STATISTICAL ANALYSIS PLAN

REGiMMUNE Corporation

Protocol: RGI-2001-003

An Open-Label, Non-Randomized Multicenter Phase 2b, Study with a Safety Run-in to Evaluate the Safety and Efficacy of RGI-2001 for the Prevention of Acute Graft-Versus-Host Disease (aGvHD) Compared to Contemporary Controls in Subjects Following Allogeneic Hematopoietic Stem Cell Transplantation (alloHSCT). NCT04014790

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LIST OF ABBREVIATIONS

aGVHD	Acute Graft-versus-host disease
AE	Adverse event
alloHSCT	alloHSCT Allogeneic Hematopoietic Stem Cell Transplantation
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
cGVHD	Chronic Graft-versus-host disease
CIBMTR	Center for International Bone and Marrow Transplant Research
CTCAE	Common Terminology Criteria for Adverse Events
DFS	Disease-Free Survival
DLT	Dose-Limiting Toxicity
eCRF	Electronic case report form
ECG	Electrocardiogram
EOS	End of Study
GFS	GVHD-free survival
GRFS	GVHD-free, relapse-free survival
GVHD	Graft-versus-Host Disease
HSCT	Hematopoietic Stem Cell Transplant
iNKT	invariant Natural Killer T
ITT	Intent-to-Treat
MedDRA	Medical Dictionary for Regulatory Activities
Mg	Milligrams
MRD	Matched-related donor
NRM	Non-relapse Mortality
OS	Overall Survival
PD	Pharmacodynamic
PK	Pharmacokinetic
PT	Preferred Term
RFS	Relapse-free Survival
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis Software
SD	Standard Deviation (statistical parameter)
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
Treg	Regulatory T cells
URD	Unrelated donor
WHO	World Health Organization

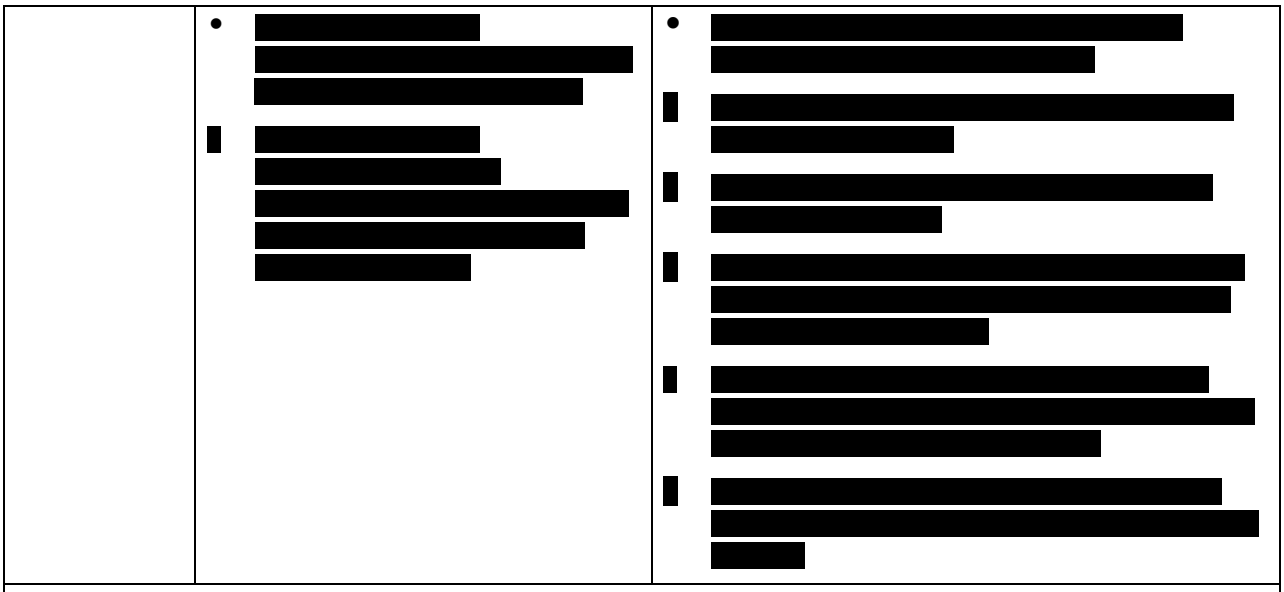
Note: The first occurrence of some abbreviations is not spelled out in the document (e.g. units of measure).

1.0 STUDY INTRODUCTION

This statistical analysis plan is based on the protocol "*An Open-Label, Non-Randomized Multicenter Phase 2b, Study with a Safety Run-in to Evaluate the Safety and Efficacy of RGI-2001 for the Prevention of Acute Graft-Versus-Host Disease (aGvHD) Compared to Contemporary Controls in Subjects Following Allogeneic Hematopoietic Stem Cell Transplantation (alloHSCT)*", Version 2.0, dated 06 March 2020.

1.1 Study Objectives and Endpoints

Type	Objectives	Endpoints
Primary	• To assess the potential efficacy of RGI-2001 in addition to standard of care (SOC) vs SOC for the prevention of acute GvHD (aGvHD) • To characterize the safety and tolerability of 6 weekly intravenous (IV) infusions of RGI-2001 in subjects following alloHSCT	• Efficacy: Grades II-IV aGvHD by Day 100 according to the Modified Keystone Criteria • Safety: Incidence, nature, and severity of treatment-emergent AEs, SAEs, laboratory test values, vital-sign measures, and graft failure
Secondary	• To assess the potential efficacy of RGI-2001 in addition to SOC vs SOC for the prevention of chronic GvHD (cGvHD) according to the secondary endpoints listed • To assess the survival of subjects who received RGI-2001 in addition to SOC vs SOC • To evaluate the pharmacodynamics (PD) effects of weekly dosing of RGI-2001	• Grades II-IV aGvHD by Day 180 according to the Modified Keystone Criteria • Total and moderate-severe cGvHD at 6 months and 1 year according to the 2014 NIH criteria for cGvHD • Non-relapse mortality (NRM) rates at Day 100, 6 months and 1 year • Disease-free survival (DFS) at 6 months and 1 year • GvHD-free, relapse-free survival (GRFS)[a] at 6 months and 1 year • Overall survival (OS) at 6 months and 1 year • Change from baseline in the percentage of CD4+CD25+CD45RA+ CD127-LO T cells (naive Tregs) on Days 14, 28, 42, 60, 100, 180
[redacted]	• [redacted]	[redacted]



[a] A GRFS event includes Grade III-IV aGVHD, cmoderate-to-severe GvHD requiring systemic immunosuppressive treatment, disease relapse or progression, or death by any cause.

