Study Title:	A Phase 1B/2 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of EQ001 in Subjects with Newly Diagnosed Acute Graft Versus Host Disease
Protocol Number:	EQ001-aGVHD-001
Investigational Product(s):	EQ001
Sponsor:	Equillium, Inc.
Development Phase:	Phase 1b/2
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CONFIDENTIAL

Statistical Analysis Plan
(Part A, Phase 1b component, only)

Protocol EQ001-aGVHD-001
Phase 1b/2

A PHASE 1b/2 STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS, AND CLINICAL ACTIVITY OF EQ001 IN SUBJECTS WITH NEWLY DIAGNOSED ACUTE GRAFT VERSUS HOST DISEASE

Sponsor: Equillium Inc. [redacted]

[redacted]

[redacted]

[redacted]

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[redacted]

[redacted]

Glossary of Abbreviations

Abbreviations pertain to the SAP only (not the TFLs).

Abbreviation	Term
aGVHD	Acute Graft Versus Host Disease
AE	Adverse Event
ATC	Anatomical Therapeutic Chemical
BOR	Best Overall Response
cGVHD	Chronic Graft Versus Host Disease
CR	Complete response
DSMC	Data and Safety Monitoring Committee
DLT	Dose-limiting Toxicity
MTD	Maximally Tolerated Dose
PD	Pharmacodynamics
PK	Pharmacokinetics
MedDRA	Medical Dictionary for Regulatory Activities
IV	Intravenous
NR	No Response
OS	Overall Survival
PD	Progressive Disease
PFS	Progression-free Survival
PR	Partial Response
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
TFLs	Tables, Figures and Listings
VGPR	Very Good Partial Response

STATISTICAL ANALYSIS PLAN AMENDMENTS

None.

1. Source Documents

[redacted]

This SAP describes the statistical methods and procedures to be implemented when summarizing the data collected during the execution of [redacted] of the study. [redacted] Specifications of tables, figures and listings (TFLs) will be contained in a separate document. In this SAP, study drug and study treatment refer to EQ001 and will be used interchangeably.

2. Protocol Details

Objectives and main design features of the protocol are described below [redacted]

2.1 Study Objectives

2.1.1 Primary Objectives

The primary objectives [redacted] are:

- Determine the safety and tolerability of intravenous (IV) dosing of EQ001 in subjects with newly diagnosed acute graft versus host disease (aGVHD)
- Determine optimal IV dose level(s) of EQ001 in subjects with newly diagnosed aGVHD

2.1.2 Secondary Objectives

The secondary objectives [redacted] are:

- To characterize the pharmacokinetics (PK) of EQ001 in subjects with newly diagnosed aGVHD

[redacted]

- To assess the clinical activity of EQ001 in subjects with newly diagnosed aGVHD

2.2 Study Design

Overall study design includes an open-label (Part A, Phase 1b) component and a double-blinded, placebo-controlled (Part B, Phase 2) component. A two-part study utilizing different designs was chosen to support the attainment of the objectives that are specific to each part of the study. Execution of Part B of the study will commence only after Part A has been completed and Part A data warrants. Description of the design features of Part A of the study follows.

Part A has been designed to explore the safety and tolerability of ascending dose levels of the IV administration of multiple doses of EQ001. An open-label design is supported by the availability of extensive safety and tolerability data on itolizumab, active ingredient of EQ001, for which to compare the open label safety data generated in this study. A cohort-based dose escalation design was chosen to rigorously evaluate, and conservatively escalate, IV doses of EQ001.

After informed consent has been obtained, all subjects will be screened for potential participation, and those meeting eligibility criteria will be offered participation in the study. The study will enroll subjects with an initial clinical diagnosis of aGVHD requiring systemic immunosuppressive treatment [redacted]

Each subject will have 2 months of study treatment and ten (10) months of clinical follow up, for a total of twelve (12) months in the study. The follow-up period will consist of a 2-month Safety Follow Up period (through Day 169) and then an 8-month Long-Term Follow-Up period (through Day 337). Figure 1 shows the study timeline for Part A.

