An Open label, Phase II study to evaluate the efficacy and safety of Tenalisib (RP6530), a novel PI3K δ/γ dual inhibitor in adult patients with relapsed/refractory indolent Non-Hodgkin's Lymphoma (iNHL)

Statistical Analysis Plan

Author and Designation:	███████ █████ ████████████████████
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Signature Page

TITLE	NAME	SIGNATURE	DATE
Authoring Statistician	████████		
Reviewing Statistician			
Manager Statistics (or equivalent)	█████████		
Sponsor Representative	█████████		

Signature above indicates approval of this plan, for the analysis and reporting of this study. Approval of the SAP and approval of any subsequent amendments is the responsibility of the Head of Statistics function or equivalent.

The approver serves as a single point of accountability for approval and must ensure that all relevant functions are in agreement with the final SAP.

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List of Abbreviations

Abbreviation	Term
AE	Adverse Event
ATC	Anatomical Therapeutic Chemical
BID	Twice Daily
CI	Confidence Interval
CR	Complete Response
CT	Computed Tomography
CTCAE	Common Terminology Criteria for Adverse Events
DLT	Dose Limiting Toxicity
DoR	Duration of Response
DRC	Data Review Committee
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
ECOG PS	Eastern Cooperative Oncology Group Performance Status
FAS	Full Analysis Set
FL	Follicular lymphoma
IgM	Immunoglobulin M
iNHL	Indolent non-Hodgkin's Lymphoma
IRB/IEC	Institutional Review Board/Independent Ethics Committee
LPL	Lymphoplasmacytic lymphoma
MedDRA	Medical Dictionary for Regulatory Activities
mITT	Modified Intent-to-Treat
MRI	Magnetic Resonance Imaging
MZL	Marginal Zone Lymphoma
NCI	National Cancer Institute
ND	Not Done
NE	Not Evaluable
NHL	Non-Hodgkin's Lymphoma
ORR	Objective Response Rate
PET	Positron Emission Tomography
PFS	Progression-Free Survival
PP	Per-Protocol
PR	Partial Response
PT	Preferred Term
Q1	First Quartile
Q3	Third Quartile
QTcF	QT interval with Fridericia's correction
SAE	Serious Adverse Events
SAP	Statistical Analysis Plan
SAS	Statistical Analysis Software
SD	Stable Disease
SOC	System Organ Class
SLL	Small Lymphocytic Lymphoma
TEAE	Treatment-Emergent Adverse Event
TID	Thrice Daily
WHO	World Health Organization
WM	Waldenstrom Macroglobulinemia

1. Amendments from Previous Version(s)

Not Applicable.

2. Introduction

Note: In this document, any text taken directly from the protocol (Number RP6530-1802, Amendment 1 to Version 1.0, Dated 15 March 2018; Amendment Version dated 04 December 2018) is *italicized*.

This SAP provides the detailed methodology for summary and statistical analyses of the data collected in study RP6530-1802. This document may modify the plans outlined in the final protocol.

2.1 Rationale

Approximately one third of NHLs are indolent. These indolent NHLs (iNHLs) are slow- growing tumors with a prolonged natural history, and most patients present with advanced disease. iNHLs are highly treatable but rarely cured.

The safety and tolerability of Tenalisib has been established up to doses of 1200 mg BID and 800 mg TID. In recent study*, Tenalisib 800 mg BID (Fasting) is established as a MTD dose in patients with T-cell lymphoma. Therefore, Tenalisib (800 mg BID) is considered for this study. It is expected that proposed monotherapy has the potential to improve response rates in the proposed patient population.*

3. Study Objectives

3.1 Primary Objective

- *To assess the anti-tumor activity of Tenalisib, as determined by the Objective Response Rate (ORR), Duration of Response (DoR) and Progression Free Survival (PFS).*

3.2 Secondary Objective

- *To characterize safety and tolerability of Tenalisib in patients with iNHL.*

4. Study Endpoints

4.1 Efficacy Endpoints

- ***ORR*** *is defined as sum of CR and PR rates and will be assessed according to the Lugano Classification for initial evaluation, staging, and response assessment of Non-Hodgkin lymphoma. (Cheson-2014)*

- ***CR rate*** *will be assessed according to the Lugano Classification for initial evaluation, staging, and response assessment of non-Hodgkin lymphoma.*

- ***DoR*** *is measured from the initial response to disease progression or death.*

- *PFS* is defined as the time of the first dose of Tenalisib to disease progression or death.

