STATISTICAL ANALYSIS PLAN

Study Title:	A Phase 2 Study to Assess the Efficacy and Safety of Idelalisib in Subjects with Indolent B-Cell Non-Hodgkin Lymphomas Refractory to Rituximab and Alkylating Agents
Name of Test Drug:	Idelalisib (IDELA; GS-1101)
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LIST OF ABBREVIATIONS

AE	adverse event
ATC	Anatomical-Therapeutic-Chemical (drug coding system)
AUC	area under the curve
AUC_{0-12}	area under the curve for 0 – 12 hours
AUC_{0-last}	area under the curve for 0 – last sampling time point
BID	twice a day
BMI	body mass index
BOR	best overall response
CI	confidence interval
CR	complete response
CRF	case report form
C_{max}	maximum plasma concentration
CSR	clinical study report
CT	computerized tomography
CTCAE	Common Terminology Criteria for Adverse Events
C_{trough}	trough drug concentration
DNA	deoxyribonucleic Acid
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
FACT-Lym	Functional Assessment of Cancer Therapy: Lymphoma
FDG	fluorodeoxyglucose
FL	follicular lymphoma
HLGT	high-level group term
HLT	high-level term
HRQL	health-related quality of life
ICH	International Conference on Harmonisation
iNHL	indolent Non-Hodgkin lymphoma
IRC	independent review committee
ITT	intent-to-treat
IWRS	interactive web response system
LLQ	lower limit of quantification
LLT	low level term
LPL	lymphoplasmacytoid lymphoma
MedDRA	Medical Dictionary for Regulatory Activities
MMRM	mixed-effects model repeated measures
MRI	magnetic resonance imaging
MZL	marginal zone lymphoma
ND	no disease

NE	not evaluable
NHL	non-Hodgkin lymphoma
ORR	overall response rate
OS	overall survival
PD	progressive disease
PET	positron-emission tomography
PFS	progression-free survival
PK	pharmacokinetic
PP	per protocol
PR	partial response
PT	preferred term
QTc	QT interval corrected
QTc-B	QT interval corrected for heart rate using Bazett's formula
QTc-F	QT interval corrected for heart rate using Fridericia's formula
SAE	serious adverse event
SAP	statistical analysis plan
SD	stable disease
SE	standard error
SLL	small lymphocytic lymphoma
StD	standard deviation
SOC	system organ class
SPD	sum of the products of the perpendicular diameters of measurable index lesions
SPEP	serum protein electrophoresis
$t_{1/2}$	half-life
TEAE	treatment-emergent adverse event
T_{max}	time of maximum concentration
TTR	time to response
WHODRUG	World Health Organization Drug Classification Dictionary

1. INTRODUCTION

This statistical analysis plan (SAP) describes the analyses to be conducted for Gilead Sciences, Inc. idelalisib (IDELA) Study 101-09. The final study analysis will be performed when all enrolled subjects have completed efficacy, safety, and other assessments through ≥ 24 weeks of evaluation.

1.1. Study Objectives

Primary Study Objectives	• To evaluate tumor regression as determined by overall response rate (ORR) in subjects receiving IDELA for treatment of iNHL refractory to rituximab and alkylating agents
Secondary Study Objectives	• To determine the onset, magnitude, and duration of tumor control and of treatment success in subjects receiving IDELA • To characterize health-related quality of life (HRQL) as reported by subjects with iNHL receiving IDELA • To evaluate the effects of IDELA on subject performance status • To assess the pharmacodynamic effects of IDELA • To evaluate IDELA treatment administration and compliance with IDELA therapy • To describe the safety profile of IDELA • To characterize IDELA plasma exposure over time PPD [redacted]

1.2. Study Design

Design Configuration and Subject Population	This protocol describes a Phase 2, open-label, single-arm, 2-stage, efficacy, safety, and pharmacodynamic study of IDELA in subjects with previously treated iNHL that is refractory both to rituximab and to alkylating-agent-containing chemotherapy. Eligible subjects will initiate oral therapy with IDELA at a starting dose of 150 mg BID given continuously. Treatment with IDELA will continue until tumor progression or unacceptable toxicity. Subjects will be followed in the clinic at 2-week intervals through the first 12 weeks of treatment, at 4-week intervals from 12 to 24 weeks of treatment, at 6-week intervals from 24 to 48 weeks of treatment, and at 12-week intervals thereafter. Tumor response will be evaluated at baseline; at 8, 16, and 24 weeks of therapy; and every 12 weeks thereafter according to standard criteria. The responses will be assessed by both the investigator and an independent review committee (IRC). The study will be conducted in 2 stages using Simon's optimal 2-stage design. In Stage 1 of the study, 31 subjects will be enrolled; if $\geq$9 of these Stage 1 subjects have a tumor response, then the study will continue. In Stage 2, a further 69 subjects will be enrolled. With a total intended sample size of 100 subjects, the study has power >0.90 to achieve a 1-sided significance level of 0.005 and will provide an ample safety database.
Treatment Groups	Starting Dose: 150 mg BID Reduced Dose -1: 100 mg, BID Reduced Dose -2: 75 mg, BID

Key Eligibility Criteria	• Age ≥ 18 years • Karnofsky performance score ≥ 60 (Eastern Cooperative Oncology Group [ECOG] performance score of 0, 1, or 2) • Histologically confirmed diagnosis of B-cell iNHL, with histological subtype limited to the following based on criteria established by the World Health Organization (WHO) 2008 classification of tumors of haematopoietic and lymphoid tissues: — Follicular lymphoma (FL) Grade 1, 2, or 3a — Small lymphocytic lymphoma (SLL) with absolute lymphocyte count <5 x 10^9/L at the time of diagnosis and on baseline laboratory assessment performed within 4 weeks prior to the start of study drug administration — Lymphoplasmacytic lymphoma/Waldenstrom Macroglobulinemia (LPL/WM) — Marginal zone lymphoma (MZL) (splenic, nodal, or extra-nodal) • Histological materials documenting diagnosis of lymphoma available for review. Note: Central pathology confirmation of diagnosis will be performed in this study. However, a subject may be enrolled without waiting for confirmation of histological diagnosis on condition that pathological materials are known to be available for review. • Presence of radiographically measurable lymphadenopathy or extranodal lymphoid malignancy (defined as the presence of ≥ 1 lesion that measures ≥ 2.0 cm in the longest dimension [LD] and ≥ 1.0 cm in the longest perpendicular dimension [LPD] as assessed by ≥ CT or magnetic resonance imaging [MRI]) • Prior treatment with ≥ 2 chemotherapy- or immunotherapy-based regimens, or with rituximab/with an alkylating agent for iNHL • Prior treatment with rituximab and with an alkylating agent (eg, bendamustine, cyclophosphamide, ifosfamide, chlorambucil, melphalan, busulfan, nitrosoureas) for iNHL. • Lymphoma that is refractory to rituximab and to an alkylating agent

	• Refractoriness is defined as: • □Rituximab (without chemotherapy): — Lack of a complete response (CR) or partial response (PR) during rituximab therapy comprising ≥4 doses of ≥375 mg/m^2 given weekly, or — Occurrence of progressive disease (PD) within 6 months of the completion of a regimen of rituximab therapy comprising ≥4 doses of ≥375 mg/m^2 given weekly, or — Occurrence of PD during rituximab maintenance therapy or within 6 months of completion of rituximab maintenance therapy • Rituximab (with chemotherapy): — Lack of a CR or PR during rituximab-containing therapy comprising ≥2 doses of ≥375 mg/m^2, or — Occurrence of PD within 6 months of the completion of a regimen of rituximab-containing therapy comprising ≥2 doses of ≥375 mg/m^2, or — Occurrence of PD during rituximab maintenance therapy or within 6 months of completion of rituximab maintenance therapy • Alkylating agent (administered with or without rituximab): — Lack of a CR or PR during alkylating-agent-containing therapy comprising ≥2 cycles of treatment, or — Occurrence of PD within 6 months of the completion of a regimen of alkylatingagent-containing chemotherapy comprising ≥2 cycles of treatment • Discontinuation of all other therapies for the treatment of iNHL ≥ 3 weeks before initiation of study treatment (Visit 2). • All acute toxic effects of any prior antitumor therapy resolved to Grade ≤1 before initiation of study treatment (Visit 2) (with the exception of alopecia [Grade ≤2 permitted], neurotoxicity [Grade ≤2 permitted], or bone marrow parameters noted in Table 1 [Grade ≤2 permitted]). • Required baseline laboratory data (within 4 weeks prior to start of study drug administration) as shown in Table 1 of the study protocol.

Study Periods/Phases	This study will consist of 3 study periods. The screening period will be 4 weeks or less. The treatment period may continue until the occurrence of any events requiring treatment discontinuation. The long-term post-treatment follow-up period will be from the last dose of study drug up to Year 5. The study will be conducted in 2 stages using Simon's optimal 2-stage design. In Stage 1 of the study, 31 subjects will be enrolled; if ≥ 9 of these Stage 1 subjects have a tumor response, then the study will continue. In Stage 2, a further 69 subjects will be enrolled. The final study analysis will be performed when all enrolled subjects have completed efficacy, safety, and other assessments through at least 24 weeks of evaluation.

Schedule of Assessments

Period	Screen	Treatment																Follow-up	
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16+	End of Treatment	Immediate post-treatment	Long-term
Week	-4	0	2	4	6	8	10	12	16	20	24	30	36	42	48	Q12 Weeks			
Study Day	Within -28 Days	1	15	29	43	57	71	85	113	141	169	211	253	295	337				
Visit Window			±2	±2	±2	±2	±2	±2	±3	±3	±3	±3	±3	±7	±7	±7			
Informed consent	X																		
Medical history	X																		
Histopathology review	X																		
Serum virology	X																		
Coagulation	X																		
Urinalysis	X																		
β-HCG	X																		
PPD																			
HRQL – FACT-Lym		X		X		X		X	X	X	X	X	X	X	X	X			
Study drug return/accounting				X		X		X	X	X	X		X		X	X	X		
Adverse events		X		X		X		X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medications	X	X		X		X		X	X	X	X	X	X	X	X	X	X		
Performance status	X	X		X		X		X	X	X	X	X	X	X	X	X	X		
Vital signs	X	X		X		X		X	X	X	X	X	X	X	X	X	X		
Hematology	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Serum chemistry	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Pharmacodynamics		X		X		X		X	X	X	X	X	X	X	X	X	X		
Drug dispensing		X		X		X		X	X	X	X		X		X	X			

Period	Screen	Treatment																Follow-up	
Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16+**		**Immediate post-treatment**	**Long-term**
Week	**-4**	**0**	**2**	**4**	**6**	**8**	**10**	**12**	**16**	**20**	**24**	**30**	**36**	**42**	**48**	**Q12 Weeks**	**End of Treatment**		
Study Day	**Within -28 Days**	**1**	**15**	**29**	**43**	**57**	**71**	**85**	**113**	**141**	**169**	**211**	**253**	**295**	**337**				
Visit Window			**±2**	**±2**	**±2**	**±2**	**±2**	**±2**	**±3**	**±3**	**±3**	**±3**	**±3**	**±7**	**±7**	**±7**			
Physical examination	X								X								X		
12-lead ECG	X								X								X		
Immunophenotyping		X				X			X		X		X		X	X	X		
Serum immunoglobulins		X				X			X		X		X		X	X	X		
Radiology assessments (CT/MRI)	X					X			X		X		X		X	X	X		
Bone marrow biopsy/aspirate[a]	X					X[a]			X[a]		X[a]		X[a]		X[a]	X[a]			
SPEP (IgM monoclonal protein)	X					X			X		X		X		X	X	X		
Idelalisib dosing in clinic		X		X		X			X										
Limited PK		X		X		X			X										
PPD																			
Study Procedures and Timing[c]																			

a Required at screening. If disease present at baseline, to be performed post-baseline to confirm response category in subjects with potential CR by radiological assessments. If the baseline bone marrow biopsy/aspirate does not show lymphoma involvement, it is not necessary to obtain a follow-up bone marrow biopsy/aspirate to establish CR.

b For subjects with LPL only, performed locally per standard of care

c For detailed information regarding activities to be performed at each visit, see Section 7. 2 of study 101-09 protocol.