EQ001 will be administered every 14 days for two months (5 doses) at the following ascending dose levels:

- Cohort 1: 0.4 mg/kg

- Cohort 2: 0.8 mg/kg
- Cohort 3: 1.6 mg/kg
- Cohort 4: 2.4 mg/kg

[redacted]

Part A of the study will utilize a standard 3+3 dose escalation design until a dose is selected. Cohort enrollment will proceed in a sequential manner starting with the lowest dose cohort. Each dose cohort will enroll 3 to 6 adult subjects. Subject incidence of dose limiting toxicities (DLTs) during the initial 29 days of treatment (DLT window) will primarily guide dose escalation decisions. [redacted]

Subjects will be considered evaluable for DLT assessment if they have received at least two doses of study drug and completed through Study Day 29 assessments or received at least one dose of study drug and had a DLT within the DLT window. During the DLT assessment window, subjects who do not complete the specified study procedures or withdraw from the study for reasons other than a DLT may be replaced. Replaced subjects will receive the same dose level and cohort assignment as the subject they are replacing.

Established Data and Safety Monitoring Committee (DSMC) will apply the following dose escalation rules based on the subject incidence of DLTs:

- If 0 of the 3 initial evaluable subjects experiences a DLT, then escalation may proceed to the next highest dose level.

- If 1 of the 3 initial evaluable subjects experiences a DLT, then 3 additional subjects will be enrolled at the same dose level for a total of up to 6 evaluable subjects.
  - If 1 out of the 6 subjects experience a DLT, then escalation may proceed to the next higher dose level.
  - If 2 or more out of the 6 subjects experience a DLT, escalation to the next dose level will not proceed, next lower dose level will enroll additional subjects for a total of 6 evaluable subjects.
- If 2 of the 3 initial evaluable subjects experience DLTs, escalation to the next dose level will not proceed, next lower dose level will enroll additional subjects for a total of 6 evaluable subjects.

Enrollment of the next higher dose cohort will not commence until all safety data from all subjects from prior cohorts and all available safety data from the current cohort through Study Day 29 have been reviewed by the DSMC and approval is granted for dose escalation.

[redacted]

3. Clinical Activity and Safety Variables for Part A

3.1 Clinical Activity Endpoints

- Response to therapy (Complete response [CR], Very Good Partial Response [VGPR], Partial response [PR], No response [NR], and Progressive disease [PD])
- Progression-free survival (PFS)

- aGVHD activity index (aGVHD-AI) and change from baseline
- Organ stages and change from baseline
- aGVHD overall clinical grade and change from baseline
- Overall survival (OS) – Time from first dose to death from any cause
- Relapse incidence and non-relapse mortality
- Corticosteroid usage
- Subjects who discontinued corticosteroids
- Disease status (disease relapse or chronic GVHD (cGVHD)) during long-term follow-up period

3.2 Safety Endpoints

Safety evaluations include adverse events (AEs), clinical laboratory, vital signs and ECG results and may also include changes in the subject's physical examination findings.

4. Analysis populations

4.1 Safety Population

Safety population consists of all subjects who receive any study medication. All data summaries except PK and PD data related summaries will use this population.

4.2 Evaluable Population

The evaluable population consists of all subject who receive at least 2 doses of study medication through Day 29. This population will be used in selected analyses of response, relapse, and survival.

4.3 Pharmacokinetic Analysis Population

Subjects in the safety population who have at least one (1) measurable post-EQ001 exposure concentration will be included in the PK analysis population.

[redacted]