2.0 STUDY DESIGN

2.1 Overview of Study Design

This is an open-label, multi-center, single-arm study to evaluate six weekly doses of RGI-2001 in combination with SOC treatment for the prevention of aGvHD in subjects following alloHSCT. Subjects will be followed for safety and adverse events during a one-year follow-up period after alloHSCT, including a 6-week treatment period and a 42-week follow-up period. In addition, there is a screening period lasting approximately 2 weeks.

Study subjects' data will be compared to a contemporaneous set of control subjects' data from the Center for International Bone and Marrow Transplant Research (CIBMTR). A description of and statistical plan for this comparison is contained in a SAP specific to that goal and separate from the current SAP.

The visit schedule for the study is provided in the protocol, Section 3.

2.2 Control Group

A non-randomized, contemporary control group from the CIBMTR database will be derived for comparison. Control subjects were selected based on eligibility requirements set forth in the protocol, Section 7. As noted above, a SAP specific to this comparison is provided separate from the current SAP.

2.3 **Sample Size**

As described in Section 12.1 of the protocol, the study plans to enroll and treat 50 subjects with RGI-2001. "Control" subjects who would have been eligible for this trial will be obtained from the CIBMTR and used for a non-randomized comparator group (details in a separate SAP).

2.4 **Study Population**

The study population consists of adult subjects aged 18 or older with specific hematologic malignancies (e.g., AML, ALL, MDS, MPD) and meeting specific inclusion/exclusion criteria (outlined in protocol, Sections 7.1 and 7.2). All subjects were assessed for suitability of alloHSCT based on institutional practice, using either a matched-related donor (MRD) or an unrelated donor (URD), and were enrolled after meeting the inclusion/exclusion criteria for this study.

2.5 **Randomization/Blinding**

This is an open-label study and there is no randomization or blinding.

2.6 **Treatment Administration**

All subjects were to receive 6 weekly doses of RGI-2001 100 μg/kg via IV administration over 30 minutes.

3.0 **ANALYSIS POPULATIONS**

As defined in the protocol the Safety Analysis Population will include all subjects with at least one infusion of study drug. Because this study is not randomized, this population is the same as the traditional intent-to-treat analysis population (ITT), excluding subjects that did not proceed with treatment. This population will be used for both the efficacy and safety analyses.

Per protocol "Subjects who do not complete the DLT window for reasons other than toxicity may be replaced". Since no subjects met this criterion, no replacement rules will be implemented in the analysis.

4.0 **STATISTICAL METHODS OF ANALYSIS**

4.1 **Statistical Considerations**

Continuous variables will be summarized (based on the subjects with non-missing values) by the number of subjects (n), mean, standard deviation (SD), median, minimum value, and maximum value. Mean and median will be accurate to one more digit decimal point than the original data, and standard deviation will be accurate to two more-digit decimal points than the original data, and the decimal points of the maximum and minimum values will be the same as the original data.

Categorical variables will be summarized (based on the subjects with non-missing values) by the frequency (count and percent) of subjects falling within the category. The denominator for all

percentages, unless otherwise specified, will be the number of subjects in the specified analysis population.

Point estimates of time-to-event outcomes will be obtained using either Kaplan-Meier or cumulative incidence estimates, depending on whether endpoints have competing risks. Survival at a variety of specific endpoints will be presented in the tabled output, including Day 100 (i.e., primary endpoint for aGvHD) and Day 365 (i.e., EOS). In addition (if applicable), the median length of survival (in days) will be presented. Furthermore, listed data for all time-to-event outcomes will be provided.

Regarding the time-to-event estimates, the time between begin and end dates for events and censors is important in the calculation. If either of the dates are invalid, then the 1st will be assumed (for missing day) and/or January will be assumed (for missing month). Assumptions will only be incorporated into the analysis if calculation of time does not result in a negative number of days. If negative, the subject will not be used in the analysis. If assumptions are needed, they will be flagged in the listings.

Almost all data from the electronic case report form (eCRF) will be listed. For example, time (mm:hh) will be excluded from almost all listings except for the PK and PD listings. From lab listings, the lab name and the original value for the dose in the units collected on the eCRF will be excluded and replaced with the value in SI units. Also a few variables collected on the AE eCRF and other eCRFs will be excluded from the listings.

Baseline will be defined as the last assessment completed prior to the administration of the study drug (Day 0, which corresponds with date of transplant).

4.2 **Methods for Handling Dose Changes**

All subjects are scheduled to receive 6 weekly doses of RGI-2001 100 µg/kg via IV administration. Deviations from this schedule or dose will be included in the administration list, and will also be displayed in the summary table that is analyzed with continuous methods (e.g., displaying mean, minimum, and maximum).

4.3 **Methods for Handling Missing Data**

No imputations will be made for missing data, except as described for the time-to-event analyses in Section 4.1 (above).

4.4 **Interim Analysis**

There will be no interim analyses described within the scope of this SAP.

5.0 STUDY SUMMARY

5.1 Subject Disposition

Subject disposition will be summarized for all subjects by frequency counts and percentages of completed and discontinued status along with reason for discontinuation. This summary analysis will be based on all subjects in the clinical study database. Subject disposition for all subjects will be listed. Furthermore, a summary table for death will be reported.

5.2 Protocol Deviations

A by-subject listing will be provided for all protocol deviations for all subjects. Major Protocol deviations will be summarized in a table.

6.0 EVALUATION OF DEMOGRAPHICS, BASELINE CHARACTERISTICS, AND PROPHYLACTIC TREATMENT

All analyses in this section will be performed using the Safety Population.

6.1 Demographics

Using the Safety Analysis Population, demographics (age, sex, race, and ethnicity) will be summarized using categorical and continuous methods, as appropriate. A by-subject listing will also be provided.

6.2 Baseline Characteristics

A by-subject listing will be provided with height, weight, and BMI. In addition, a summary table will be provided.

6.3 Disease Status Prior to HSCT

A table will be provided to summarize: time since initial diagnosis, type of disease prior to HSCT, and other pre-enrollment disease characteristics collected on the *Initial Disease Status and Evaluation Prior to HSCT* eCRF. A by-subject listing will also be provided.

6.4 Graft Source and Donor Characteristics

A table will be provided to summarize: donor/recipient sex matching, graft source, donor relationship to the subject, and donor/recipient CMV serostatus. A by-subject listing will also be provided.

6.5 Preparative Conditioning Regimen

A summary table will be provided. In addition, a by-subject listing will be provided with regimen, dose, route, start date, and other preparative information.