Abbreviations: β-HCG, beta human chorionic gonadotropin; HRQL, health-related quality of life; FACT-Lym, Functional Assessment of Cancer Therapy- Lymphoma; ECG, electrocardiogram; CT, computed tomography; LPL, lymphoplasmacytoid lymphoma; MRI, magnetic resonance imaging; SPEP, serum protein electrophoresis; CR, complete response

Randomization	No randomization will be performed in the study.
Site and/or Stratum Enrollment Limits	Study subjects will be enrolled at investigational sites in North America and Europe. At least 50 subjects with prior bendamustine exposure will be enrolled. The IWRS will gate accrual of subjects without prior bendamustine treatment.
Study Duration	All subjects may receive study drug indefinitely unless any of the withdrawal criteria (such as withdrawal of consent, experienced an adverse event, or tumor progression) indicated in Section 9 of the protocol is met. Subjects will be followed in the clinic at 2-week intervals through the first 12 weeks of treatment, at 4-week intervals from 12 to 24 weeks of treatment, at 6-week intervals from 24 to 48 weeks of treatment, and at 12-week intervals thereafter. Tumor response will be evaluated at baseline; at 8, 16, and 24 weeks of therapy; and every 12 weeks thereafter according to standard criteria. The responses will be assessed by both the investigator and an independent review committee (IRC), with the IRC-reviewed responses treated as primary in the efficacy analyses. Enrollment is planned to occur over $\leq$ 15 months; subject follow-up will continue through $\geq$ 6 months.

1.3. Sample Size and Power

Planned Sample Size	Up to 120 subjects may be enrolled in order to ensure enrollment of $\geq$ 100 subjects (31 in Stage 1, and 69 in Stage 2) who have a documented diagnosis of lymphoma, who have confirmed refractory disease, and who can be evaluated for tumor response with baseline and on-study scans (through the planned 24-week, follow-up tumor assessment).
Power Statement	The null hypothesis that the IRC-reviewed ORR is $\leq$ 20% will be tested against the alternative hypothesis that it is $\geq$ 39% (ie, ~40%). Using Simon's optimal 2-stage design [Simon 1989], a sample size of 100 subjects has power > 0.90 to achieve a 1-sided significance level of < 0.005 and will provide an adequate safety database.
Actual Enrollment and Impact on Power	A total of 125 subjects have been enrolled into this study and this will provide > 0.90 power to test the primary hypothesis.

2. TYPE OF PLANNED ANALYSIS

2.1. Interim Analysis

A single formal interim analysis is planned under Simon's optimal 2-stage design. The sole purpose of this interim analysis is to determine if there is a sufficient ORR observed early in the study to warrant continuing the study to completion. The interim analysis constitutes a futility analysis; it will not be used to stop the trial early for positive efficacy.

In Stage 1 of the study, 31 subjects will be enrolled. If ≥ 9 Stage 1 subjects have a response (ie, complete response or partial response), then the study will continue. If < 9 Stage 1 subjects have a response, accrual to the study will be halted. At the end of Stage 1, the probability of erroneously proceeding with the study is 0.151 under the null hypothesis and of erroneously discontinuing the study is 0.091 under the alternative hypothesis.

If the required Stage 1 tumor ORR is seen based on investigator assessments, accrual can proceed in Stage 2 without interruption. If the required total number of subjects are accrued to Stage 1 but follow-up is not sufficiently mature (ie, through the Week 16 radiographic evaluation) in all Stage 1 subjects to reasonably assess the Stage 1 ORR, accrual to Stage 2 may proceed while the Stage 1 data are being collated. All available tumor response and progression data will be considered at the time of the assessment. At the latest, the interim analysis will be performed when the last of the Stage 1 subjects has been enrolled and has completed the 16-week tumor assessment and these data are evaluated.

2.2. Final Analysis

In Stage 2 of the study, it is planned that 69 subjects will be enrolled to achieve the total intended sample size of 100 subjects. The final study analysis will be performed when all enrolled subjects have completed efficacy, safety, and other assessments through at least 24 weeks of evaluation.

3. GENERAL CONSIDERATIONS FOR DATA ANALYSES

3.1. Analysis Sets

3.1.1. Intent-to-Treat Analysis Set

The intent-to-treat (ITT) analysis set will comprise all subjects who receive ≥1 dose of IDELA. The ITT analysis set will be used in the analyses of ORR, progression-free survival (PFS), overall survival (OS), safety, and study drug administration and compliance. The ITT analysis set will be the primary analysis set for all the efficacy variables.

Duration of response (DOR) and time-to-response (TTR) will be analyzed based on all ITT subjects who achieve a CR or PR (including MR for subjects with WM). Lymph node response rate (LNR) will be analyzed based on all ITT subjects who have both baseline and ≥1 evaluable post-baseline tumor assessments.

3.1.2. Per Protocol Analysis Set

It is anticipated that ITT subjects who meet any of the following criteria will not be included in the per protocol (PP) analysis set:

- Do not have a diagnosis of lymphoma or documented refractory disease (refractory to both rituximab and an alkylating agent)
- Do not have measurable nodal disease at baseline as determined by the IRC
- Do not have a PFS event (PD or death), and do not have baseline and on-study tumor evaluation.

The PP analysis set will be used in analyses of ORR, DOR, TTR, LNR and PFS.

3.1.3. Pharmacodynamic/Pharmacokinetic Analysis Sets

The pharmacodynamic/pharmacokinetic analysis sets include data from subjects in the ITT analysis set who have the necessary baseline and on-study measurements to provide interpretable results for the specific parameters of interest.

3.2. Subject Groups

There is only 1 treatment group for this study.

3.3. Treatment Strata

There is only 1 treatment group for this study and no treatment strata were planned. However, given the increasing relevance of bendamustine as a component of treatment for subjects with iNHL, the IWRS will gate ≤50 subjects without prior bendamustine treatment.

3.4. Examination of Subject Subsets

The efficacy endpoints (ORR, DOR, TTR and PFS) will be examined in the following subject subsets:

- Refractory to last therapy status (Yes or No)
- Number of prior therapies (<4 or ≥4)
- Number of times refractory to an Alklating Agent (≤ 1 or > 1)
- Number of times refractory to Rituximab (≤ 2 or > 2)
- Refractory to bendamustine (Yes or No)
- Disease subcategory (FL, SLL, WM or MZL)
- Suite for radioimmunotherapy (Yes or No)
- Bulky status (Longest diameter of baseline lesion <7cm or ≥ 7cm)
- Gender (Male or Female)
- Age group (<65 or ≥65 years)
- Race (White or Non-White)
- Region (US or Non-US)

AEs will be examined in the following subject subsets:

- Sex (Male or Female)
- Age group (<65 or ≥65 years)
- Race (White or Non-White)
- Region (US or Non-US)

3.5. Multiple Comparisons

Not applicable.

3.6. Missing Data and Outliers

Missing Data

A missing data point for a given study visit may be due to any of the following reasons:

- A visit occurred in the window but data were not collected or were unusable
- A visit did not occur in the window
- A subject permanently discontinued from the study before reaching the window

In general, values for missing data will not be imputed unless methods for handling missing data are specified.

Missing data in Functional Assessment of Cancer Therapy: Lymphoma (FACT-Lym) will be handled according to the administration and scoring guidelines (Section 6.4.2.5).

Outliers

No data will be excluded from the analyses, including any outliers.

3.7. Data Handling Conventions and Transformations

- By-subject listings will be presented for subjects in the ITT analysis set and sorted by subject number, visit, and time (if applicable).
- Summary tables for continuous variables will contain the following statistics: N (number in analysis set), n (number with data), mean, standard deviation (StD), 95% CI, median, Q1, Q3, minimum, and maximum. The same number of decimal places as in the raw data will be presented when reporting minimum and maximum, 1 more decimal place than in the raw data will be presented when reporting mean, median, Q1 and Q3, and 2 more decimal places than in the raw data will be presented when reporting StD and 95% CI.
- Summary tables for categorical variables for baseline and safety data will include: N, n, percentage. The tables for efficacy endpoints will include standard error, and 95% CIs on the percentage, where appropriate. Unless otherwise indicated, 95% CIs for binary variables will be calculated using the binomial distribution. The denominator for the percentages will be the number of subjects in the respective analysis set, unless otherwise specified. Missing data will be included as a row in tables where it is appropriate. All percentages will be presented as one-decimal point, unless otherwise specified. Percents equal to 100 will be presented as 100% and percents will not be presented for zero frequencies.
- Data from all sites will be pooled for all analyses.
- Unscheduled visits will only be included in listings and the best or worst post-baseline summary. Unscheduled visits will not be included in the by-visit summary tables, unless otherwise specified.

- Unless otherwise specified, all analyses will be 2-sided at the 0.05 level of significance.
- For Kaplan-Meier (KM) estimates, the 95% CIs will be calculated using Greenwood's formula with (complementary) log-log transformation.

3.7.1. Data Handling for Efficacy Endpoints

If there is a significant degree of non-normality for a continuous endpoint, analysis may be performed on log-transformed data or using nonparametric methods, as appropriate.

3.7.2. Data Handling for Laboratory data

Laboratory data that are continuous in nature but are less than the lower limit of quantitation or above the upper limit of quantitation will be imputed as follows:

- A value that is 1 unit less than the limit of quantitation will be used for calculation of descriptive statistics if the data is reported in the form of "<x" (x is considered the limit of quantitation). For example, if the values are reported as <50 and <5.0, then values of 49 and 4.9 will be used for calculation of summary statistics, respectively. However, for direct bilirubin, a value of "<0.1" will be treated as 0.05 for calculation of summary statistics.
- A value that is 1 unit above the limit of quantitation will be used for calculation of descriptive statistics if the data is reported in the form of ">x" (x is considered the limit of quantitation). For example, if the values are reported as >50 and >5.0, then values of 51 and 5.1 will be used for calculation of summary statistics, respectively.
- The limit of quantitation will be used for calculation of descriptive statistics if the data is reported in the form of "≤ x" or "≥ x" (x is considered as the limit of quantitation).