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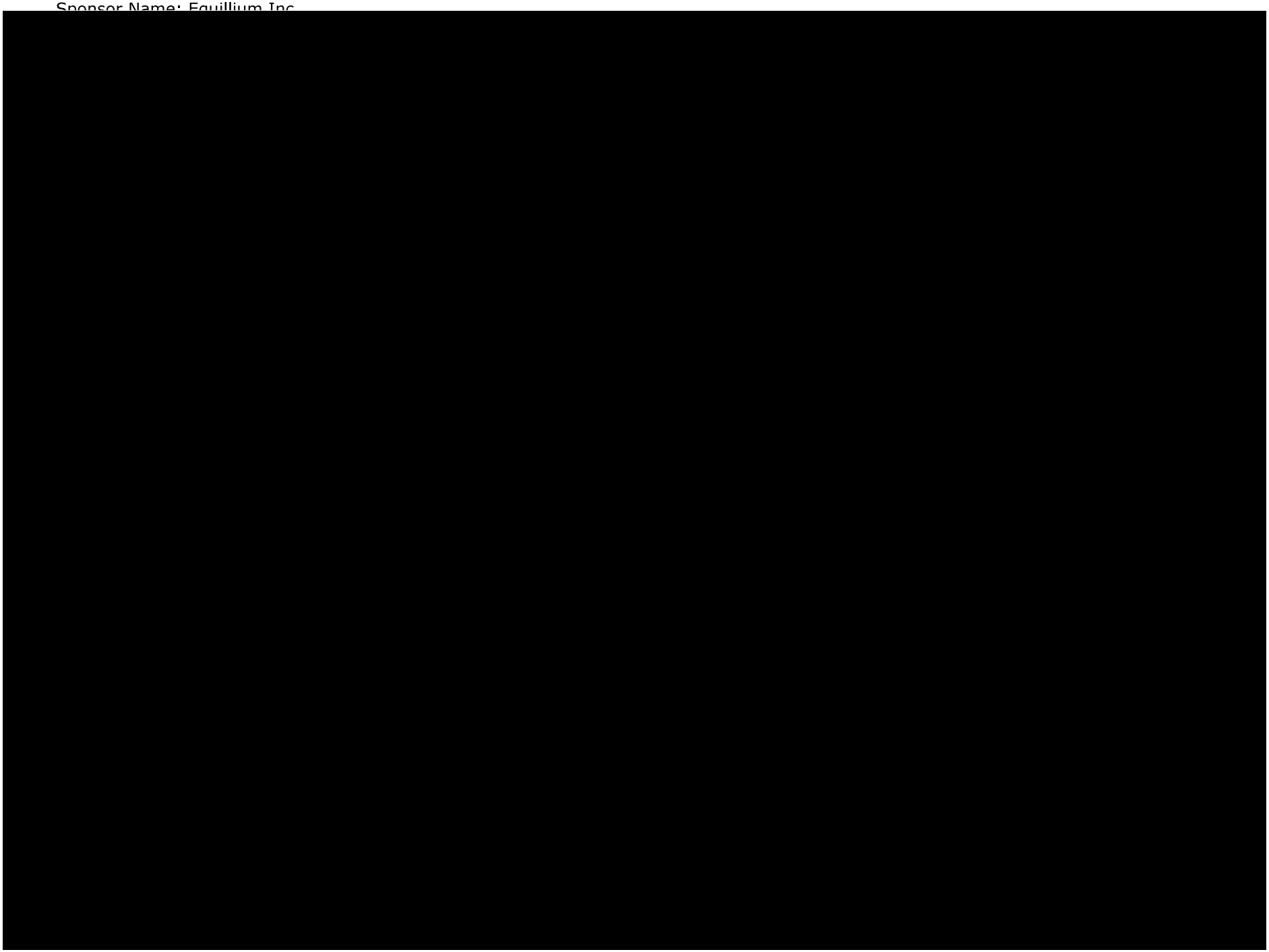

[redacted]

[redacted]

[redacted]

[redacted]

6. Statistical Methods

6.1 General Principles

All data summary tables, listings and figures will be produced using the SAS® software Version 9.4 or higher.

Analysis Data Model (ADaM) datasets will be prepared using Clinical Data Interchange Standards Consortium (CDISC) ADaM Version 2.1, and CDISC ADaM Implementation Guide Version 1.1. Pinnacle 21 Community Validator Version 2.2.0 will be utilized to ensure compliance with CDISC standards.

[redacted]

[redacted]

6.1.1 Definition of Baseline and Change from Baseline

Baseline value of a parameter is defined as the last non-missing measurement prior to first dose of study treatment, including unscheduled readings (see Section 6.1.2 for definitions of unscheduled readings).

Change from baseline will be calculated by subtracting the baseline value from the value at the timepoint of interest.

6.1.2 Repeat and Unscheduled Readings

All assessments not performed at scheduled timepoints (e.g., clinical laboratory assessments) are considered unscheduled assessments. Unscheduled measurements will be labelled as 'Unscheduled' in the listings. Data from unscheduled assessments will not be included in the by-visit data summaries except for clinical activity data summaries.