4.2   Safety Endpoints

- *Adverse Event (AE), Grade 3/ 4 AEs, Serious and fatal Adverse Event (SAE), graded using NCI CTCAE Version 5.0.*

5.   Study Design

The study is designed as a Phase II, open label, two parts study in relapsed/refractory iNHL patients. The mandatory Part 1 of the study will assess the efficacy and safety of Tenalisib in 20 patients with iNHL. After all patients enrolled in Part 1 have had the opportunity to provide at least three tumor outcome assessments, the Data Review Committee (DRC) will evaluate the efficacy (anti-tumor activity) and safety results for each of the subtypes (e.g. FL, MZL or WM). If the committee believes there are potential clinically meaningful responses for certain subtype, the committee will recommend initiation of Part 2 to evaluate efficacy and safety for that subtype. If not, the study will be terminated without initiating Part 2. The sample size for Part 2 will be derived based on the outcome from Part 1. Data from Part 1 will not be included in the analysis of Part 2 of the study.

The study treatment Tenalisib (800 mg BID) will be administered orally in 28-days of cycle over a period of 8 months in absence of definitive disease progression or unacceptable toxicity. Treatment will be continued in patients experiencing clinical benefit until the occurrence of definitive disease progression, unacceptable toxicity, or withdrawal from the study due to investigator decision or other reasons; maximum for up to 24 months.

The efficacy response will be evaluated on Weeks 8 (C3D1± 7 days), Weeks 16 (C5D1± 7 days) and then every 12 weeks thereafter, and/ or at the EOT or as clinically indicated (if clinical progression is suspected or for confirmation of complete response/disease progression).

Group	N	Patient population	Tenalisib
Part 1	20	Refractory/ relapsed iNHL.	800 mg BID in 28-Days Cycle for 8 Cycles[1]
Part 2	The sample size will be derived based on the outcome from Part 1	Refractory/ relapsed iNHL patients of one of the specific subtype (e.g. FL, MZL, WM)	800 mg BID in 28-Days Cycle for 8 Cycles[1]

[1]*Post cycle 8, treatment will be continued in patients experiencing clinical benefit up to 24 months unless progression of disease or toxicity warranting discontinuation of therapy. The decision to continue the treatment will be determined by the PI after consultation with Sponsor on case to case basis.*

5.1 *The Expected Duration of Subject Participation and Follow-up*

The expected duration of subject participation in the study will be 8 months. Treatment will be continued in patients experiencing clinical benefit up to 2 years unless progression of disease or toxicity warranting discontinuation of therapy. The decision to continue the treatment will be taken by PI after consultation with sponsor on case to case basis.

Notes:
- After reviewing the emerging efficacy data, the study has been closed due to absence of clinically meaningful response to single agent Tenalisib in Part 1 of the study. Therefore, Part 2 will not be performed.
- The analysis proposed in this SAP is considering the available data at the time of completion of the study.
- The data on DLT was erroneously captured on the CRF and which is not applicable for this study. Hence, the DLT information will not be displayed in any of the reports.

6. Sample Size Considerations

The sample size for Part 1 is not based on statistical considerations. After all patients enrolled in Part 1 had the opportunity to provide at least three tumor outcome assessments, the DRC will evaluate the efficacy and safety results for each of the subtypes. If the committee believes there are potential clinically meaningful benefits for certain subtype, the committee will recommend initiation of Part 2 to evaluate efficacy and safety for that subtype. The sample size for Part 2 will be derived based on ORR data from Part 1.

__Part 1__: 20 patients with relapsed/refractory iNHL will be enrolled.

Part 2 will not be initiated as the study is closed due to absence of clinically meaningful response to single agent Tenalisib

7. Analysis Populations

The following 4 analysis populations are planned for Part 1 of the study.

7.1 Modified Intent-to-Treat Population (mITT)

The mITT is the primary efficacy analysis population and will include data from all patients who received at least 1 dose of study medication and provide at least 1 post-baseline efficacy assessment.

7.2 Per-Protocol (PP) Population

The PP Population is a subset of the modified Intent-to-Treat Population and will include patients without major protocol deviations.

Major deviations shall include:

– Deviation from an IEC/IRB approved protocol which compromise the safety and welfare of participating subjects or the integrity of the study and /or the completeness, accuracy and reliability of study data. Examples deviations included but not limited to:
  o Failure to obtain informed consent (e.g., there is no documentation of informed consent) for a subject;
  o Informed consent is obtained after initiation of study procedures;
  o Enrollment of subject who has failed to meet the inclusion/exclusion criteria.