3.8. Visit Windows

3.8.1. Definition of Study Day 1 and Baseline

Study Day 1 is defined as the day of first dose of study medication.

Baseline is defined as the last observation before the first dose, unless otherwise specified.

3.8.2. Analysis Windows

For parameters that will be summarized by visit, the nominal visit as recorded on the electronic case report form will be used. For parameters assessed at the end of treatment (EOT) visit, the assessment results will be assigned to the next scheduled visit where the respective data were scheduled to be collected for summary. There will be no additional analysis windowing done based on the assessment date.

3.8.3. Selection of Data in the Event of Multiple Records in a Window

Depending on the statistical analysis method, single values may be required for each analysis window. For example, change from baseline by visit usually requires a single value per visit. Unless otherwise noted throughout the rest of this document, when a single value is needed, the following rule(s) will be used:

- If more than 1 assessment occurs during the same nominal visit, select the record closest to the nominal day for that visit.
- If there are 2 assessments that are equidistant from the nominal day, the data of the assessment after the scheduled study day will be used.
- The last measurement will be used if multiple measurements are taken on the same day.

4. SUBJECT DISPOSITION

4.1. Subject Enrollment

The number and percentage of subjects treated with IDELA will be summarized. A listing of subjects treated will be provided to describe site, subject number, inform consent date, screening date, and date of first dose of IDELA.

A listing of screen failed subjects will be provided to include date of informed consent and the reasons for screen failing.

4.2. Disposition of Subjects

A summary of subject disposition will be provided. This summary will present number of subjects:

- screened
- treated with study drug (ie, ITT analysis set)
- treatment ongoing
- treatment completed due to disease progression or death
- discontinued the study treatment (with summary of reasons for not completing),
- entered the 5-year long-term follow-up
- in the PP, phamacodynamic and pharmacokinetic analysis sets

The denominator for the percentages of subjects in each category will be the number of subjects in the ITT analysis set.

Subjects who completed and discontinued long-term follow-up through 5 years will be summarized separately. The reasons for not completing the 5-year follow-up will be summarized as well.

A data listing of reasons for premature study treatment discontinuation will be provided along with subject number, site number, first and last dosing date, duration of treatment, and last contact date. The most recent, non-missing primary and key secondary endpoint values prior to discontinuation will also be included in this listing.

4.3. Extent of Exposure

4.3.1. Duration of Exposure to Study Drug

Duration of exposure to study drug will be defined as (min(last dose date, data cutoff date) – first dose date + 1), regardless of temporary interruptions in study drug administration, and will be expressed in months. Duration of exposure to study drug will be summarized for ITT analysis set using descriptive statistics and as the number and percentage of subjects exposed for at least 1 day, 2, 4, 6, 12 months, and every 6 months thereafter.

Number and percentage of subjects who had dose modification (dose reduction and dose re-escalation) will also be summarized.

IDELA dosing records, drug accountability (dispense and return) records and dose modification records will be listed in details.

4.3.2. Adherence (Compliance) with Study Drug

Adherence (%) with study drug will be calculated as:

Adherence (%) = {sum of pills dispensed minus pills returned for each dosing period} divided by {sum over all dosing period of (total daily pills x dosing duration)}, taking into account physician-prescribed reductions, escalations and interruptions.

Descriptive statistics for adherence along with the number and percentage of subjects belonging to adherence categories (eg, $< 80\%$ or $\geq 80\%$) will be provided for the ITT analysis set. No inferential statistics will be provided.

4.4. Protocol Deviations

Protocol deviations will be identified by the Gilead clinical team. Major protocol deviations will be summarized by type of deviation in the clinical study report (CSR) based on ITT analysis set. A listing will be provided for all major protocol deviations.

5. BASELINE DATA

5.1. Demographics and Baseline Characteristics

Demography including gender, race, ethnicity, age (years), weight (kg), height (cm) and body mass index (BMI, kg/m^2) will be summarized for the ITT analysis set.

Age will be calculated as the number of years between date of birth and date of first dose.

Age (years) = (date of first dose – date of birth+1) / 365.25 (round down to an integer)

BMI (kg/m^2) = weight / $(height)^2$ (round to 1 decimal point)

Number and percentage of subjects <65 and ≥65 years will also be summarized. A data listing will be presented for date of birth and the above demographic data. ECOG performance status collected at the baseline will also be summarized.

5.2. Medical History

Summary tables will be provided based on the ITT analysis set.

5.2.1. Indolent NHL Disease History/Status

Number and percent of subjects with different types of disease history (as categorized in the CRF) for indolent Non-Hodgkin lymphoma (iNHL) and results for organ assessment will be summarized using ITT analysis set. Data listings will be presented separately for iNHL history and organ assessments. Time since disease diagnosis (in years) will also be summarized using descriptive statistics.

All disease history with partial diagnosis date will be identified and the partial dates will be imputed as follows:

- If day and month are missing but year is available, then the imputed day and month will be 01 Jan.
- If day is missing but the month and year are available, then the imputed day will be the first day of the month.

No imputation will be done if the year of diagnosis is missing.

A similar summary will be provided for the PP analysis set.

5.2.2. General Medical History

Medical conditions will be coded to system organ class (SOC), high level term (HLT), and preferred term (PT) using Medical Dictionary for Regulatory Activities (MedDRA) coding dictionary version 15.1. Ongoing medical conditions will be graded per Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0 (1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening or disabling and 5=Fatal).

General medical history, history of liver disease and clinically significant elevated transaminase (alanine aminotransferase/aspartate aminotransferas) or bilirubin will be summarized by SOC, HLT, and PT. The summary will be sorted in descending frequency by SOC, HLT, and PT. Data will be listed for the 3 types of histories separately.

Ongoing general medical history will be summarized separately by SOC, HLT, PT, and severity.

6. EFFICACY ANALYSES

Imaging-based tumor assessments will be performed within 28 days prior to the start of treatment. On-study tumor assessments will be performed at ~8- to 12-week intervals at visits 1, 6, 9, 11, 13, and 15 (corresponding to baseline, Weeks 8, 16, 24, 36, and 48) and every 12 weeks thereafter. An end-of-treatment tumor assessment (if the subject withdraws from the study for reasons other than tumor progression on a routine imaging/scan) should be performed if the last assessment was performed > 4 weeks prior to end-of-treatment visit.

Imaging-based tumor assessments include site of lesion and bi-dimensional measures for the largest diameter and the perpendicular diameter. Tumor response will be evaluated by both investigators and IRC.

Data will be presented for both investigators assessments and IRC assessments. A subject's response status at each visit, best overall response (BOR), date of progression and date of first response will be determined by IRC and recorded in the IRC database. The findings of IRC will be considered primary for analyses of ORR and other tumor control endpoints (ie, DOR, TTR, % changes in tumor size and PFS). Consistency of evaluation between IRC and investigator assessments will be summarized by the percent agreement for overall response.

6.1. Definition of the Primary Efficacy Endpoint

A best overall response of CR, PR, stable disease (SD), PD, not evaluable (NE) and no disease (ND) is allowed. For subjects with WM, a minor response (MR) is also allowed. In the event that a single PD is followed by an assessment that is SD, PR or CR which is the same or better than the prior nadir response and there is substantial interruption of exposure to study drug, that PD may not be considered in the BOR evaluation in accordance with the Gilead Protocol 101-09 Imaging Charter.

ORR is defined as the proportion of subjects who achieve a CR or PR (or MR for subjects with WM) during the IDELA treatment. The response definitions for each category are based on standard criteria and defined in Section 8.1.5 of the protocol. Subjects who do not have sufficient baseline or on-study tumor status information to be adequately assessed for response status (ie, those with best overall responses of NE or ND) will be included in the denominators in calculations of response rates.

6.2. Statistical Hypothesis for the Primary Efficacy Endpoint

The study will test the hypothesis that ORR is $\geq 39\%$ (i.e. $\geq$ ~40%) against the null hypothesis that it is $\leq 20\%$.

6.3. Analysis of the Primary Efficacy Endpoint

The ORR and 95% CI will be presented along with the corresponding p-value from the exact binomial test. The number and proportion of subjects who were evaluated as CR, PR, SD, PD, NE, and ND will also be tabulated.

The primary analysis for ORR will be conducted in the ITT set based on the IRC assessments. The investigator assessments will also be summarized. Both investigator and IRC assessments for tumor response will be listed in detail including site of lesion, date and method of evaluation, bidirectional measures and sum of the products of the perpendicular diameters of measurable index lesions (SPD). Summaries will also be provided for response at each visit separately when tumor assessment is available.

Agreement in best overall response between IRC and investigator assessments will be summarized.

6.4. Secondary Efficacy Endpoints

6.4.1. Definition of Secondary Efficacy Endpoints

- DOR – defined as the interval from the first documentation of CR or PR (or MR for WM subjects) to the earlier of the first documentation of disease progression or death from any cause
- LNR – defined as the proportion of subjects who achieve a ≥□ 50% decrease from baseline in the SPD
- TTR – defined as the interval from the start of study drug to the first documentation of CR or PR (or MR for WM subjects)
- PFS – defined as the interval from the start of study drug to the earlier of the first documentation of disease progression or death from any cause
- OS - defined as the interval from the date of first IDELA to death from any cause
- Changes in HRQL as reported by subjects using the FACT-Lym
- Changes in performance status as documented using the Karnofsky performance criteria

6.4.2. Analysis Methods for Secondary Efficacy Endpoints

6.4.2.1. Duration of Response and Progression-Free Survival

The date of definitive progression will be the timepoint at which progression is first identified by relevant radiographic or imaging data. Death occurring ≤ 30 days following the discontinuation of study drug will be considered as an event for the DOR and PFS calculation. Data will be censored on the date of the last tumor assessment (including assessments with a NE outcome) for subjects

- who do not have disease progression or die within 30 days after discontinuation of the study drug, or
- who start new anti-tumor therapy prior to documented disease progression, or
- who have 2 or more consecutive missing tumor assessments before disease progression or death.

Subjects without adequate baseline tumor response evaluation will be censored on Study Day 1. PFS will also be summarized for responding subjects (ie, subjects with a CR or PR) and non-responding subjects separately.

To assess the robustness of the primary DOR and PFS results, the following sensitivity analyses will be performed:

- DOR and PFS will be assessed based on IRC assessments using the PP analysis set based on the same censoring rules as above.
- DOR and PFS will be assessed based on investigators assessments using the same censoring rules as above.
- DOR and PFS will be assessed based on the first PD identified by IRC without consideration of any drug interruption or the response status post that PD with all other censoring rules staying the same as the primary analysis.