6.6 Concomitant Medications

Per protocol, concomitant medications are any prescription or over-the-counter preparations used from 2 days prior to the preparatory regimen before Day 0 through the end of the subject's study participation.

Medications will be coded using the World Health Organization (WHO) Drug Reference List version 1Q2019. These will be summarized via categorical methods by ATC class and preferred term, and all will be provided in a by-subject listing.

In addition to the summary table for all concomitant medication, two subset tables will be presented. The first will be a summary table to describe the concomitant medications given as aGvHD prophylaxis. The second will be a summary table to describe the concomitant therapies given as treatment for GvHD with the first 100 days. This second table will include a summary of the total dose received. Total Dose will be calculated as: Daily Dose (in mg units) * Adjusted_Duration (in days), where Daily Dose and Adjusted_Duration are defined per below using the start/stop/frequency/unit information recorded on the Concomitant Medication eCRF.

Daily Dose	First calculate, Dose_mg: • If "Dose Unit" (on eCRF) = mg then Dose_mg = "Dose" (from eCRF) • If the "Dose Unit" (on eCRF) not mg then calculate the dose for conversion to mg Next calculate, Daily_Dose: • If "Frequency" (on eCRF) = daily then Daily_Dose = Dose_mg • If "Frequency" (on eCRF) = twice daily then Daily_Dose = Dose_mg*2 • If "Frequency" (on eCRF) = every other day then Daily_Dose = Dose_mg*0.5 • If "Frequency" (on eCRF) is specified differently than the examples above, use similar logic to adjust in order to obtain the "Daily_Dose".
Adjusted_Duration (days)	First a *Day100* variable: • Day100 = Date of first treatment with RGI-2001 (ie, Start Date [Day 0]) plus 100 Next calculate, Adjusted_Duration: • If Stop Date is provided and Stop Date ≤ Day100 then Duration = Stop Date minus Start Date plus 1. • If Stop Date is provided and Stop Date > Day100 then Duration = Date_100 minus Start Date plus 1. • If Stop Date is not provided then Duration = Day100 minus Start Date plus 1.

7.0 **TREATMENT EXPOSURE**

Exposure to RGI-2001 will be summarized by the number of doses administered and the duration of exposure. The duration of exposure will be derived as the difference between the first administration date and the last administration date.

Actual dose intensity (µg/kg/day) and the dose intensity (%) relative to the planned dose will be determined and summarized.

A by-subject listings will also be provided.

8.0 EVALUATION OF EFFICACY PARAMETERS

All efficacy analyses will be performed on the Safety Analysis Population. As noted above, outcomes will ultimately be compared to data obtained from the CIBMTR and details of this comparison are contained in a separate SAP that is specific to this goal. Methods for estimation of efficacy parameters are provided below without mention of the methods that will be used for comparing efficacy parameters to the CIBMTR data.

Binary outcomes will be summarized with proportions, continuous outcomes with means and medians, and time-to-event outcomes with Kaplan-Meier estimates or cumulative incidence estimates for endpoints with competing risks.

Definitions of occurrence and timing of outcomes are described below.

8.1 Acute GVHD

For the primary and secondary endpoints as well as certain exploratory endpoints, Keystone criteria will be used for the determination of the severity of aGVHD. For outcomes at a defined time points, the event time will be defined as the time from the "start date" of first RGI-2001 infusion (i.e., transplant date/Day 0) to the first date aGvHD is diagnosed with Keystone criteria Grades II-IV. The first date of aGVHD will be identified using the following eCRFs:

- Initial report*: aGvHD_d* eCRFs with Question 10 = II-IV (i.e., Keystone Grades)
- Maximum report: *aGvHDmax* eCRFs with Question 1 = II-IV (i.e., Keystone Grades)

The first diagnosis date across the eCRFs meeting the above criteria will be used to define the "event time" for this analysis. Censoring: Subjects who are alive without these events will be censored at the date of completion of the last aGvHD assessment, with follow-up truncated at 180 days. Subjects who die without aGVHD will be treated as competing-risk events. The occurrence of aGVHD as a function of time will be calculated using cumulative-incidence estimates.

As an exploratory outcome, MAGIC criteria will be used for the determination of the severity of aGVHD. Event time will be defined as the time from the "start date" of first RGI-2001 infusion to the first date aGvHD is diagnosed with MAGIC criteria Grades II-IV The first date will be identified using the following eCRFs:

- Initial report*: aGvHD_d* eCRFs with Question 8 = II-IV (i.e., MAGIC Grades)
- Maximum report: *aGvHDmax* eCRFs with any of the following three categories:
    - Grade II: Stage 3 skin and/or stage 1 liver and/or stage 1 upper GI and/or stage 1 lower GI (questions 3,4,5, and 6 on the eCRF)
    - Grade III: Stage 2-3 liver and/or stage 2-3 lower GI, with stage 0-3 skin and/or stage 0-1 upper GI
    - Grade IV: Stage 4 skin, liver, or lower GI involvement, with stage 0-1 upper GI

The first diagnosis date across the eCRFs meeting the above criteria will be used to define the "event time" for this analysis. Censoring and competing-risk considerations will be the same as with the Keystone criteria (above). The occurrence of aGVHD as a function of time will be calculated using cumulative-incidence estimates.

Similar to above, the analysis will be repeated for Keystone and Magic separately using only Grades III and IV.

8.2 **Chronic GvHD**

Chronic GvHD (cGvHD) will be summarized visually as a function of time up to one year as a cumulative incidence estimates as well as by-visit frequency analysis.

Severity ratings according to 2014 NIH Criteria will be used. Event time will be defined as the time from the "start date" of first RGI-2001 infusion (i.e., transplant date) to the first date cGvHD is diagnosed with moderate or severe cGvHD (if multiple cGvHD_d eCRFs exist with moderate/severe ratings, the first diagnosis date across the eCRFs will be used for this event). Censoring: Subjects who are alive without these events will be censored at the date of completion of the last cGvHD assessment, with follow-up truncated at one year (365 days). Subjects who die or relapse without cGVHD will be treated as competing-risk events at the time of death. The occurrence of cGVHD as a function of time will be calculated using cumulative-incidence estimates.

Similar to above, the analysis will be repeated for using all severities (not just moderate and severe).

8.3 **Overall Survival**

Overall survival (OS) probabilities will be calculated using Kaplan-Meier methodology. Overall survival will be defined as the time from the "start date" of first RGI-2001 infusion to the date of death due to any cause. Death date will be obtained from *Discontinuation* eCRF. Censoring: Subjects who are known to have not died are censored at the date last known to be alive (usually EOS visit date), with follow-up truncated at one year (365 days). There are no competing risk events. Kaplan-Meier estimates of this endpoint as a function of time will be provide for visual purposes.