6.2 Subject Disposition

Subject disposition data will be summarized and will include number and percent of subjects on study, completed the study, discontinued the study prematurely by the primary reason for discontinuation. Similar disposition table will also be created summarizing the treatment completion status. This table will include subjects on treatment, completed treatment, and withdrew study treatment by the primary reason for withdrawal of study treatment in the number of subjects and percentage format. Subject enrollment by study site and important protocol deviations will also be summarized.

6.3 Demographics and Baseline Characteristics

Demographics and other baseline characteristics will be summarized. These include age, sex, race, ethnicity, weight and height. Baseline disease and graft characteristics data include primary disease resulting in transplant, time from graft to onset of GVHD, organ involvement (skin only, GI (upper and/or lower) only, liver only, ≥2 organs), aGVHD clinical grade, donor's age, sex and relationship, graft source, HLA matching status, conditioning regimen, and aGVHD prophylaxis regimen(s). If data are available, Ann-Arbor risk classification score at baseline

based on the MAGIC algorithm will also be categorically summarized for subjects with a clinical diagnosis of aGVHD grade II at baseline.

6.4 Medical History

Medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 21.1 (or a later version if updated during the study). All medical history data will be listed, and the number and percentage of subjects with any medical history will be summarized by system organ class (SOC) and preferred term (PT).

6.5 Prior and Concomitant Medications

Medications received prior to or after the first study treatment will be coded using the WHO Drug Dictionary, Version 092018 Enhanced Dictionary Version B3 format (or a later version if updated during the study), Anatomical Therapeutic Chemical (ATC) Classification codes.

Prior medications and concomitant medications are defined as follows:

- Prior medications are those taken prior to the first dose date of study treatment.
- Concomitant medications are those with a start date on or after the first dose date of study treatment, or those with a start date before the first dose date of study treatment and a stop date on or after the first dose date of study treatment or ongoing at the end of study.

A medication can be a prior medication and a concomitant medication at the same time if it starts before first dose date and continues on or after the first dose date.

If a medication cannot be classified as "prior" or "concomitant" due to missing or partial date information, it will be classified as concomitant.

Subject incidence of prior and concomitant medications will be summarized by therapeutic class (ATC Level 2) and chemical subgroup (ATC Level 4) within therapeutic class.

Prior medications and concomitant medications will be listed. This listing will include reported term of the medication, therapeutic class, chemical subgroup within the therapeutic class, start and stop dates and indication.

6.6 Exposure to Study Treatment

An overall summary of exposure to study treatment will be presented. This summary will include:

- Number and percentage of subjects who received 1 dose, 2 doses, …, 5 doses of study treatments.

- Descriptive summary (n, mean, median, SD, minimum, maximum) of number of doses of study treatment.

6.7 Pharmacokinetic Assessment

6.7.1 Statistical Analysis of Pharmacokinetic Variables for Part A

All PK data analyses and summaries will use the PK population. Description of the methods of calculations of PK parameters is not part of this SAP; PK parameter calculations may be done elsewhere. However, descriptive summaries and listings of the raw data (serum concentrations) may be produced based on the availability of the data.

[redacted]

6.9 Clinical Activity

6.9.1 Response to therapy (CR, VGPR, PR, NR, and PD)

At each assessment visit, overall response to therapy will be recorded as complete response (CR), very good partial response (VGPR), partial response (PR), no response (NR), or progressive disease (PD) by the investigator.

Number and percent of subjects with a complete or near complete response (i.e., CR or VGPR) and with any response (i.e., CR, VGPR or PR) will be presented along with 90% exact confidence intervals by assessment visit. If a subject ended treatment prior to an assessment visit that follows immediately after ending treatment, last observed response will be carried forward if the disease assessment was not performed at that visit. However, if the assessment was done but after receiving new aGVHD treatment(s), response will be considered as PD. Disease assessments done after receiving new aGVHD treatments will not be included in summary tables. A bar chart of percent of responders by cohort and visit will be generated. Best overall response (BOR) during the study will also be summarized by BOR category (CR, VGPR, PR, NR and PD). In evaluating BOR for a subject during the study, the hierarchy CR>VGPR>PR>NR>PD will be used where the symbol '>' indicating 'better than'. For example, if a subject has a response of NR

at Days 15 and 29, VGPR at Day 43, and later progressed (PD), BOR will be VGPR for that subject. A bar chart will also be constructed to graphically display the BOR data.