PPD

DOR and PFS will be summarized using KM methods and KM curves for DOR and PFS will be provided. All the derived endpoints will be listed.

6.4.2.2. Lymph Node Response Rate

The LNR will be summarized with 95% CI using the exact method based on the ITT and PP analysis sets using both the IRC assessments and investigators assessments.

The SPD and percent change in SPD from baseline to each subsequent assessment will be summarized using both the IRC assessments and investigators assessments. The best percent change from baseline during the study will also be summarized based on the first reader of each reader pair ([Gilead Protocol 101-09 Imaging Charter]) unless the adjudicator choose the second reader. The best percent change from baseline in SPD is defined as the largest decrease in tumor size while the subject was on-treatment. The baseline SPD will be the last value prior to the start of IDELA therapy. Note that for subjects who only have increases in tumor size from baseline, the smallest increase will be considered as the best change from baseline in SPD. Analyses will be conducted for the ITT and PP analysis sets.

A waterfall plot of best on-treatment percent change in SPD based on the IRC and investigators assessments will be provided. Individual records for measurable and nonmeasurable lesions will be listed in detail.

6.4.2.3. Time to Response

TTR will be evaluated using both the IRC and investigators data based on ITT and PP subjects who achieve a CR or PR (or MR for WM subjects). TTR will be summarized using descriptive statistics.

6.4.2.4. Overall survival

OS will be analyzed using the KM method and KM curves for OS will be provided based on the ITT analysis set. An on-study OS analysis will be performed by only including deaths that occur while a subject is on study treatment or within 30 days post-last study treatment. Furthermore, OS will be analyzed by including the long-term follow-up data and considering any death as an event. Data from surviving subjects will be censored at the last time that the subject was known to be alive.

6.4.2.5. Health-Related Quality of Life

The FACT-Lym questionnaire includes subscales for physical well-being (PWB, 7 items), social/ family well-being (SWB, 7 items), emotional well-being (EWB, 6 items), functional well-being (FWB, 7 items) and additional concerns (Lymphoma Subscale, LymS, 15 items). The FACT-Lym scoring guide identifies those negatively stated items that must be reversed before being added to obtain subscale totals. Negatively stated items are reversed by subtracting the response from "4". After reversing proper items, all subscale items are summed to a total, which is the subscale score. For all FACT-Lym scales and symptom indices, the higher score is associated with the better quality of life. The scores in the following items need to be reversed:

- Physical well-being: all individual items
- Social/family well-being: none
- Emotional well-being: 5 individual items (except for the second item, "I am satisfied with how I am coping with my illness")

- Functional well-being: none
- Additional concerns: all individual items

The subscale scores will be a summation of each individual item score. If ≤ 50% of item scores are missing, the subscale score will be calculated by multiplying the sum of the item scores by the number of items in the subscale, then divided by the number of non-missing item scores. This imputes the missing scores by the mean of the non-missing scores within a subscale.

Prorated subscale score = [sum of item scores] x [N of items in subscale]□/ [N of items answered]

The following composite scores will be derived from the above subscale total scores:

- FACT_Lym Trial Outcome Index (TOI, score range: 0-116) = PWB + FWB + LymS
- FACT_G Total Score (score range: 0-108) = PWB + SWB + EWB + FWB
- FACT_Lym Total Score (score range: 0-168) = PWB + SWB + EWB + FWB + LymS

The FACT-G and FACT-Lym Total scores will be set to missing if 20% or more of the included items are missing (eg, only calculated if at least 22 of 27 FACT-G items are completed) or any of the component subscales are missing. TOI scores are set to missing if any of the component subscales are missing.

If the baseline value is missing for subscale (ie, PWB, SWB, EWB, FWB and LymS), mean values of the corresponding subscale scores will be used to impute the baseline value. The mean and change from baseline in mean scores to each subsequent assessment will be summarized for the subscale and composite scores. The best change from baseline during the study, defined as the highest positive value among all post-baseline visits minus the baseline value, will also be summarized.

Each subject's lymphoma subscale score and FACT-General subscales (ie, PWB, EWB, SWB, and FWB) scores at each assessment will be compared to their baseline scores. The minimally important difference (MID) for the FACT-Lym subscale is 3-5 points (Hlubocky et al, in press) and the MID for FACT-General subscales is 2-3 points (Yost and Eton 2005). As recommended by Yost and Eton (2005), the high end of this range will be used for interpreting individual subject change. An increase of at least 5 points will be required as a definition of symptom improvement for the lymphoma subscale and 3 points will be required as a definition of symptom improvement for the FACT-General subscales. A decline of at least 5 points will define symptom worsening for the lymphoma subscale and a decline of at least 3 points will define symptom worsening for the FACT-General subscales. Time to symptom response will be assessed by defining the first occurrence of symptom improvement as an event. Subjects who do not experience a symptom improvement compared to baseline will be censored at their last available PRO assessment time. Time-to-event analyses will be performed using the KM method. The cumulative distribution function (CDF) of best (or worst) change from baseline will be also provided. For the MID improvement comparison in Lyms, subjects with baseline score >55 will be excluded (ie, subjects with no room for improvement). For the MID improvement comparison in FACT-General subscales subjects with baseline score >57 will be excluded.

A data listing for each individual item, the subscale scores and the composite scores will be presented for each subject at each visit.

6.4.2.6. Performance Status

The Karnofsky performance status scores and the change from baseline scores to each subsequent assessment will be summarized. The best and worst changes from baseline during the study will also be summarized. The best change from baseline is defined as the highest change score at post baseline. The worst change from baseline is defined as the lowest change score at post baseline.

7. SAFETY ANALYSES

7.1. Adverse Events and Deaths

The start of the AE reporting for a study subject will coincide with signing of the informed consent. The end of the adverse-event-reporting period occurs 30 days after discontinuation from study or when any ongoing drug-related AEs and/or serious adverse events (SAEs) have resolved or become stable.

The focus of AE summarization will be on treatment-emergent AEs using the ITT analysis set. All AEs will be listed.

7.1.1. Adverse Event Dictionary

AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 15.1. System organ class (SOC), high level group term (HLGT), high level term (HLT), preferred term (PT), and lower level term (LLT) will be attached to the clinical database.

7.1.2. Adverse Event Severity

The severity of AEs will be graded by the investigator according to the CTCAE, Version 3.0, whenever possible. If a CTCAE criterion does not exist, the grade corresponding to the appropriate adjective will be used by the investigator to describe the maximum intensity of the AE. The severity grade will be categorized as:

- Grade 1 (mild)
- Grade 2 (moderate)
- Grade 3 (severe)
- Grade 4 (life threatening), or
- Grade 5 (fatal)

A missing severity grade will be considered as missing.

7.1.3. Relationship of Adverse Events to Study Drug

The investigator-described relationship of the adverse event to the study drug will be categorized as:

- Definite
- Probable

- Possible
- Unlikely, or
- Unrelated

AE will be considered as treatment-related if the causal relationship with study drug is recorded as definite, probable or possible. Events for which the investigator did not record relationship to study drug will be considered related and data listings will show relationship as missing.

7.1.4. Serious Adverse Events

SAEs are those identified as serious in the clinical database. The clinical database will be reconciled with the SAE database from the Drug Safety and Public Health (DSPH) department before database finalization.

7.1.5. Treatment-Emergent Adverse Events

7.1.5.1. Definition of Treatment-Emergent

Treatment-emergent AEs are events in a given study period that meet one of the following criteria:

- Events with onset dates on or after the start of treatment and up to 30 days after the permanent discontinuation of the study medication.
- The continuing AEs diagnosed prior to the start of treatment and worsening in severity grade, or non-serious AEs at baseline which become serious, or AEs resulting in treatment discontinuation after the start of treatment.

7.1.5.2. Incomplete Dates

All AEs with partial onset or stop dates will be identified and the partial dates will be imputed as follows:

- For AE onset date: If day and month are missing but year is available, then the imputed day and month will be 01Jan or the first dosing date if they have the same year, whichever is later. If day is missing but the month and year are available, then the imputed day will be the first day of the month or the first dosing date if they have the same month and year, whichever is later.
- For AE stop date: If day and month are missing but year is available, then the imputed day and month will be 31Dec or 30 days after the last dose of IDELA if they have the same year, whichever is earlier. If day is missing but the month and year are available, then the imputed day will be the last day of the month or 30 days after the last dose of IDELA if they have the same month and year, whichever is earlier.

7.1.6. Summaries of Adverse Events and Deaths

A brief summary of treatment-emergent AEs will show the number and percentage of subjects who (1) had any AE, (2) had any Grade ≥3 AE, (3) had any treatment-related AE, (4) had any Grade ≥3 treatment-related AE, (5) had any SAE, (6) had any treatment-related SAE, (7) discontinued from study drug due to an AE, (8) dose reduction due to an AE, (9) death due to AEs (10) death during study drug treatment up to 30 days post last dose and (11) all deaths including long-term follow up .

Summaries (number and percentage of subjects) of treatment-emergent AEs (by SOC, HLT and PT) will be provided as follows:

- All AEs
- All AEs by severity
- Grade ≥3 AE
- All AEs occurring in at least 10% of subjects
- All treatment-related AEs
- All treatment-related AEs by severity
- Grade ≥3 treatment-related AEs
- All SAEs
- All treatment-related SAEs
- All AEs that caused discontinuation from study drug
- AEs leading to deaths

Multiple events will be counted once only per subject in each summary. For data presentation, SOC, HLT and PT will be sorted by decreasing frequency. For summaries by severity grade, the most severe event will be selected. In addition to the presentation by SOC and HLT, each summary listed above will also be presented by preferred term in decreasing frequency.

Summary of all treatment-emergent AEs will also be summarized by SOC, HLT and PT, and by PT only in the following subgroups: sex (Male or Female), age group (<65 or >=65 years) and race (White or Non-White).

In addition to the by-treatment summaries, data listings will be provided for the following:

- All AEs (with a variable indicating whether the event is treatment-emergent)

- SAEs (with a variable indicating whether the event is treatment-emergent)
- AEs leading to deaths
- AEs leading to discontinuation of study drug

Relative day from first dose date will be provided for each AE in the listings. If the AE onset date is after the first dose date, the relative day will be calculated as (AE onset date – first dose date + 1), however, if the AE onset date is prior to the first dose date, the relative day will be calculated as (AE onset date- first dose date).

7.2. Laboratory Evaluations

All laboratory data will be listed. Summaries of laboratory data will be based on observed data and will be reported using SI units. The focus of laboratory data summarization will be on treatment-emergent laboratory abnormalities using the ITT analysis set.

7.2.1. Summaries of Numeric Laboratory Results

Descriptive statistics (sample size, mean, standard deviation, median, Q1, Q3, minimum and maximum) will be provided for each laboratory test specified in the study protocol as follows:

- Baseline values
- Values at each post-baseline analysis window
- Change from baseline at each post-baseline analysis window

In the case of multiple values in an analysis window, data will be selected for analysis as described in Section 3.8.3. In addition, the mean change from baseline for lab parameters will be plotted over time.