8.4 **Disease-Free Survival (DFS)**

DFS rates (synonymous with Relapse-Free Survival [RFS]) will be calculated using Kaplan-Meier methodology. For each subject, DFS will be calculated as time from the "start date" of first RGI-2001 infusion to relapse, disease progression, or death from any cause, whichever occurs first. Censoring: Subjects who do not experience any DFS events will be censored on the last evaluation of relapse/progression (using the *Disease Status Follow-up* eCRF), with follow-up not extending beyond one year. There are no competing risk events. Kaplan-Meier estimates of this endpoint as a function of time will be provide for visual purposes.

Date of first relapse will be obtained using the *Disease Status Follow-up* eCRF where Question 7 "Disease Status" = "1st relapse" or "Relapse from complete remission". This eCRF contains three dates: Question 1 Date of Bone Marrow Aspirate, Question 2 Date of Bone Marrow Biopsy, and Visit Date. If multiple dates are provided, the first will be used to define the Date of First Relapse.

Date of first progression will be obtained using the *Disease Status Follow-up* eCRF where Question 7 "Disease Status" = "Progression from hematologic improvement". Similar to relapse, the first of the three dates will be used to define the Date of First Progression.

8.5 **Non-Relapse Mortality (NRM)**

Non-relapse mortality (NRM) rates will be calculated using a cumulative incidence estimate for visual purposes. NRM will be defined as the occurrence of death without prior relapse, with relapse a competing risk for NRM. For each subject, time to death will be calculated as described in the above OS section and time to relapse will be calculated as described in the DFS section.

Event and censoring assignments will proceed as follows:

- Subjects with no relapse and no death will be censored at the last time known to be alive.
- Subjects with no relapse who die will be counted as events.
- Subjects with relapse will be considered a competing risk at the time of first relapse.
- Follow-up will not extend beyond one year.

8.6 **Acute GVHD-Free Survival (GFS)**

Failure for the composite endpoint Grades II-IV aGvHD-free survival at Day 180 is the occurrence of Grades II-IV aGvHD by Day 180 or death. The time of failure, if both components occur, is the earliest of the two failures; if only one component occurs time of failure is the day of that failure. Grades III-IV aGvHD-free survival at Day 180 will also be calculated. For each of these, aGvHD will be graded according to Keystone criteria. Kaplan-Meier estimates of each will be provided for visual purposes, and in addition to the point estimates at Day 180, point estimates at one year will also be provided. Censoring is performed as described in the Acute GVHD and Overall Survival sections above. There are no competing risk events.

8.7 **GvHD-Free, Relapse-Free Survival (GRFS)**

GRFS rates will be calculated using Kaplan-Meier methodology. For each subject, GRFS will be calculated as time from first infusion of RGI-2001 to date of Grade III-IV aGVHD (defined below), moderate-to-severe cGVHD requiring systemic immune suppression (defined below), disease relapse or progression (defined above), or death by any cause (using *Discontinuation* eCRF), whichever occurs first. Censoring: Subjects who do not experience any of these events will

be censored on the last evaluation of relapse/progression (3 dates from last *Disease Status* eCRF), with follow-up truncated at one year (365 days). There are no competing risk events.

Date of first Grade III-IV aGvHD will be obtained using Keystone Grading and the diagnosis date recorded on the *aGvHD_d* eCRF.

Date of first use of systemic therapy for cGvHD will be defined using the *Concomitant Medication* eCRF as described in "Time to First Use of Systemic Therapy for GvHD" section below.

8.8 **Time to First Use of Systemic Therapy for GvHD**

Date of first use of systemic therapy will be defined using the *Concomitant Medication* eCRF. A subset of the *Concomitant Medication* eCRFs will be used to identify the first start date for the medication; this subset is defined in the TLF attachment on the applicable table. This time analysis will be tabulated using continuous methods (mean/median/etc), and number of patients with at least one of these medications will be calculated using a simple proportion of the safety population.

9.0 **EVALUATION OF SAFETY PARAMETERS**

All safety analyses will be performed using the Safety Analysis population.

9.1 **Adverse Events**

Per protocol, an adverse event is defined as "any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment" (examples delineated in the protocol Section 10.1).

Severity is defined from 1(mild) through 5(fatal), as described in protocol Section 10.2.2.

An AE is considered as treatment emergent (TEAE) if it appears on or after the first dose date of RGI-2001, or was already present and worsened after the first dose date, up to 30 days after the last RGI-2001 dose date. Any medical condition that is present at the time that the subject is screened will be considered as baseline and not be reported as an AE (instead as medical history). However, if the subject's condition deteriorates at any time during the study, it will be recorded as an AE. Almost all AEs collected on the eCRFs will be considered TEAEs, no onset dates will be imputed. If an onset date is missing/invalid, then only included in listing and not included in summary table. If AE onset date is >30 days after the last RGI-2001 dose date, then it will not be considered a TEAE and therefore not included in the summary tables (only included in the listings).

A summary table of TEAEs with a count and percent of subjects in various TEAE categories will be provided (for example: one or more TEAEs, study-medication related TEAEs, serious TEAEs, discontinued due to TEAEs).

Verbatim adverse events will be mapped to preferred term (PT) and system organ class (SOC) using MedDRA V22.0. All TEAEs will be summarized with frequency counts and percentages by

MedDRA SOC and PT. A subject with multiple occurrences of an AE will be counted only once in the AE SOC-PT category in summary tables.

Incidences of TEAEs by SOC and PT will be summarized by counts and percentages and provided for: (1) overall for all TEAEs and (2) various subsets (for example, Serious TEAEs, Related TEAEs, Grade 3 or 4 TEAEs, etc.).

In addition, incidences of TEAEs by PT (not SOC) will be summarized by counts and percentages and provided for: (1) overall for all TEAEs and (2) various subsets. For these PT-specific summary tables, the following hematologic preferred terms will be grouped and summarized under a common term: thrombocytopenia (i.e., thrombocytopenia and platelet count decreased), leukopenia (i.e., leukopenia and white blood cell count decreased), neutropenia (i.e., neutropenia and neutrophil count decreased), anemia (i.e., anemia and red blood cell count decreased), and lymphopenia (i.e., lymphopenia and lymphocyte decreased).

All AEs will be provided in a by-subject listing, as well as individual AE listings for various subsets (e.g., serious, leading to study discontinuation, etc.).

The by-subject listings will include the duration of each event. Duration will be calculated as the stop date of the event minus the start date, unless the event is determined ongoing at exit. Duration will not be calculated for events with invalid start/stop dates, where invalid is defined as a non-calendar date (e.g., 32-dec-2021, 15-hex-2020).

