Early Termination Visit will be performed for all patients who are prematurely discontinued from the study up to Week 26. It is very important to ensure that all procedures are performed in such patients at this visit prior to discontinuing the patient from the trial. Most importantly, a plasma sample for AdV, BKV, CMV, HHV-6, and JCV and a PCMB sample for EBV for PCR testing at the central laboratory should be collected at this visit.

[b] Adverse event monitoring should include the collection of all adverse events through follow-up in all patients, including those who have discontinued study treatment but are continuing in the study. Positive pregnancy and partner pregnancy information up to 90 days after last study drug administration will be collected.

[c] Viral loads of AdV, BKV, CMV, HHV-6, and JCV in plasma and in PCMBs for EBV will be measured and evaluated at the central lab. Additional post-infusion samples may be collected if clinically indicated. If patient develops any clinically significant infection of AdV, BKV, CMV, EBV, HHV-6, or JCV at any point during the study periods, infection assessments should be completed prior to initiating standard of care therapy.

[d] Patient peripheral blood mononuclear cells will be assessed for the presence of virus-reactive T cells using enzyme-linked immunospot.

[e] The infection assessment will be performed for all patients who require either treatment for disease or initiation of preemptive therapy during both the primary study period and the follow-up period through Week 26. It is very important to ensure that all procedures, as outlined in the SoA, are performed immediately prior to the initiation of treatment of viral diseases or initiation of preemptive therapy (ie, on the day anti-viral therapy is initiated). Most importantly, a plasma

sample for AdV, BKV, CMV, HHV-6, and JCV and a PCMB sample for EBV for PCR testing at the central laboratory should be collected. After developing an infection, such patients will continue to be followed in the study and complete all remaining visits through Week 26.

[f] Assessment of quality of life (using FACT-BMT, EQ-5D-5L, EQ-5D-Y, and EQ-5D-Y Proxy Version 1questionnaires, as age-appropriate) should be completed prior to any study procedures at this visit.