7.2.2. Summaries of Categorical Laboratory Results

Laboratory data that are categorical will be summarized using number and percentage of subjects in the study with the given response at baseline and each scheduled post-dose assessment.

7.2.3. Graded Laboratory Values

Applicable hematological and serum biochemistry laboratory data will be programmatically graded according to CTCAE, Version 4.03 severity grade [grade laboratory results as Grade 0, mild (Grade 1), moderate (Grade 2), severe (Grade 3), or life threatening (Grade 4)]. Grade 0 includes all values that do not meet criteria for an abnormality of at least Grade 1. Some laboratory tests have criteria for both increased and decreased levels; analyses for each direction (ie, increased, decreased) will be presented separately.

7.2.3.1. Treatment-Emergent Laboratory Abnormalities

A treatment-emergent laboratory abnormality is defined as an abnormality that, compared to baseline, worsens by ≥1 grade in the period from the first dose of IDELA to 30 days after the last dose of study treatment. If baseline data are missing, then any graded abnormality (ie, an abnormality that is Grade ≥1 in severity) will be considered treatment-emergent.

7.2.3.2. Summaries of Laboratory Abnormalities

The following summaries (number and percentage of subjects) of treatment-emergent laboratory abnormalities will be provided (subjects will be categorized according to most severe abnormality grade):

- Baseline and worst post-baseline laboratory abnormalities
- Grade ≥ 3 laboratory abnormalities

For all summaries of laboratory abnormalities, the denominator is the number of subjects in the ITT analysis set. A listing of treatment-emergent Grade ≥ 3 laboratory abnormalities will be provided.

7.2.4. Shift in CTCAE Grade Relative to Baseline

Shift tables will be presented by showing change in CTCAE severity grade from baseline to the worst grade post baseline.

7.2.5. Transaminase elevations

Analysis of transaminase elevations will be based on laboratory values. Number and percentage of subjects will be summarized for subjects

- with Grade 3 or 4 ALT/AST elevation
- with Grade 3 or 4 ALT/AST elevation resolved to both ALT/AST of Grade 1 or less
- re-challenged after dose interruption due to Grade 3 or 4 ALT/AST elevation

- with recurrence of grade 3 or 4 ALT/AST elevation

- with recurrent Grade 3 or 4 ALT/AST elevation resolved to both ALT/AST of Grade 1 or less

Kaplan-Meier curves and estimates will be provided for time to onset of first Grade 3 or 4 treatment-emergent ALT/AST elevations. Time to onset of first event is defined as time from start of study treatment to the start date of first Grade 3 or 4 treatment-emergent ALT/AST elevation, ie, time in days is calculated as (start date of first occurrence) – (date of first dose of study drug) +1. In the absence of an event, the censoring date applied will be the earliest from the following dates: last dose date (if treatment discontinued) + 30 days, analysis data cut-off date and death.

For subjects with at least 1 episode of Grade 3 or 4 ALT/AST elevation, time to resolution of first episode of treatment-emergent Grade 3 or 4 ALT/AST elevation to Grade 1 or less will be summarized using Kaplan-Meier estimates. The same censoring rule described above for time to onset will be used. In addition, the same analysis will be performed for subjects who are rechallenged due to Grade 3 or 4 treatment-emergent ALT/AST elevations.

7.3. Vital Signs

Vital sign data (body temperature, sitting systolic and diastolic blood pressures, and sitting pulse rate) will be summarized in the following tables:

- Actual values and the changes from baseline by visit for each measure

- Number and percent of subjects by systolic (SBP) and diastolic blood pressure (DBP) category (high, normal, low) at each visit categorizing SBP $\geq$ 140 mmHg as high and $<$ 90 mmHg as low; DBP $\geq$ 90 mmHg as high and $<$ 60 mmHg as low.

Data for body weight and height will be listed with the vital signs as collected in the CRF. High or low values for vital signs will be flagged.

7.4. Prior Therapy and Prior Radiation

Number of prior regimens and time since the completion of last regimen will be summarized using descriptive statistics (sample size, mean, standard deviation, median, Q1, Q3, minimum and maximum). A partial completion date will be imputed using the following algorithm for the last regimen:

- If day and month are missing but year is available, then the imputed day and month will be 01Jan or the starting date of the last regimen, whichever is later;

- If day is missing but the month and year are available, then the imputed day will be the first day of the month, or the starting date of the last regimen, whichever is later;

- If year is missing, no imputation will be done and the completion date will be treated as missing.

Number (%) of subjects who received 1, 2, 3, ... prior regimens will also be provided. In addition, number (%) of subjects refractory to rituximab, refractory to alkylating-agent, refractory to bendamustine, and refractory to last therapy will also be summarized. Descriptive statistics will be provided for number of subjects who received certain regimens (eg, BR, CHOP, R-CHOP). Descriptive statistics will also be provided for the last regimen subjects received prior to study entry. The best response (n, %) to last therapy, and duration of response to the last therapy will be summarized.

Number of subjects received prior radiation will be summarized and will be listed.

7.5. Concomitant Medications

Concomitant medications will be coded by means of the World Health Organization Drug Dictionary (WHO DRUG) dictionary, June 2010 into Anatomical-Therapeutic-Chemical classification (ATC) codes.

Concomitant medications are defined as any medications meeting the following criteria:

- Starting on or after the first dose of IDELA treatment up to 30 days post the last dose
- Starting before and continuing after the first dose of IDELA treatment up to 30 days post the last dose

The incomplete dates handling method used for AE summaries will be used for concomitant medication summaries (section 7.1.5.2).

Prior medications are defined as any medications stopped before the first dose of study drug. Summaries of the number and percentage of subjects who used prior and concomitant medications will be presented in tabular form by preferred drug name based on ITT analysis set. The summary tables will be sorted by descending frequency of preferred term in the total column. Subjects will only be counted once for multiple drug use (by preferred drug name) per subject.

Concomitant medications started on/-after the start of study medication or ongoing medications will be flagged on the prior and concomitant medication data listing.

The summaries and listings will be based on the ITT analysis set.

7.6. Electrocardiogram Results

The following analyses of electrocardiogram (ECG) results are intended to identify gross changes in QT intervals. The 12-lead ECG measurements will be collected at screening, Visit 9 (Week 16), and end of treatment visit.

7.6.1. Corrected QT Intervals

Corrected QT (QTc) intervals will be derived by using Bazett and Fridericia methods:

Bazett: QTc-B = QT / $(RR)^{1/2}$, and

Fridericia: QTc-F = QT / $(RR)^{1/3}$,

Where, RR is calculated as [60 / Heart Rate (beats/min)].

The QTc data (msec) obtained by using the Bazett and Fridericia corrections will be categorized separately into the following classifications and summarized by visit:

- ≤ 450
- 451–480
- 481–500
- > 500

The change in QTc values (msec) obtained by using the Bazet's and Fridericia's correction will also be categorized separately as follows:

- ≤ 30
- 31-60
- > 60

QTcB, QTcF, and uncorrected QT values at each visit and change from baseline at each visit will be summarized for the ITT analysis set using descriptive statistics (sample size, mean, standard deviation, median, Q1, Q3, minimum, and maximum).

7.6.2. Investigator Assessment of ECG Readings

The number and percentage of subjects in the ITT analysis set with an investigator's ECG assessment of normal, abnormal and clinically significant, or abnormal but not clinically significant will be summarized for baseline and for each visit.

7.7. Physical Examination

Physical examination results will be summarized by body system and visit. All results will be listed.

7.8. Post Treatment Assessments

Information for post IDELA therapy for iNHL, new non-iNHL-related health problems and follow-up contact records will be listed as reported in the CRF.

8. PHARMACOKINETIC ANALYSES

Limited plasma samples will be collected for concentrations of IDELA and its metabolite, GS-563117 (formerly CAL-244), prior to dosing and 1.5 hours (± 5 minutes) post dose on Days 1, 29, 57, and 113 for all subjects. PPD

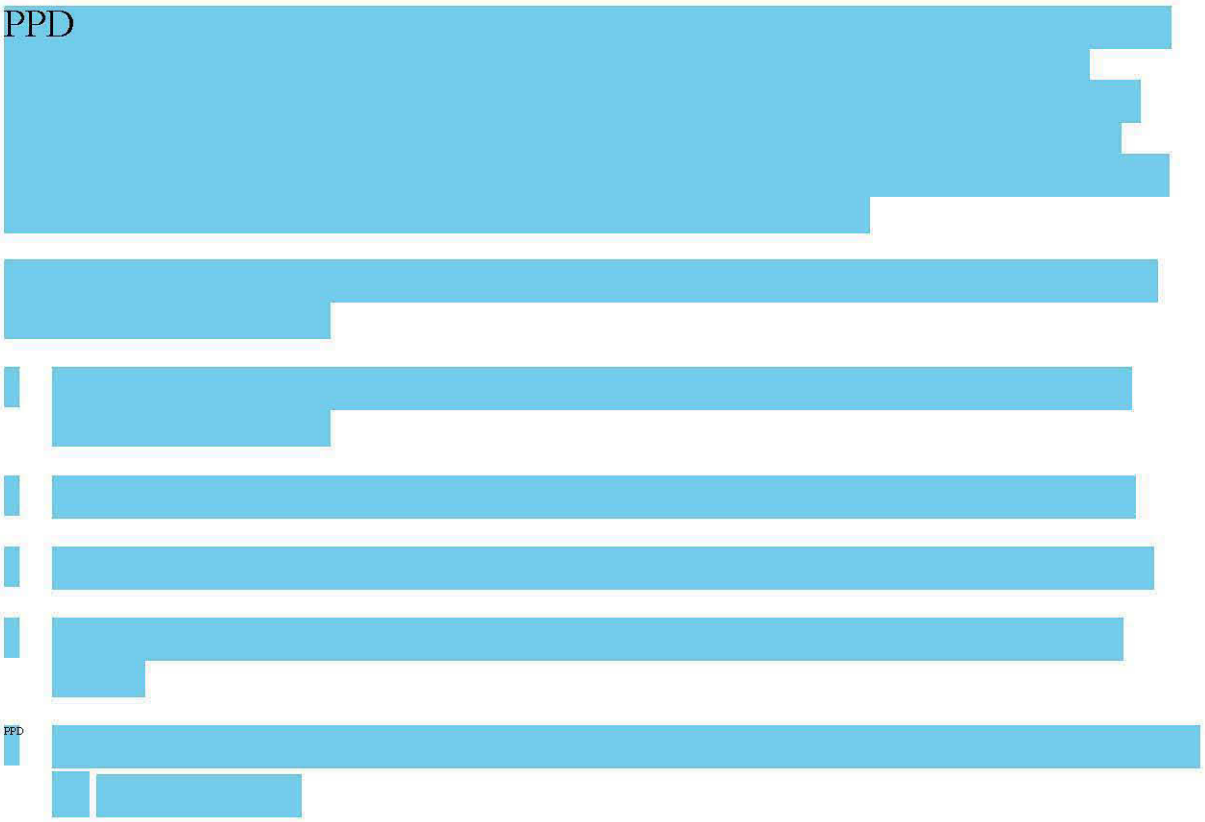
8.1. Estimation of Pharmacokinetic Parameters

PPD

PPD

8.2. Statistical Analysis Methods

PPD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PPD

9. PHARMACODYNAMIC ANALYSES

If data are available, pharmacodynamic measures may be summarized. For example, the concentrations of relevant chemokines and cytokines with a particular focus on CCL7, CCL17, CCL22, CXCL12, CXCL13, interleukin-6, tumor necrosis factor-α, and C-reactive protein, serum iron metabolism (eg, hepcidin, iron, ferritin, transferrin) will be summarized. IDELA drug concentration and pharmacodynamic measures will be listed.