9.2 **Infections**

Incidence of any TEAE infection will be provided, as well as a frequency distribution to describe the type of infection (e.g., bacterial/viral/fungal). These will also be provided in a by-subject listing.

9.3 **Myeloid and Platelet Engraftment**

Per protocol, “Myeloid engraftment will be defined as the first of 3 consecutive days when the absolute neutrophil counts (ANC) exceeds 0.5 x 10^9/L and platelet engraftment will be defined as the first of 3 consecutive days when the platelet count exceeds 20 x 10^9/L without transfusion support.”.

The time to ANC engraftment will be calculated based on the date recorded in the CRF by the sites (calculated as: Date of ANC Recovery minus Initial RGI-2001 Infusion date). Engraftment times (using the first date for each subject) will be summarized using continuous methods among those who engraft, and the median time to ANC engraftment will be estimated as the time that the cumulative incidence estimate of the probability of engraftment reaches or exceeds 0.5 x10^9/L.

Similar tabulated analyses will be presented for time of platelet recovery/engraftment.

9.4 Vital Signs

Vital signs including systolic and diastolic blood pressure (BP), body temperature, heart rate, and respiratory rate were to be obtained within 15 minutes prior to RGI-2001 infusion and were to be repeated within 30 minutes after the infusion. These will be summarized in a table and provided in a by-subject listing.

9.5 Karnofsky Performance Status

The Karnofsky Performance Status (scale ranging from 0-100) is collected at screening and at various timepoints throughout the Treatment and Follow-Up Periods, as indicated in the schedule of events in the protocol. This score will be summarized at baseline and Day 60, with change from baseline to Day 60. The analysis will be performed using continuous methods. All data, including other timepoints besides Day 60 will be provided in a by-subject listing.

9.6 Evaluation of Laboratory Parameters

Chemistry, hematology, urinalysis, coagulation and other laboratory parameters will be collected at screening and various timepoints throughout the treatment and follow-up periods, as indicated in the schedule of events in the protocol.

Local laboratories were used for all laboratory assessments. Laboratory testing, results, and normal ranges were provided by local laboratories. Out-of-range values (i.e., “low”, “normal”, or “high”) will be derived by the Sponsor’s database using the normal ranges provided by the individual local laboratories. Descriptive statistics by visit for laboratory parameters will be provided including change from baseline; these summaries will be based on SI units since each local laboratories may record values using different units.

In addition, for selected parameters, shift tables from baseline and figures of the values over time will be provided. For these selected parameters, if applicable, grading will be assigned using CTCAE version 5.0 guidelines (Appendix A) and summary tables will be provided.

9.7 Evaluation of Donor/Host Chimerism

Chimerism (method, cell source, number of donor cells and percent donor cells) will be presented in a by-subject listing.

9.8 Evaluation of Other Safety Parameters

Physical Exam and Urine Pregnancy Test were to be performed or measured at the scheduled time-points as indicated in the schedule of events in the protocol. A by-subject listing will be provided for each of them.

Pharmacokinetic, pharmacodynamics and biomarker endpoints (as described in Protocol Sections 9.3.2-9.3.4) will be analyzed outside the scope of this SAP; separate reports will be created, as needed.

10.0 CONVENTIONS FOR CALCULATIONS AND TABULATIONS

Table 10.0 Conventions for Calculations and Tabulations

CONVENTION	DESCRIPTION
Age calculation	Age is derived within the database; it will not be calculated in SAS (Statistical Analysis Software). It is calculated as an integer in years as the difference between the subject's date of informed consent and the date of birth.
Baseline	Baseline is defined as the last assessment completed prior to the administration of the study drug on Day 0, (which also corresponds to date of transplant), unless specified otherwise.
Study Day	Date of visit or evaluation – date of first administration of RGI-2001. Per protocol, the first dose will be administered on Day 0.
Percentage calculation	Percentages are calculated as 100 x (numerator/denominator). Rounding is not necessary because rounding is handled by the display format. Denominator is the total number of subjects in a column group unless otherwise specified.
AE counting: general summary	In summary displays, AEs are counted only once per subject within a category (e.g., overall and preferred term).
AE counting: summary by assessment	When AEs are summarized within levels of another AE assessment (e.g., causality or severity), AEs are counted once per subject at the worst level of the assessment (e.g., least complementary relationship or greatest severity).
Change from Baseline	Current visit value – baseline visit value
Percent Change from Baseline	100 x ((current visit value – baseline visit value) / baseline visit value)

11.0 SPECIFICATIONS FOR ANALYSIS DISPLAYS

All headers, titles, footnotes, and footers specified in the table and listing shells will be displayed in the produced output. Notes to the programmer will not be included in the produced output. Any minor deviation will not necessitate a revision to the Statistical Analysis Plan (SAP) nor will it be considered a deviation from planned analyses. Only major differences in the analysis methods or

data handling will necessitate such documentation. The shells of tables and listings will be provided in a separate document from this SAP.

11.1 **Format**

All analysis displays will be created by using statistical and summarization procedures in SAS®, Version 9.4 or later, using a line size of 132 and a page size of 50. All margins of all tables and listings will be a minimum of 0.8 inch.

All displays are intended to be printed in landscape layout unless otherwise specified.

At the top of each table/listing, a number followed by the title will be presented. After the title line, a sub-title or population information may be presented. Horizontal lines will appear before and after the column heading of the table/listing. Footnotes will be under the main body of the table or listing display.

The sponsor's name, protocol number, status of the output (i.e., draft or final), SAS program name, and the date and time of creation will be on the output. The page number will appear on the upper right corner of each output (Page X of Y).

Also included will be the source of the data (SDTM module for Listings, and Listing number for Tables).

Conventions for Tables

Tables will be delivered to the sponsor in Microsoft Word, Times New Roman, 10-point font. If necessary for formatting, an alternate font type or size may be used. The conventions for the analysis displays are shown in Table 11.1.1.

Table 11.1.1 Conventions for Tables

CONVENTION	DESCRIPTION
Decimals for summary statistics	General Rule: Relative to the number of decimals in the original data, 1 more decimal for the mean, median, and percentiles, 2 more decimals for standard deviation (SD) will be displayed, and the same number for minimum, maximum, and/or range. The maximum number of decimals will be 4. Some lab parameters or other data may require judicious deviation from this rule. Wherever possible, data will be decimal aligned.
Decimals and format for percentages	Unless otherwise specified, frequency tabulations will be presented by number and percentage, with the percentage in parentheses following the number. Percentages will be displayed to 1 decimal. A count of zero will exclude any percentage

	display. The '%' will not follow the percentage value if 'n (%)' is displayed in the column header.