The list of protocol deviations with categorization with respect to major and minor deviations will be generated. This population will also be used for efficacy assessment.

Note: In situation, the patients qualifying for mITT set are same as the patients qualifying for PP set, the respective tables and figures proposed using PP set will not be produced to avoid the duplication of the results.

7.3 Safety Population

The Safety Population will include all subjects who receive at least 1 dose of the study drug.

7.4 Full Analysis Set (FAS)

The FAS includes all the patients who sign the Informed Consent Document and are enrolled into the study. This set will be used for reporting patient demographic data and any available patient baseline characteristics as captured in the Case Report Form (CRF).

Membership in the analysis populations will be determined before database lock.

8. Randomization and Blinding

This is a non-randomized, open label study.

9. Method of Analysis

9.1 Statistical Hypotheses

There are no formal statistical hypotheses.

9.2 Interim Analysis

After all patients enrolled in Part 1 have had the opportunity to provide at least three tumor outcome assessments, the DRC will evaluate the efficacy (anti-tumor activity) and safety results for each of the subtypes. If the committee believes there are potential clinically meaningful responses for certain subtype, the committee will recommend initiation of Part 2 to evaluate efficacy and safety for that subtype. Else, the study will be terminated.

The DRC will continue to monitor safety of Tenalisib (or toxicity trends that may be of concern) at interval of approximately 3 months from initiation of study until the completion of the study. In the event of one (1) death attributed to the study drug, study accrual will be suspended pending

further investigation, and will only be resumed at the recommendation of the DRC. The DRC will have discretion to terminate the trial if an additional death occurs that can be attributed to the study drug.

9.3   Handling of Missing Data

9.3.1   Missing Dates for Adverse Events and Concomitant Medications

Adverse events and concomitant medications with completely or partially missing assessment dates will have imputation performed as explained below for the purposes of calculation of durations or relativity to study medication.

For the end of a concomitant medication or adverse event:

- **If only Day of end date is missing**:
  The last date of the month and year reported or the date of the final contact with the subject, whichever is earlier, will be used as the end date.

- **If Day and Month of end date are missing**:
  The last date of year i.e. December 31 of the year reported or the date of the last study contact with the subject, whichever is earlier, will be used as the end date.

- **If Year of end date or complete end date is missing**:
  If the year of end of medication/event is missing or end date is completely missing, then no end date will be imputed.

For the start of a concomitant medication or adverse event:

- **If only Day of start date is missing:**
  - If the start year and month of medication/event are the same as that for the first dose date, then following approach will be used:
    - If the end date of medication/event is NOT before the first dose date or end date of medication/event is completely missing, then impute the start day as the day of first dose date
    - Otherwise, impute the start day as 1.

  - If the start year and month of medication/event are NOT same as that for the first dose date, then
    - Impute the start day as 1.

- **If Day and Month of start date are missing:**

  - If start year of medication/event is same as first dose year, then following approach will be used:
    - i.   For medication, impute the start Month as January and the Day as 1

> ii.   For adverse event,
> - If the end date of event is NOT before the first dose date or end date of event is completely missing, then impute the start Month and Day as the Month and Day of first dose date;
> - Otherwise, impute the start Month as January and the Day as 1.

> o   If start year of medication/event is NOT same as first dose year, then
>   - Impute start Month as January and the Day as 1.

- **If Year of start date or complete start date is missing:**

If the year of start of medication/event is missing or start date is completely missing, then no start date will be imputed.

9.3.2   Missing Dates for Efficacy Endpoints

For time-to-event endpoints (Progression Free Survival, Overall Response and Duration of response), if the date is completely missing, no imputation will be performed.

However, the incomplete/partial dates will be handled following the general conventions as detailed in Section 9.3.1.

Patient without measurable and/or assessable lesions will not be assessed for response.

Measurable lesions are defined as those that can be accurately measured in at least two dimensions with conventional techniques (CT/PET/PET-CT, MRI, x-ray) or as >1.5 cm with CT scan.

9.3.3   Missing dates for Primary Diagnosis/Prior therapy

Partial Primary diagnosis and prior therapy dates will have imputation performed as explained below for the purposes of calculation of relativity to study medication.

- If only Day is missing, impute the day 1

- If Day and Month are missing, impute the Month as January and the Day as 1.

- If the year of primary diagnosis is missing or the date of primary diagnosis is completely missing, then no date will be imputed.