For each pharmacodynamic variable, the concentration at each assessment will be described. The change from baseline to each assessment will be summarized. The best change from baseline during the study will also be summarized.

10. REFERENCES

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonised Tripartite Guideline, Statistical Principles for Clinical Trials (E9), 5 February 1998.

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The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation, Kimberly Webster, David Cella* and Kathleen Yost, 16 December 2003. http://www.hqlo.com/content/1/1/79

Simon R. Optimal two-stage designs for phase II clinical trials. Control Clin Trials. 1989 Mar;10(1):1-10.

BioClinica Bio-READ® Imaging Charter for Gilead Sciences, Inc. Protocol 101-09.

11. SOFTWARE

SAS® Software Version 9.1 or higher, SAS Institute Inc. , Cary, NC, USA.

12. SAP REVISION

Revision Date (dd month, yyyy)	Section	Summary of Revision	Reason for Revision

13. APPENDICES

Table Number	Title	Analysis Set
1.1.1	Demographics	ITT Analysis Set
1.1.2	Baseline Characteristics	ITT Analysis Set
1.2.1	Subject Disposition	ITT Analysis Set
1.2.2	Subject Disposition at Long-term Follow-up	ITT Analysis Set
1.3	Major Protocol Deviations	ITT Analysis Set
1.4.1	Disease History	ITT Analysis Set
1.4.2	Disease History	Per Protocol Analysis Set
1.4.3	Baseline Disease Status	ITT Analysis Set
1.4.4	Baseline Disease Status	Per Protocol Analysis Set
1.5.1	Medical History - General	ITT Analysis Set
1.5.2	Medical History - Liver Disease	ITT Analysis Set
1.5.3	Medical History - Clinically Significant Elevated Transaminase (ALT/AST) or Bilirubin Levels	ITT Analysis Set
1.6.1	Prior Therapy	ITT Analysis Set
1.6.1.1	Prior Therapy by Regimen Type	ITT Analysis Set
1.6.1.2	Prior Therapy Subjects Refractory To by Regimen Type	ITT Analysis Set
1.6.1.3	Prior Therapy by Preferred Terms	ITT Analysis Set
1.6.2	Most Recent Regimen Prior to Receiving Study Drug	ITT Analysis Set
1.6.2.1	Most Recent Regimen Prior to Receiving Study Drug by Regimen Type	ITT Analysis Set
1.6.3	Prior Radiation	ITT Analysis Set
1.7	Concomitant Medications by Preferred Terms	ITT Analysis Set
1.8	Study Drug Exposure	ITT Analysis Set
2.1.1	Overall Response Rate (ORR)	ITT Analysis Set
2.1.1.1	Overall Response Rate (ORR) by Gender	ITT Analysis Set
2.1.1.2	Overall Response Rate (ORR) by Age	ITT Analysis Set
2.1.1.3	Overall Response Rate (ORR) by Race	ITT Analysis Set
2.1.1.4	Overall Response Rate (ORR) by Disease	ITT Analysis Set
2.1.1.5	Overall Response Rate (ORR) by Number of Prior Therapies	ITT Analysis Set
2.1.1.6	Overall Response Rate (ORR) by Refractory to Last Prior Therapy	ITT Analysis Set
2.1.1.7	Overall Response Rate (ORR) by Longest Diameter of Baseline Lesion	ITT Analysis Set
2.1.1.8	Overall Response Rate (ORR) by Prior Use of Bendamustine	ITT Analysis Set
2.1.1.9	Overall Response Rate (ORR) by Refractory to Bendamustine	ITT Analysis Set

Table Number	Title	Analysis Set
2.1.1.10	Overall Response Rate (ORR) by Number of Times Refractory to an Alkylating Agent	ITT Analysis Set
2.1.1.11	Overall Response Rate (ORR) by Number of Times Refractory to Rituximab	ITT Analysis Set
2.1.1.12	Overall Response Rate (ORR) by Suitability for Radioimmunotherapy	ITT Analysis Set
2.1.1.13	Overall Response Rate (ORR) by Region	ITT Analysis Set
2.1.2	Overall Response Rate (ORR)	Per Protocol Analysis Set
2.2.1	Lymph Node Response – Independent Review Committee (IRC)	ITT Analysis Set
2.2.2	Lymph Node Response – Investigator Assessments	ITT Analysis Set
2.3.1	Tumor Response by Visit - Independent Review Committee (IRC) Assessments	ITT Analysis Set
2.3.2	Tumor Response by Visit - Investigator Assessments	ITT Analysis Set
2.3.3	Tumor Response by Visit - Agreement between Independent Review Committee (IRC) and Investigator Assessments	ITT Analysis Set
2.4.1	Duration of Response - Independent Review Committee (IRC) Assessments	ITT Analysis Set
2.4.1.1	Duration of Response - Independent Review Committee (IRC) Assessments - by Gender	ITT Analysis Set
2.4.1.2	Duration of Response - Independent Review Committee (IRC) Assessments - by Age	ITT Analysis Set
2.4.1.3	Duration of Response - Independent Review Committee (IRC) Assessments - by Race	ITT Analysis Set
2.4.1.4	Duration of Response - Independent Review Committee (IRC) Assessments - by Disease	ITT Analysis Set
2.4.1.5	Duration of Response - Independent Review Committee (IRC) Assessments - by Number of Prior Therapies	ITT Analysis Set
2.4.1.6	Duration of Response - Independent Review Committee (IRC) Assessments - by Refractory to Last Prior Therapy	ITT Analysis Set
2.4.1.7	Duration of Response - Independent Review Committee (IRC) Assessments - by Longest Diameter of Baseline Lesion	ITT Analysis Set
2.4.1.8	Duration of Response - Independent Review Committee (IRC) Assessments - by Prior Use of Bendamustine	ITT Analysis Set
2.4.1.9	Duration of Response - Independent Review Committee (IRC) Assessments - by Refractory to Bendamustine	ITT Analysis Set
2.4.1.10	Duration of Response - Independent Review Committee (IRC) Assessments - by Number of Times Refractory to an Alkylating Agent	ITT Analysis Set
2.4.1.11	Duration of Response - Independent Review Committee (IRC) Assessments - by Number of Times Refractory to Rituximab	ITT Analysis Set

Table Number	Title	Analysis Set
2.4.1.12	Duration of Response – Independent Review Committee (IRC) Assessments – by Suitability for Radioimmunotherapy	ITT Analysis Set
2.4.1.13	Duration of Response – Independent Review Committee (IRC) Assessments – by Region	ITT Analysis Set
2.4.2	Duration of Response - Investigator Assessments	ITT Analysis Set
2.4.2.1	Duration of Response - Investigator Assessments - by Gender	ITT Analysis Set
2.4.2.2	Duration of Response - Investigator Assessments - by Age	ITT Analysis Set
2.4.2.3	Duration of Response - Investigator Assessments - by Race	ITT Analysis Set
2.4.2.4	Duration of Response - Investigator Assessments - by Disease	ITT Analysis Set
2.4.2.5	Duration of Response - Investigator Assessments - by Number of Prior Therapies	ITT Analysis Set
2.4.2.6	Duration of Response - Investigator Assessments - by Refractory to Last Prior Therapy	ITT Analysis Set
2.4.2.7	Duration of Response - Investigator Assessments - by Longest Diameter of Baseline Lesion	ITT Analysis Set
2.4.2.8	Duration of Response - Investigator Assessments - by Prior Use of Bendamustine	ITT Analysis Set
2.4.2.9	Duration of Response - Investigator Assessments - by Refractory to Bendamustine	ITT Analysis Set
2.4.2.10	Duration of Response - Investigator Assessments - by Number of Times Refractory to an Alkylating Agent	ITT Analysis Set
2.4.2.11	Duration of Response - Investigator Assessments - by Number of Times Refractory to Rituximab	ITT Analysis Set
2.4.2.12	Duration of Response – Investigator Assessments – by Suitability for Radioimmunotherapy	ITT Analysis Set
2.4.2.13	Duration of Response – Investigator Assessments – by Region	ITT Analysis Set
2.4.3	Duration of Response - Independent Review Committee (IRC) Assessments	Per Protocol Analysis Set
2.4.4	Duration of Response - Investigator Assessments	Per Protocol Analysis Set
2.4.5	Duration of Response – Investigator Assessments (Sensitivity Analysis)	ITT Analysis Set
2.5.1	Progression Free Survival - Independent Review Committee (IRC) Assessments	ITT Analysis Set
2.5.1.1	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Gender	ITT Analysis Set
2.5.1.2	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Age	ITT Analysis Set
2.5.1.3	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Race	ITT Analysis Set
2.5.1.4	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Disease	ITT Analysis Set

Table Number	Title	Analysis Set
2.5.1.5	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Number of Prior Therapies	ITT Analysis Set
2.5.1.6	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Refractory to Last Prior Therapy	ITT Analysis Set
2.5.1.7	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Longest Diameter of Baseline Lesion	ITT Analysis Set
2.5.1.8	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Prior Use of Bendamustine	ITT Analysis Set
2.5.1.9	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Refractory to Bendamustine	ITT Analysis Set
2.5.1.10	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Number of Times Refractory to an Alkylating Agent	ITT Analysis Set
2.5.1.11	Progression Free Survival - Independent Review Committee (IRC) Assessments - by Number of Times Refractory to Rituximab	ITT Analysis Set
2.5.1.12	Progression Free Survival – Independent Review Committee (IRC) Assessments – by Suitability for Radioimmunotherapy	ITT Analysis Set
2.5.1.13	Progression Free Survival – Independent Review Committee (IRC) Assessments – by Region	ITT Analysis Set
2.5.2	Progression Free Survival - Investigator Assessments	ITT Analysis Set
2.5.2.1	Progression Free Survival - Investigator Assessments - by Gender	ITT Analysis Set
2.5.2.2	Progression Free Survival - Investigator Assessments - by Age	ITT Analysis Set
2.5.2.3	Progression Free Survival - Investigator Assessments - by Race	ITT Analysis Set
2.5.2.4	Progression Free Survival - Investigator Assessments - by Disease	ITT Analysis Set
2.5.2.5	Progression Free Survival - Investigator Assessments - by Number of Prior Therapies	ITT Analysis Set
2.5.2.6	Progression Free Survival - Investigator Assessments - by Refractory to Last Prior Therapy	ITT Analysis Set
2.5.2.7	Progression Free Survival - Investigator Assessments - by Longest Diameter of Baseline Lesion	ITT Analysis Set
2.5.2.8	Progression Free Survival - Investigator Assessments - by Prior Use of Bendamustine	ITT Analysis Set
2.5.2.9	Progression Free Survival - Investigator Assessments - by Refractory to Bendamustine	ITT Analysis Set
2.5.2.10	Progression Free Survival - Investigator Assessments - by Number of Times Refractory to an Alkylating Agent	ITT Analysis Set
2.5.2.11	Progression Free Survival - Investigator Assessments - by Number of Times Refractory to Rituximab	ITT Analysis Set