Conventions for Listings

Listings will be delivered to the sponsor in Microsoft Word, Courier New, 8-point font. If necessary for formatting, an alternate font type or size may be used. The conventions for the listings are shown in Table 11.1.2 and apply for each listing where relevant.

Table 11.1.2 Conventions for Listings

CONVENTION	DESCRIPTION
Population	All enrolled subjects will be included unless otherwise specified.
Subject Number	Subject numbers will be displayed as site number – subject number (XX-XXX).
Dates	Date information in the listing will use the *date9.* format (i.e., 01JAN2011) where possible. Otherwise, date formats will be displayed as recorded on the eCRF.
Unknown	'U' will represent 'Unknown' in date variables and categorical variables unless otherwise specified on the eCRF.
Missing Values	Missing values will be listed as represented in the clinical database (e.g., blanks, 'NR' for not reported).
Variable Units	In the listings, a unit associated with a variable will be presented within parentheses in the column label.
Visit Description	A visit column will be provided with the visit label and an adjacent column with the corresponding date of evaluation, if available. Screening will be the label for screening visits.
Sort Order	All listings will be sorted by subject number, followed by the visit date (if available), then by collection date (if available), then time (if available), or in the case of AEs and medications, start date followed by stop date.

11.2 **Summary Tables to Be Provided**

Table 11.2 Summary Tables

Table Number and Title	**Analysis Population**
Table 14.1.1: Subject Disposition (All Subjects)	All
Table 14.1.2: Deaths	Safety Analysis
Table 14.1.3: Subject Enrollment by Site	Safety Analysis
Table 14.1.4: Major Protocol Deviations	Safety Analysis
Table 14.1.5: Demographics	Safety Analysis
Table 14.1.6: Study Disease Characteristics	Safety Analysis
Table 14.1.7: Donor Characteristics (Safety Population)	Safety Analysis
Table 14.1.8: Conditioning Regimen (Safety Population)	Safety Analysis
Table 14.1.9: RGI-2001 Treatment Exposure (Safety Population)	Safety Analysis
Table 14.1.10: Concomitant Medications (Safety Population)	Safety Analysis
Table 14.1.11: Concomitant Medications Given as Acute GvHD Prophylaxis (Safety Population)	Safety Analysis
Table 14.1.12: Systemic Steroids and Other Therapies Given for Treatment of GvHD (Safety Population)	Safety Analysis
Table 14.2.2.1: Acute GVHD Incidence (Safety Population)	Safety Analysis
Table 14.2.2.2: Chronic GVHD Incidence (Safety Population)	Safety Analysis
Table 14.2.2.3: Acute GVHD by Organ by Stage by Keystone Criteria - Incidence (Safety Population)	Safety Analysis
Table 14.2.2.4: Acute GVHD by Organ by Stage by MAGIC Criteria - Incidence (Safety Population)	Safety Analysis
Table 14.2.2.5: Acute GvHD-Free Survival (GFS) using Keystone Criteria (Safety Analysis Population)	Safety Analysis
Table 14.2.2.6: Non-Relapse Mortality (NRM) (Safety Analysis Population)	Safety Analysis
Table 14.2.2.7: GvHD-Free, Relapse-Free survival (GRFS) (Safety Analysis Population)	Safety Analysis
Table 14.2.2.8: Overall Survival (OS) (Safety Analysis Population)	Safety Analysis
Table 14.2.2.9: Relapse-Free survival (RFS) (Safety Analysis Population)	Safety Analysis
Table 14.2.2.10: Time to Myeloid Engraftment (Safety Analysis Population)	Safety Analysis
Table 14.2.2.11: Time to Platelet Engraftment Criteria (Safety Analysis Population)	Safety Analysis
Table 14.2.3: Karnofsky Performance Status – Observed and Change from Baseline (Safety Population)	Safety Analysis
Table 14.3.1.1: Summary of Treatment-Emergent Adverse Events (Safety Population)	Safety Analysis
Table 14.3.1.2: Treatment-Emergent Adverse Events - Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.3: Serious TEAEs – Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis

Table Number and Title	Analysis Population
Table 14.3.1.4: Related TEAEs – Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.5: Serious and Related TEAEs – Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.6: Grade 3 or 4 TEAEs – Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.7: Grade 3 or 4 TEAEs and Related – Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.8: Grade 5 TEAEs – Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.9: Grade 5 TEAEs and Related – Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.10: TEAEs occurring in ≥20% of Subjects– Incidence by SOC and Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.11: TEAEs – Incidence by SOC and Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.12: Grade 3 or 4 TEAEs – Incidence by SOC, Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.13: Grade 3 or 4 TEAEs and Related – Incidence by SOC, Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.14: TEAEs occurring in ≥20% of Subjects– Incidence by SOC, Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.15: TEAEs Leading to RGI-2001 Dose Interruption or Reduction – Incidence by SOC, Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.16: TEAEs Leading to Discontinuation of RGI-2001 – Incidence by SOC, Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.17: TEAEs Leading to Discontinuation from the Study – Incidence by SOC, Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.18: TEAEs with Dose-Limiting Toxicity – Incidence by SOC, Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.19: Infection TEAEs – Incidence by SOC, Preferred Term, and Worst Grade (Safety Population)	Safety Analysis
Table 14.3.1.20: TEAEs – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.21: Related TEAEs – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.22: Serious TEAEs – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.23: Grade 3 or 4 TEAEs – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.24: Grade 3 or 4 TEAEs and Related – Incidence by Preferred Term (Safety Population)	Safety Analysis

Table Number and Title	Analysis Population
Table 14.3.1.25: Grade 5 TEAEs – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.26: Grade 5 TEAEs and Related – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.27: TEAEs occurring in ≥20% of Subjects– Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.28: TEAEs Leading to RGI-2001 Dose Interruption or Reduction – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.29: TEAEs Leading to Discontinuation of RGI-2001 – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.30: TEAEs Leading to Discontinuation from the Study – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.31: TEAEs with Dose-Limiting Toxicity – Incidence by Preferred Term (Safety Population)	Safety Analysis
Table 14.3.1.32: Treatment-Emergent Infections by Type (Safety Population)	Safety Analysis
Table 14.3.5.1: Serum Chemistry Laboratory Values – Observed and Change from Baseline (Safety Population)	Safety Analysis
Table 14.3.5.2: Hematology Laboratory Values – Observed and Change from Baseline (Safety Population)	Safety Analysis
Table 14.3.5.3: Coagulation Laboratory Values – Observed and Change from Baseline (Safety Population)	Safety Analysis
Table 14.3.5.4: Urinalysis Laboratory Values – Observed and Change from Baseline (Safety Population)	Safety Analysis
Table 14.3.5.5: ECG Parameter Values – Observed and Change from Baseline (Safety Population)	Safety Analysis
Table 14.3.5.6: Vital Sign Values – Observed and Change from Baseline (Safety Population)	Safety Analysis
Table 14.3.5.7: Hematology Laboratory Values Worsening from Baseline Grade 0-2 to Grade 3-4 During the Treatment-Emergent Period (Safety Population)	Safety Analysis
Table 14.3.5.8: Serum Chemistry Laboratory Values Worsening from Baseline Grade 0-2 to Grade 3-4 During the Treatment-Emergent Period (Safety Population)	Safety Analysis
Table 14.3.5.9: Shifts in Hematology Laboratory from Baseline During the Treatment-Emergent Period (Safety Population)	Safety Analysis
Table 14.3.5.10: Shifts in Serum Chemistry Laboratory from Baseline During the Treatment-Emergent Period (Safety Population)	Safety Analysis