Further, Day 29 response will be summarized by GVHD clinical grade at screening, worst clinical grade observed on or prior to Day 29 and by categorical grade change (grade worsened, no change, grade improved) from baseline to latest available grade on or prior to Day 29. Additionally, to assess the durability of response seen at Day 29, for subjects with an objective response (i.e., PR or better) at Day 29, disease assessment data will be summarized at assessments done at visits following Day 29.

[redacted]

6.9.2 Progression-free Survival

Progression-free survival (PFS) is defined as the time (days) from the date of first dose of study treatment to the earliest observation of disease progression, relapse of underlying malignancy or death. For subjects not meeting the criteria for a PFS event will be considered censored and PFS will be calculated using the last response assessment date (not the last known alive date). PFS in days will be calculated as:

(PFS event date or censoring date – first dose date + 1)

Number and percentage of subjects with events further broken down by event type (disease progression, relapse of underlying malignancy or death) will be summarized. In addition, Kaplan-Meier (KM) method will be used to estimate the survival distribution function of PFS and the median (80% confidence interval). First and third quartiles of PFS will also be presented. Estimated survival distribution function of PFS will be plotted using the data from all cohorts.

6.9.3 aGVHD-AI (change from baseline)

aGVHD-AI total index score ranges from 0 to 100 with high scores indicating more severe disease activity. The total index score and change from baseline will be summarized by assessment visit.

6.9.4 Organ Stages

Skin, gastrointestinal tract (upper and lower) and liver are the principal organs involved in the diagnosis of aGVHD. As outlined in an appendix in the protocol, each organ is assigned a stage score (0-4) by the investigator based on severity of disease associated with that organ, with a score of 0 reflecting no organ involvement or normal organ function and a score of 5 reflecting most severe disease. Each organ stage and categorical change from baseline over time (improvement by at least one point, no change, worsening by at least one point) will be summarized by assessment visit.

6.9.5 aGVHD Overall Clinical Grade

An overall aGVHD clinical grade (0, I, II, III or IV) will be assigned by the investigator based on the organ stages at the time of assessment with Grade 0 indicating no disease and Grade IV indicating most severe disease. aGVHD overall clinical grade and categorical changes from baseline over time (improvement by at least one grade, no grade change, worsening by at least one grade) will be summarized by assessment visit.

6.9.6 Overall Survival

Overall survival (OS) is defined as time from first dose to death from any cause. For subjects who are alive at the time of analysis, OS will be calculated as the time from for first dose to last known alive date and will be considered as censored. OS in days will be calculated as:

(Death date or censoring date – first dose date + 1)

OS data will be summarized similar to PFS data.

In addition to the safety population, this analysis will also be conducted using the evaluable population, the safety population for subjects with ≤ 3 day of systemic steroid dosing prior to dosing of study medication, and the safety population for subjects with > 3 day of systemic steroid dosing prior to dosing of study medication.

6.9.7 Corticosteroid Usage

Initial induction dose of systemically administered corticosteroids is 2 mg/kg/day of prednisone (or equivalent), and this dose should be maintained until disease stabilization is achieved for a duration of 1 week. Total corticosteroid dose administered through Day 29 by Day 29 response will be summarized. eCRF forms

only capture the daily total dose administered, not the daily dosing regimen. For subjects belonging to each response category, total dose administered through Day 29 will be calculated and summarized [redacted]

Total dose is then the sum of the individual daily doses after converting to the dose to the prednisone equivalent dose. If a subject took multiple medications or had multiple doses of the same medication recorded where the end date of a previous medication/dose coincides with the start date of the next medication/dose, then it will be assumed that subjects did not take the previous medication/dose on the coincident date and started the next dose on that date (i.e. the end date of the previous medication/dose will be set to the end date of that medication/dose – 1). If the subject has a missing end date and the medication/dose is marked as ongoing, then the end date of that medication/dose will be set to the last date known alive or, if the subject died, to the death date -1.

In addition, total dose administered through the earliest time showing an objective response will be summarized for subjects with a response of PR or better. Average daily dose administered (mg/kg) will be calculated by dividing the total dose administered by (subjects baseline weight x number of days until the earliest time showing an objective response) and summarized. Of those subjects who showed an objective response, the number and percentage of subjects discontinued corticosteroid dosing prior to showing an objective response (PR or better) will also be displayed.

Total dose administered through the earliest time showing disease progression, disease relapse or death will also be summarized similarly.