Table Number	Title	Analysis Set
2.5.2.12	Progression Free Survival – Investigator Assessments – by Suitability for Radioimmunotherapy	ITT Analysis Set
2.5.2.13	Progression Free Survival – Investigator Assessments – by Region	ITT Analysis Set
2.5.3	Progression Free Survival - Independent Review Committee (IRC) Assessments	Per Protocol Analysis Set
2.5.4	Progression Free Survival - Investigator Assessments	Per Protocol Analysis Set
2.5.5	Progression Free Survival – Investigator Assessments (Sensitivity Analysis)	ITT Analysis Set
2.6.1	Time to Response - Independent Review Committee (IRC) Assessments	ITT Analysis Set
2.6.1.1	Time to Response - Independent Review Committee (IRC) Assessments - by Gender	ITT Analysis Set
2.6.1.2	Time to Response - Independent Review Committee (IRC) Assessments - by Age	ITT Analysis Set
2.6.1.3	Time to Response - Independent Review Committee (IRC) Assessments - by Race	ITT Analysis Set
2.6.1.4	Time to Response - Independent Review Committee (IRC) Assessments - by Disease	ITT Analysis Set
2.6.1.5	Time to Response - Independent Review Committee (IRC) Assessments - by Number of Prior Therapies	ITT Analysis Set
2.6.1.6	Time to Response - Independent Review Committee (IRC) Assessments - by Refractory to Last Prior Therapy	ITT Analysis Set
2.6.1.7	Time to Response - Independent Review Committee (IRC) Assessments - by Longest Diameter of Baseline Lesion	ITT Analysis Set
2.6.1.8	Time to Response - Independent Review Committee (IRC) Assessments - by Prior Use of Bendamustine	ITT Analysis Set
2.6.1.9	Time to Response - Independent Review Committee (IRC) Assessments - by Refractory to Bendamustine	ITT Analysis Set
2.6.1.10	Time to Response - Independent Review Committee (IRC) Assessments - by Number of Times Refractory to an Alkylating Agent	ITT Analysis Set
2.6.1.11	Time to Response - Independent Review Committee (IRC) Assessments - by Number of Times Refractory to Rituximab	ITT Analysis Set
2.6.1.12	Time to Response – Independent Review Committee (IRC) Assessments – by Suitability for Radioimmunotherapy	ITT Analysis Set
2.6.1.13	Time to Response – Independent Review Committee (IRC) Assessments – by Region	ITT Analysis Set
2.6.2	Time to Response - Investigator Assessments	ITT Analysis Set
2.6.2.1	Time to Response - Investigator Assessments - by Gender	ITT Analysis Set
2.6.2.2	Time to Response - Investigator Assessments - by Age	ITT Analysis Set
2.6.2.3	Time to Response - Investigator Assessments - by Race	ITT Analysis Set
2.6.2.4	Time to Response - Investigator Assessments - by Disease	ITT Analysis Set

Table Number	Title	Analysis Set
2.6.2.5	Time to Response - Investigator Assessments - by Number of Prior Therapies	ITT Analysis Set
2.6.2.6	Time to Response - Investigator Assessments - by Refractory to Last Prior Therapy	ITT Analysis Set
2.6.2.7	Time to Response - Investigator Assessments - by Longest Diameter of Baseline Lesion	ITT Analysis Set
2.6.2.8	Time to Response - Investigator Assessments - by Prior Use of Bendamustine	ITT Analysis Set
2.6.2.9	Time to Response - Investigator Assessments - by Refractory to Bendamustine	ITT Analysis Set
2.6.2.10	Time to Response - Investigator Assessments - by Number of Times Refractory to an Alkylating Agent	ITT Analysis Set
2.6.2.11	Time to Response - Investigator Assessments - by Number of Times Refractory to Rituximab	ITT Analysis Set
2.6.2.12	Time to Response – Investigator Assessments – by Suitability for Radioimmunotherapy	ITT Analysis Set
2.6.2.13	Time to Response – Investigator Assessments – by Region	ITT Analysis Set
2.6.3	Time to Response - Independent Review Committee (IRC) Assessments	Per Protocol Analysis Set
2.6.4	Time to Response - Investigator Assessments	Per Protocol Analysis Set
2.7.1	Percent Change in SPD - Independent Review Committee (IRC) Assessments	ITT Analysis Set
2.7.2	Percent Change in SPD - Investigator Assessments	ITT Analysis Set
2.7.3	Percent Change in SPD - Independent Review Committee (IRC) Assessments	Per Protocol Analysis Set
2.8.1	Overall Survival during Study Treatment	ITT Analysis Set
2.8.2	Overall Survival including Data from Long-Term Follow-Up	ITT Analysis Set
2.9.1	Health Related Quality of Life (HRQL) – Summary of Change in FACT-Lym Subscale Scores	ITT Analysis Set
2.9.2	Health Related Quality of Life (HRQL) - Summary of Symptom Improvement/Worsening [a] in FACT-Lym Subscale Scores	ITT Analysis Set
2.9.3.1	Health Related Quality of Life (HRQL) - Relation Between Symptom Improvement/Worsening and Best Overall Response - Independent Review Committee (IRC) Assessments	ITT Analysis Set
2.9.3.2	Health Related Quality of Life (HRQL) - Relation Between Symptom Improvement/Worsening and Best Overall Response - Investigator Assessments	ITT Analysis Set
2.10	Change in Karnofsky Performance Status	ITT Analysis Set
3.1.1	Overall Summary of Treatment-Emergent Adverse Events	ITT Analysis Set
3.1.1.1	Overall Summary of Treatment-Emergent Adverse Events - by Age	ITT Analysis Set

Table Number	Title	Analysis Set
3.1.1.2	Overall Summary of Treatment-Emergent Adverse Events - by Race	ITT Analysis Set
3.1.1.3	Overall Summary of Treatment-Emergent Adverse Events - by Gender	ITT Analysis Set
3.1.1.4	Overall Summary of Treatment-Emergent Adverse Events – by Region	ITT Analysis Set
3.1.2.1	Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term	ITT Analysis Set
3.1.2.1.1	Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term - by Age	ITT Analysis Set
3.1.2.1.2	Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term - by Race	ITT Analysis Set
3.1.2.1.3	Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term - by Gender	ITT Analysis Set
3.1.2.1.4	Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term – by Region	ITT Analysis Set
3.1.2.2	Grade 3 or Higher Treatment-Emergent Adverse Events - by System Organ Class, High Level Term and Preferred Term	ITT Analysis Set
3.1.2.2.1	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term - by Age	ITT Analysis Set
3.1.2.2.2	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term - by Race	ITT Analysis Set
3.1.2.2.3	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term - by Gender	ITT Analysis Set
3.1.2.2.4	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term and Preferred Term – by Region	ITT Analysis Set
3.1.2.3	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term	ITT Analysis Set
3.1.2.3.1	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Age	ITT Analysis Set
3.1.2.3.2	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Race	ITT Analysis Set
3.1.2.3.3	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Gender	ITT Analysis Set
3.1.2.3.4	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term – by Region	ITT Analysis Set

Table Number	Title	Analysis Set
3.1.2.4	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term	ITT Analysis Set
3.1.2.4.1	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Age	ITT Analysis Set
3.1.2.4.2	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Race	ITT Analysis Set
3.1.2.4.3	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Gender	ITT Analysis Set
3.1.2.4.4	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term – by Region	ITT Analysis Set
3.1.2.5	Serious Adverse Events by System Organ Class, High Level Term and Preferred Term	ITT Analysis Set
3.1.2.5.1	Serious Adverse Events by System Organ Class, High Level Term and Preferred Term - by Age	ITT Analysis Set
3.1.2.5.2	Serious Adverse Events by System Organ Class, High Level Term and Preferred Term - by Race	ITT Analysis Set
3.1.2.5.3	Serious Adverse Events by System Organ Class, High Level Term and Preferred Term - by Gender	ITT Analysis Set
3.1.2.5.4	Serious Adverse Events by System Organ Class, High Level Term and Preferred Term – by Region	ITT Analysis Set
3.1.2.6	Treatment-Emergent Serious Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term	ITT Analysis Set
3.1.2.6.1	Treatment-Emergent Serious Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Age	ITT Analysis Set
3.1.2.6.2	Treatment-Emergent Serious Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Race	ITT Analysis Set
3.1.2.6.3	Treatment-Emergent Serious Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term - by Gender	ITT Analysis Set
3.1.2.6.4	Treatment-Emergent Serious Adverse Events Related to Study Drug by System Organ Class, High Level Term and Preferred Term – by Region	ITT Analysis Set
3.1.2.7	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class, High Level Term and Preferred Term	ITT Analysis Set
3.1.2.7.1	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class, High Level Term and Preferred Term - by Age	ITT Analysis Set

Table Number	Title	Analysis Set
3.1.2.7.2	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class, High Level Term and Preferred Term - by Race	ITT Analysis Set
3.1.2.7.3	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class, High Level Term and Preferred Term - by Gender	ITT Analysis Set
3.1.2.7.4	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class, High Level Term and Preferred Term – by Region	ITT Analysis Set
3.1.2.8	Treatment-Emergent Adverse Events Leading to Death by System Organ Class, High Level Term and Preferred Term	ITT Analysis Set
3.1.2.8.1	Treatment-Emergent Adverse Events Leading to Death by System Organ Class, High Level Term and Preferred Term - by Age	ITT Analysis Set
3.1.2.8.2	Treatment-Emergent Adverse Events Leading to Death by System Organ Class, High Level Term and Preferred Term - by Race	ITT Analysis Set
3.1.2.8.3	Treatment-Emergent Adverse Events Leading to Death by System Organ Class, High Level Term and Preferred Term - by Gender	ITT Analysis Set
3.1.2.8.4	Treatment-Emergent Adverse Events Leading to Death by System Organ Class, High Level Term and Preferred Term – by Region	ITT Analysis Set
3.1.3.1	Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity	ITT Analysis Set
3.1.3.1.1	Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity - by Age	ITT Analysis Set
3.1.3.1.2	Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity - by Race	ITT Analysis Set
3.1.3.1.3	Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity - by Gender	ITT Analysis Set
3.1.3.1.4	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term, and Severity – by Region	ITT Analysis Set
3.1.3.2	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term, and Severity	ITT Analysis Set
3.1.3.2.1	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term, and Severity - by Age	ITT Analysis Set
3.1.3.2.2	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term and Severity by Race	ITT Analysis Set
3.1.3.2.3	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term and Severity - by Gender	ITT Analysis Set