11.3 **Listings to Be Provided**

Listings are numbered considering the ICH guidance.

Table 11.3 Listings

Listing Number and Title	**Analysis Population**
Listing 16.2.1 Study Completion	All Subjects
Listing 16.2.2 Protocol Deviations	All Subjects
Listing 16.2.3 Eligibility	All Subjects
Listing 16.2.4.1 Demographics	All Subjects
Listing 16.2.4.2 Height and Weight	Safety
Listing 16.2.4.3 Medical History	Safety
Listing 16.2.4.4 Initial Disease Status and Evaluation Prior to HSCT	Safety
Listing 16.2.4.5 Prior Therapies	Safety
Listing 16.2.4.6 HLA Typing and Donor Information	Safety
Listing 16.2.4.7 ECG	Safety
Listing 16.2.5.1 AlloHSCT Product Manipulation Methods	Safety
Listing 16.2.5.2 AlloHSCT Administration	Safety
Listing 16.2.5.3 Study Drug RGI-2001 IV infusion Administration	Safety
Listing 16.2.6.1 ANC and Platelet Recovery	Safety
Listing 16.2.7.1 Adverse Events	Safety
Listing 16.2.7.2 Serious Adverse Events	Safety
Listing 16.2.7.3 Dose-Limiting Toxicities	Safety
Listing 16.2.7.4 AEs Leading to Study Discontinuation	Safety
Listing 16.2.7.5 AEs Leading to Study Drug Interruption, Reduction, or Discontinuation	Safety
Listing 16.2.7.6 AEs Leading to Death	Safety
Listing 16.2.7.7 List of Serious Adverse Events (Part 2)	Safety
Listing 16.2.7.8 Infections	Safety
Listing 16.2.8.1 Laboratory Results – Serum Chemistry	Safety
Listing 16.2.8.2 Laboratory Results - Hematology	Safety
Listing 16.2.8.3 Laboratory Results - Coagulation	Safety
Listing 16.2.8.4 Laboratory Results - Urinalysis	Safety
Listing 16.2.8.5 Laboratory Results – Microscopic Urinalysis	Safety
Listing 16.2.8.6 Laboratory Results – Viral Tests	Safety
Listing 16.2.8.7 Serum Pregnancy Test	Safety
Listing 16.2.9 Preparative Regimen	Safety
Listing 16.2.10 PK Blood Draw	Safety
Listing 16.2.11 Blood samples for Immunophenotyping and Exploratory Studies	Safety
Listing 16.2.12 Molecular Diagnostics	Safety

Listing Number and Title	Analysis Population
Listing 16.2.13 Physical Exam	Safety
Listing 16.2.14 Assessments of aGvHD and cGvHD	Safety
Listing 16.2.15 Dates for aGVHD and cGVHD	Safety
Listing 16.2.16 aGvHD Assessments Keystone Criteria	Safety
Listing 16.2.17 aGvHD Assessments MAGIC Criteria	Safety
Listing 16.2.18 cGvHD Development and Maximum Grade since Last Report	Safety
Listing 16.2.19 Karnofsky Performance Status (KPS)	Safety
Listing 16.2.20 Chimerism	Safety
Listing 16.2.21 Disease Status (Part A)	Safety
Listing 16.2.22 Disease Status (Part B)	Safety
Listing 16.2.23 Concomitant Medications Given for GvHD Prophylaxis	Safety
Listing 16.2.24 Concomitant Medications – Other Than Those Given for GVHD Prophylaxis	Safety
Listing 16.2.25 Concomitant Procedures	Safety
Listing 16.2.26 Vital Signs	Safety
Listing 16.2.27 AlloHSCT Product Analysis	Safety
Listing 16.2.28 Lising for Time-to-Event Analyses	Safety
Listing 16.2.29 Acute GvHD via Keystone Criteria: Lising for Time-to-Event Analyses	Safety
Listing 16.2.30 Acute GvHD via MAGIC Criteria: Lising for Time-to-Event Analyses	Safety
Listing 16.2.31 Chronic GvHD: Lising for Time-to-Event Analyses	Safety
Listing 16.2.32 Dates for aGVHD and cGVHD	Safety
Listing 16.2.33 Dates for Outcomes	Safety

11.4 **Figures to Be Provided**

Table 11.4 Figures

Figure Number and Title	Analysis Population
Figure 1.1 Hemoglobin by Study Day Scatter Plot	Safety
Figure 1.2 Leukocytes by Study Day Scatter Plot	Safety
Figure 1.3 Lymphocytes by Study Day Scatter Plot	Safety
Figure 1.4 Neutrophils by Study Day Scatter Plot	Safety
Figure 1.5 Platelets by Study Day Scatter Plot	Safety
Figure 1.6 BUN by Study Day Scatter Plot	Safety
Figure 1.7 Creatine by Study Day Scatter Plot	Safety

Figure Number and Title	Analysis Population
Figure 1.8 AST by Study Day Scatter Plot	Safety
Figure 1.9 ALT by Study Day Scatter Plot	Safety
Figure 1.10 GGT by Study Day Scatter Plot	Safety
Figure 1.11 Albumin by Study Day Scatter Plot	Safety
Figure 1.12 Total Bilirubin by Study Day Scatter Plot	Safety
Figure 1.13 Direct Bilirubin by Study Day Scatter Plot	Safety
Figure 2.1 GvHD-free Survival (Keystone Grades II-IV)	Safety
Figure 2.2 GvHD-free Survival (Keystone Grades III-IV)	Safety
Figure 2.3 Overall Survival (OS)	Safety
Figure 2.4 Non-Relapse Mortality (NRM)	Safety
Figure 2.5 Relapse Free-Survival (RFS)	Safety
Figure 2.6 GvHD-free, relapse-free survival GRFS	Safety