6.9.8 Chronic GVHD

Number and percentage of subjects developing chronic GVHD (cGVHD) will be presented by visit and during anytime during the study. If data permits, time from first study treatment to developing cGVHD will be summarized using KM method analogous to PFS.

6.9.9 Disease Status

Number and percentage of subjects with a diagnosis of disease relapse (Yes/No) or cGVHD (Yes/No) as assessed at Study Days 253 and 337 will be presented by visit.

In addition to the safety population, this analysis will also be conducted using the evaluable population, the safety population for subjects with ≤ 3 day of systemic steroid dosing prior to dosing of study medication, and the safety population for subjects with > 3 day of systemic steroid dosing prior to dosing of study medication.

6.10 Safety

All safety data summaries will use the safety population. Safety analyses will be presented by cohort and overall unless otherwise specified.

Number and percent of subjects experiencing any DLTs will be presented by cohort. A listing of DLTs will also be provided.

6.10.1 Adverse Events

Adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 20.1 or higher and graded by the investigator using the CTCAE v5.0 or the current version. All adverse events (AEs) will be classified as either pre-treatment AEs or treatment-emergent AEs (TEAEs) as follows:

- Pre-treatment AEs are events that start prior to the date of first dose of study treatment that do not qualify to be treatment-emergent as per the definition below.
- TEAEs are events with start date on or after the first dose of study treatment or events that started prior to the first dose of study treatment whose severity worsened on or after the first dose of study treatment. All adverse events considered by the investigator as at least possibly related to the study treatment will be considered as treatment-emergent irrespective of the start date.

Subject incidence of treatment-emergent TEAEs, treatment-emergent serious AEs (TESAEs), DLT AEs, TEAEs leading to treatment discontinuation and TEAEs with an outcome of death will be summarized by SOC and PT. These Adverse events will also be further summarized by worst severity grade and relationship to study treatment.

TEAEs of special interest (TEAESIs) will also be summarized by SOC, PT, and worst severity grade.

All AE data will be listed for each cohort. Treatment-emergence status will be flagged in the listing. In addition, listings of serious AEs (SAEs), AEs leading to discontinuation of study treatment and AEs resulting in death will be produced.

The severity of all AEs is recorded as mild, moderate, or severe. The relationship between an AE and study treatment is assessed as Not Related, Unlikely Related, Possibly, Probably, Related by the investigator. A study treatment-related AE is an AE considered by the investigator as one that is at least 'possibly related' to study treatment or with unknown/missing relationship to study treatment.

An overview table will summarize the number and percentage of subjects with at least one of the following TEAEs, where subjects with more than one TEAE in a particular category are counted only once in that category:

- Any TEAE
- Any DLT AE
- [redacted]
- Any TEAE by severity (mild, moderate, severe)
- Any TEAE related to study treatment
- Any Grade 3 or higher TEAE
- Any TEAE leading to study treatment discontinuation
- Any TEAE leading to discontinuation from the study
- Any TEAE with an outcome of death
- Any TESAE
- Any TESAE related to study treatment
- Any TESAE with an outcome of death
- Any TESAE related to study treatment with an outcome of death
- Any TESAE leading to treatment discontinuation
- Any TESAE leading to discontinuation from the study

The number and percentage of subjects reporting TEAEs will be summarized by SOC and PT. Tables will be sorted by the descending order of incidence in overall total column with respect to SOC first and descending order of incidence with respect to PT within SOC. The following summaries will be produced:

- TEAEs by SOC and PT
- DLT AEs by SOC and PT
- TEAEs related to study treatment by SOC and PT
- TEAEs by worst severity grade by SOC and PT
- TEAEs leading to the discontinuation of study treatment by SOC and PT
- TESAEs by SOC and PT
- TESAEs related to study treatment by SOC and PT
- TEAEs with an outcome of death by SOC and PT

- TESAEs with an outcome of death by SOC and PT

In the above summaries, subjects with more than one AE within a particular SOC are counted only once for that SOC. Similarly, subjects with more than one AE within a particular PT are counted only once for that PT. For summaries by worst severity grade, subjects with multiple AEs within a particular SOC or PT will be counted under the worst severity grade within that SOC or PT.