Table Number	Title	Analysis Set
3.1.3.2.4	Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term, and Severity – by Region	ITT Analysis Set
3.1.4.1	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity	ITT Analysis Set
3.1.4.1.1	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity - by Age	ITT Analysis Set
3.1.4.1.2	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity - by Race	ITT Analysis Set
3.1.4.1.3	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity - by Gender	ITT Analysis Set
3.1.4.1.4	Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, High Level Term, Preferred Term, and Severity – by Region	ITT Analysis Set
3.1.4.2	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term, and Severity	ITT Analysis Set
3.1.4.2.1	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term ,and Severity - by Age	ITT Analysis Set
3.1.4.2.2	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term, and Severity - by Race	ITT Analysis Set
3.1.4.2.3	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term, and Severity - by Gender	ITT Analysis Set
3.1.4.2.4	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by System Organ Class, High Level Term, Preferred Term, and Severity – by Region	ITT Analysis Set
3.1.5.1	Treatment-Emergent Adverse Events by Preferred Term	ITT Analysis Set
3.1.5.1.1	Treatment-Emergent Adverse Events by Preferred Term - by Age	ITT Analysis Set
3.1.5.1.2	Treatment-Emergent Adverse Events by Preferred Term - by Race	ITT Analysis Set
3.1.5.1.3	Treatment-Emergent Adverse Events by Preferred Term - by Gender	ITT Analysis Set
3.1.5.1.4	Treatment-Emergent Adverse Events by Preferred Term – by Region	ITT Analysis Set
3.1.5.2	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term	ITT Analysis Set

Table Number	Title	Analysis Set
3.1.5.2.1	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term - by Age	ITT Analysis Set
3.1.5.2.2	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term - by Race	ITT Analysis Set
3.1.5.2.3	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term - by Gender	ITT Analysis Set
3.1.5.2.4	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term – by Region	ITT Analysis Set
3.1.5.3	Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term	ITT Analysis Set
3.1.5.3.1	Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term - by Age	ITT Analysis Set
3.1.5.3.2	Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term - by Race	ITT Analysis Set
3.1.5.3.3	Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term - by Gender	ITT Analysis Set
3.1.5.3.4	Treatment-Emergent Adverse Event Related to Study Drug by Preferred Term – by Region	ITT Analysis Set
3.1.5.4	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term	ITT Analysis Set
3.1.5.4.1	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term - by Age	ITT Analysis Set
3.1.5.4.2	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term - by Race	ITT Analysis Set
3.1.5.4.3	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term - by Gender	ITT Analysis Set
3.1.5.4.4	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term – by Region	ITT Analysis Set
3.1.5.5	Serious Adverse Events by Preferred Term	ITT Analysis Set
3.1.5.5.1	Serious Adverse Events by Preferred Term - by Age	ITT Analysis Set
3.1.5.5.2	Serious Adverse Events by Preferred Term - by Race	ITT Analysis Set
3.1.5.5.3	Serious Adverse Events by Preferred Term - by Gender	ITT Analysis Set
3.1.5.5.4	Serious Adverse Events by Preferred Term – by Region	ITT Analysis Set
3.1.5.6	Treatment-Emergent Serious Adverse Events Related to Study Drug by Preferred Term	ITT Analysis Set
3.1.5.6.1	Treatment-Emergent Serious Adverse Events Related to Study Drug by Preferred Term - by Age	ITT Analysis Set
3.1.5.6.2	Treatment-Emergent Serious Adverse Events Related to Study Drug by Preferred Term - by Race	ITT Analysis Set
3.1.5.6.3	Treatment-Emergent Serious Adverse Events Related to Study Drug by Preferred Term - by Gender	ITT Analysis Set
3.1.5.6.4	Treatment-Emergent Serious Adverse Events Related to Study Drug by Preferred Term – by Region	ITT Analysis Set

Table Number	Title	Analysis Set
3.1.5.7	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Preferred Term	ITT Analysis Set
3.1.5.7.1	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Preferred Term - by Age	ITT Analysis Set
3.1.5.7.2	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Preferred Term - by Race	ITT Analysis Set
3.1.5.7.3	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Preferred Term - by Gender	ITT Analysis Set
3.1.5.7.4	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Preferred Term – by Region	ITT Analysis Set
3.1.5.8	Treatment-Emergent Adverse Events Leading to Death by Preferred Term	ITT Analysis Set
3.1.5.8.1	Treatment-Emergent Adverse Events Leading to Death by Preferred Term - by Age	ITT Analysis Set
3.1.5.8.2	Treatment-Emergent Adverse Events Leading to Death by Preferred Term - by Race	ITT Analysis Set
3.1.5.8.3	Treatment-Emergent Adverse Events Leading to Death by Preferred Term - by Gender	ITT Analysis Set
3.1.5.8.4	Treatment-Emergent Adverse Events Leading to Death by Preferred Term – by Region	ITT Analysis Set
3.1.5.9	Treatment-Emergent Adverse Events Occurring in At Least 10% of Subjects by Preferred Term	ITT Analysis Set
3.1.5.9.1	Treatment-Emergent Adverse Events Occurring in At Least 10% of Subjects by Preferred Term - by Age	ITT Analysis Set
3.1.5.9.2	Treatment-Emergent Adverse Events Occurring in At Least 10% of Subjects by Preferred Term - by Race	ITT Analysis Set
3.1.5.9.3	Treatment-Emergent Adverse Events Occurring in At Least 10% of Subjects by Preferred Term - by Gender	ITT Analysis Set
3.1.5.9.4	Treatment-Emergent Adverse Events Occurring in At Least 10% of Subjects by Preferred Term – by Region	ITT Analysis Set
3.1.6.1	Treatment-Emergent Adverse Events by Preferred Term and Severity	ITT Analysis Set
3.1.6.1.1	Treatment-Emergent Adverse Events by Preferred Term and Severity - by Age	ITT Analysis Set
3.1.6.1.2	Treatment-Emergent Adverse Events by Preferred Term and Severity - by Race	ITT Analysis Set
3.1.6.1.3	Treatment-Emergent Adverse Events by Preferred Term and Severity - by Gender	ITT Analysis Set
3.1.6.1.4	Treatment-Emergent Adverse Events by Preferred Term and Severity – by Region	ITT Analysis Set
3.1.6.2	Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity	ITT Analysis Set
3.1.6.2.1	Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity - by Age	ITT Analysis Set

Table Number	Title	Analysis Set
3.1.6.2.2	Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity - by Race	ITT Analysis Set
3.1.6.2.3	Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity - by Gender	ITT Analysis Set
3.1.6.2.4	Treatment-Emergent Adverse Events Related to Study Drug y Preferred Term and Severity – by Region	ITT Analysis Set
3.1.7.1	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term and Severity	ITT Analysis Set
3.1.7.1.1	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term and Severity - by Age	ITT Analysis Set
3.1.7.1.2	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term and Severity - by Race	ITT Analysis Set
3.1.7.1.3	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term and Severity - by Gender	ITT Analysis Set
3.1.7.1.4	Grade 3 or Higher Treatment-Emergent Adverse Events by Preferred Term and Severity – by Region	ITT Analysis Set
3.1.7.2	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity	ITT Analysis Set
3.1.7.2.1	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity - by Age	ITT Analysis Set
3.1.7.2.2	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity - by Race	ITT Analysis Set
3.1.7.2.3	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity - by Gender	ITT Analysis Set
3.1.7.2.4	Grade 3 or Higher Treatment-Emergent Adverse Events Related to Study Drug by Preferred Term and Severity – by Region	ITT Analysis Set
3.1.8.1	Treatment-Emergent Adverse Events Leading to Study Drug Reduction by Preferred Term	ITT Analysis Set
3.1.8.1.1	Treatment-Emergent Adverse Events Leading to Study Drug Reduction by Preferred Term - by Age	ITT Analysis Set
3.1.8.1.2	Treatment-Emergent Adverse Events Leading to Study Drug Reduction by Preferred Term - by Race	ITT Analysis Set
3.1.8.1.3	Treatment-Emergent Adverse Events Leading to Study Drug Reduction by Preferred Term - by Gender	ITT Analysis Set
3.1.8.1.4	Treatment-Emergent Adverse Events Leading to Study Drug Reduction by Preferred Term – by Region	ITT Analysis Set
3.2.1.1	Hematology: Summary of Actual Values and Change from Baseline	ITT Analysis Set
3.2.1.2	Hematology: Summary by Treatment-Emergent CTCAE Severity Grade	ITT Analysis Set

Table Number	Title	Analysis Set
3.2.1.3	Hematology: Shift from Baseline by CTCAE Severity Grade	ITT Analysis Set
3.2.2.1	Serum Chemistry: Summary of Actual Values and Change from Baseline	ITT Analysis Set
3.2.2.2	Serum Chemistry: Summary by Treatment-Emergent CTCAE Severity Grade	ITT Analysis Set
3.2.2.3	Serum Chemistry: Shift from Baseline by CTCAE Severity Grade	ITT Analysis Set
3.2.2.4	Summary of Transaminase Elevations	ITT Analysis Set
3.2.2.5	Time to Onset and Time to Resolution of Transaminase Elevations	ITT Analysis Set
3.2.3	Urinalysis: Summary of Actual Values at Baseline	ITT Analysis Set
3.2.4	Immunophenotyping Immunoglobulin and Serum protein electrophoresis (SPEP): Actual and Change from Baseline	ITT Analysis Set
3.2.5	Physical Examination	ITT Analysis Set
3.2.6	Palpable Lymphoma	ITT Analysis Set
3.2.7	Vital Signs: Actual and Change from Baseline	ITT Analysis Set
3.2.8	Vital Signs: Blood Pressure by Abnormal Status	ITT Analysis Set
3.2.9.1	12-Lead Electrocardiograms: Actual and Change from Baseline	ITT Analysis Set
3.2.9.2	12-Lead Electrocardiograms: Overall Results Shift From Baseline	ITT Analysis Set
3.2.9.3	12-Lead Electrocardiograms: QTc Interval and QTc Interval Change from Baseline	ITT Analysis Set
3.2.9.4	12-Lead Electrocardiograms: QTc Interval Shift from Baseline	ITT Analysis Set
3.3.1	IDELA Plasma Pharmacokinetic Concentration	PK Analysis Set
3.3.2	GS-563117 Plasma Pharmacokinetic Concentration	PK Analysis Set
3.3.3	PPD	
3.3.4		
3.3.5		
3.3.6		