Appendix A

Assignment of CTCAE grades for Laboratory values using CTCAE Version 5.0:

Parameter	CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
ALT	Alanine aminotransferase increased	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	-
ALP	Alkaline phosphatase increased	>ULN - 2.5 x ULN if baseline was normal; 2.0 - 2.5 x baseline if baseline was abnormal	>2.5 - 5.0 x ULN if baseline was normal; >2.5 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	-
AST	Aspartate aminotransferase increased	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	-
Total Bilirubin	Blood bilirubin increased	>ULN - 1.5 x ULN if baseline was normal; > 1.0 - 1.5 x baseline if baseline was abnormal	>1.5 - 3.0 x ULN if baseline was normal; >1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 10.0 x ULN if baseline was normal; >3.0 - 10.0 x baseline if baseline was abnormal	>10.0 x ULN if baseline was normal; >10.0 x baseline if baseline was abnormal	-
Direct Bilirubin	Blood bilirubin increased	>ULN - 1.5 x ULN if baseline was normal; > 1.0 - 1.5 x baseline if	>1.5 - 3.0 x ULN if baseline was normal; >1.5 - 3.0 x baseline if	>3.0 - 10.0 x ULN if baseline was normal; >3.0 - 10.0 x baseline if	>10.0 x ULN if baseline was normal; >10.0 x baseline if baseline was abnormal	-

Parameter	CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
		baseline was abnormal	baseline was abnormal	baseline was abnormal		
BUN	Blood Urea Nitrogen Increased	23 – 26	27 – 31	> 31	-	-
Cholesterol	Cholesterol high	>ULN - 300 mg/dL; >ULN - 7.75 mmol/L	>300 - 400 mg/dL; >7.75 - 10.34 mmol/L	>400 - 500 mg/dL; >10.34 - 12.92 mmol/L	>500 mg/dL; >12.92 mmol/L	-
Creatine Phosphokinase (CPK)	CPK increased	>ULN - 2.5 x ULN	>2.5 x ULN - 5 x ULN	>5 x ULN - 10 x ULN	>10 x ULN	-
Creatinine	Creatinine increased	>ULN - 1.5 x ULN	>1.5 - 3.0 x baseline; >1.5 - 3.0 x ULN	>3.0 x baseline; >3.0 - 6.0 x ULN	>6.0 x ULN	-
Fibrinogen	Fibrinogen decreased	<1.0 - 0.75 x LLN; if abnormal, <25% decrease from baseline	<0.75 - 0.5 x LLN; if abnormal, 25 - <50% decrease from baseline	<0.5 - 0.25 x LLN; if abnormal, 50 - <75% decrease from baseline	<0.25 x LLN; if abnormal, 75% decrease from baseline; absolute value <50 mg/dL	-
Hemoglobin	Hemoglobin increased	Increase in >0 - 2 g/dL	Increase in >2 - 4 g/dL	Increase in >4 g/dL	-	-
Hemoglobin	Anemia	Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; <LLN - 100 g/L	Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L;	-	-
Lymphocyte	Lymphocyte count decreased	<LLN - 800/mm^3; <LLN - 0.8 x 10e9/L	<800 - 500/mm^3; <0.8 - 0.5 x 10e9 /L	<500 - 200/mm^3; <0.5 - 0.2 x 10e9 /L	<200/mm^3; <0.2 x 10e9 /L	-
Lymphocyte	Lymphocyte count increased	-	>4000/mm^3 - 20,000/mm3	>20,000/mm^3	-	-

Parameter	CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Neutrophil	Neutrophil count decreased	<LLN - 1500/mm^3; <LLN - 1.5 x 10e9 /L	<1500 - 1000/mm^3; <1.5 - 1.0 x 10e9 /L	<1000 - 500/mm^3; <1.0 - 0.5 x 10e9 /L	<500/mm^3; <0.5 x 10e9 /L	-
Platelet	Platelet count decreased	<LLN - 75,000/mm^3; <LLN - 75.0 x 10e9 /L	<75,000 - 50,000/mm^3; <75.0 - 50.0 x 10e9 /L	<50,000 - 25,000/mm^3; <50.0 - 25.0 x 10e9 /L	<25,000/mm^3; <25.0 x 10e9 /L	-
Leukocytes	White blood cell decreased	<LLN - 3000/mm^3; <LLN - 3.0 x 10e9 /L	<3000 - 2000/mm^3; <3.0 - 2.0 x 10e9 /L	<2000 - 1000/mm^3; <2.0 - 1.0 x 10e9 /L	<1000/mm^3; <1.0 x 10e9 /L	-
Leukocytes	Leukocytosis	-	-	>100,000/mm^3	-	-
Mag-nesium	Hyper-magnesemia	>ULN - 3.0 mg/dL; >ULN - 1.23 mmol/L	-	>3.0 - 8.0 mg/dL; >1.23 - 3.30 mmol/L	>8.0 mg/dL; >3.30 mmol/L;	
Triglycerides	Hyper-triglyceridemia	150 mg/dL - 300 mg/dL; 1.71 mmol/L - 3.42 mmol/L	>300 mg/dL - 500 mg/dL; >3.42 mmol/L - 5.7 mmol/L	>500 mg/dL - 1000 mg/dL; >5.7 mmol/L - 11.4 mmol/L	>1000 mg/dL; >11.4 mmol/L;	
Albumin	Hypo-albuminemia	<LLN - 3 g/dL; <LLN - 30 g/L	<3 - 2 g/dL; <30 - 20 g/L	<2 g/dL; <20 g/L		
Blood Glucose	Hypoglycemia	<LLN - 55 mg/dL; <LLN - 3.0 mmol/L	<55 - 40 mg/dL; <3.0 - 2.2 mmol/L	<40 - 30 mg/dL; <2.2 - 1.7 mmol/L	<30 mg/dL; <1.7 mmol/L;	
Mag-nesium	Hypo-magnesemia	<LLN - 1.2 mg/dL; <LLN - 0.5 mmol/L	<1.2 - 0.9 mg/dL; <0.5 - 0.4 mmol/L	<0.9 - 0.7 mg/dL; <0.4 - 0.3 mmol/L	<0.7 mg/dL; <0.3 mmol/L;	
GGT	GGT Increased	>ULN - 2.5 x ULN if baseline was normal; 2.0 - 2.5 x baseline if baseline was abnorma	>2.5 - 5.0 x ULN if baseline was normal; >2.5 - 5.0 x baseline if	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	

Parameter	CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
			baseline was abnormal	baseline was abnormal		