6.10.2 Laboratory Evaluations

Clinical laboratory data will be collected using local labs and thus normal ranges may differ from lab to lab making head-to-head comparison of laboratory values or their changes across labs not very meaningful. Therefore, data including changes from baseline will not be summarized by assessment visit. All laboratory parameters that can be graded using the CTCAE will be graded; these include all scheduled and unscheduled laboratory data. For selected parameters, following summaries will be produced:

- Worst post-baseline severity grade
- Shift summary of baseline grade to worst post-baseline severity grade.

In addition, for selected parameters (ALT, AST, Total Bilirubin, ALP, GGT and LDH), number and percentage of subjects with worsening grade shifts (1 grade increase, 2 grades increase, and 3 or more grades increase) from baseline to worst post-baseline grade will be summarized. For the above parameters, time to earliest grade increase will also be summarized using the KM method. For subjects not showing any grade increase, time to earliest grade increase will be considered censored at the last known laboratory assessment visit.

[redacted]

6.10.3 Vital Signs

Vital signs data and their changes from baseline will be summarized by nominal assessment visits and worst post-baseline using standard descriptive statistics. For these by-visit summaries, only data from scheduled visits will be included.

Number and percentage of subjects showing each of the following vital sign abnormalities at any post-baseline assessment (including unscheduled assessments) will be summarized:

[redacted]

6.10.4 Electrocardiograms

The following quantitative ECG measurements will be listed and summarized by nominal assessment visits and worst post-baseline using standard descriptive statistics:

- Heart rate (bpm)
- RR interval (msec)
- PR interval (msec)
- QRS interval (msec)
- QT interval (msec)
- QTcF interval (msec) (calculated using QT and Heart rate or RR interval)

Where QTcF denotes the QT corrected for heart rate calculated using the Fridericia's formula:

$$QTcF = 10xQT/(RR)^{1/3}$$

Worst post-baseline overall interpretation of ECGs ('normal', 'abnormal, not clinically significant', 'abnormal, clinically significant') across all available post-baseline ECG data including any unscheduled assessments will be summarized in the frequency and percent format. Further, a categorical summary of baseline QTcF and of worst (highest) post-baseline QTcF result (msec) will be summarized for the categories defined below:

- ≤450

- >450-≤480
- >480-≤500
- >500

In addition, worst QTcF increase from baseline will also be summarized for the following categorical increases:

- ≤30
- >30-≤60
- >60

6.10.5 Relapse of Underlying Malignancy and Death

Number and percentage of subjects whose underlying malignancy relapsed or died will be summarized for the following categories:

- Malignancy relapsed by Day 29
- Death by Day 29
- Death by Day 29 with no relapse of malignancy
- Malignancy relapsed during the study
- Death during study with no relapse of malignancy
- Death during study after relapse of malignancy

6.10.6 Physical Examination

Abnormalities identified from physical examination are recorded in the eCRF will be listed.

6.10.7 Anti-Drug Antibody (ADA) and Neutralizing ADA (NAB)

Serum samples collected for detection of ADA against EQ001 will be batched and run at the end of Part A unless a subject has a suspected hypersensitivity reaction, the samples collected for that subject will be analyzed in real time. If data are available, ADA and NAB data will be summarized by visit further broken down the confirmed positive results by titer level.

7. Topline Results

When the last subject in last cohort in Part A completes Day 29 visit (data cut-off date), data from all Part A cohorts may be summarized to release topline results. For this analysis, all the assessments done on or prior to the data cut-off date will be entered and cleaned prior to data summarization. A selected set of summary tables, figures and listings will be produced. These may include but not limited to:

- Subject Disposition

- Demographic and Baseline Characteristics
- Baseline Disease and Graft Characteristics
- Exposure to EQ001
- Response to Therapy by Assessment Day
- aGVHD Activity Index Score and Changes from Baseline by Assessment Day
- Overall Summary of Treatment-Emergent Adverse Events
- Treatment-emergent adverse events by System Organ Class and Preferred Term
- Line Plot of Absolute Lymphocyte Counts Over Time by Subject – Cohort 1
- Line Plot of Absolute Lymphocyte Counts Over Time by Subject – Cohort 2
- Bar Graph of Response Rates at Day 29 – Cohort 1
- Bar Graph of Response Rates at Day 29 – Cohort 2

8. Changes in Planned Analysis

None

[redacted]