10.   Statistical Analysis

Due to early closure of the study, the analysis proposed in the SAP is based on the available data at the time of study closure.

The safety endpoints will be listed and/or summarized. No inferential statistical analyses will be performed.

Unless otherwise stated, all statistical analyses will be performed using a two-sided hypothesis test at the overall 5% level of significance.

When count data are presented, the percentage will be suppressed when the count is zero in order to draw attention to the non-zero counts. A row denoted "Missing" will be included in count tabulations where necessary to account for dropouts and missing patients. Unless otherwise specified, the denominator for percentages will be the number of patients with a non-missing assessment in a given treatment group within the analysis population of interest.

All statistical analyses will be performed using SAS 9.4 or higher.

10.1   Patient Disposition

A tabular presentation of the patient disposition data will be provided. It will include the number of patients screened, enrolled, assigned treatment, completed, as well as the number of dropouts, with reasons for discontinuation, number in each population sets, number of patients with dose reductions or interruptions (if applicable), etc. All patients' data will be used for this report.

10.2   Demographic and Baseline Characteristics

Analysis set: FAS

Demographic and baseline characteristics data will be summarized using descriptive statistics (n, mean, Standard Deviation, median, minimum, maximum) for continuous variables, and using frequencies and percentages for categorical variables.

Demographic characteristics will include age, race, gender, height, weight, etc.

Disease characteristics will include time from initial diagnosis to enrollment, Subtype of iNHL, Staging, number of prior therapies, (systemic therapy, radiotherapy and cancer surgery), number of subject relapsed or refractory to the last therapy, time from date of last therapy to enrollment, ECOG performance status, etc.

10.3   Medical and Surgical History

Analysis set: FAS

This data will be summarized using frequencies and percentages by System Organ Class and Preferred Term. A listing will also be provided.

The medical history data will be coded using MedDRA dictionary [Version 23.0 (Hierarchy)].

10.4   Prior and Concomitant Medications

Analysis set: FAS

Concomitant medications are those that were taken while on study drug. Also, the medications / non-drug treatments which start after study treatment end date will be termed as 'Concomitant'.

Prior medications are those that were taken prior to the initial dose of study drug.

The medication data will be coded using WHO-Drug dictionary (WHODRUG GLOBAL B3 March 1, 2020) and the non-drug treatments data will be coded using MedDRA dictionary [Version 23.0 (Hierarchy)].

A summary of frequencies and percentages by ATC level 2 and Preferred Terms and the listing of the prior and concomitant treatments taken will be provided.

10.5   Efficacy Analysis

Analysis Set: mITT and PP

*   The analysis will be done as per the disease subtypes [Follicular lymphoma (FL), Marginal zone lymphoma (MZL), Waldenstrom's macroglobulinemia (WM) and Small lymphocytic lymphoma (SLL)] and overall.

Note: The analyses outlined below are subject to availability of adequate data. In absence of adequate data, some of the efficacy endpoints discussed below will be presented with basic summaries and/or plots and listings, as appropriate.

10.5.1 Objective Response Rate (ORR)

It is *defined as sum of CR and PR rates. Only those patients who have had a pre-treatment baseline efficacy evaluation and at least one post-treatment efficacy evaluation or confirmed disease progression will be considered evaluable for response. Subtype specific and overall ORR will be calculated.*

Additionally, Disease Control Rate (DCR= CR+PR+SD) will be presented.

This data will be summarized using frequency, and percentage. Due to low number of patients observed in each of the disease subtype, the 95% CI (Using exact method based on binomial distribution, subject to availability of adequate data) will be presented for the Overall group only.

 The corresponding listing will also be provided.

10.5.2 Complete Response (CR) Rate

For assessment of CR, only those patients who have had a pre-treatment baseline efficacy evaluation and at least one post-treatment efficacy evaluation or confirmed disease progression will be considered evaluable for response.

This data will be summarized using frequency, and percentage. Due to low number of patients observed in each of the disease subtype, the 95% CI (Using exact method based on binomial distribution, subject to availability of adequate data) will be presented for the Overall group only.

10.5.3 Progression Free Survival (PFS)

It is defined as time of the first dose of Tenalisib to disease progression or death. Subjects who die without a reported prior progression will be considered to have progressed on the date of their death. Subjects who did not progress or die will be censored on the date of their last tumor assessment.

This data will be summarized using the Kaplan-Meier method and displayed graphically per the disease subtype and Overall. The following reports will be generated:

- The Q1, median and Q3 PFS time will be provided. Due to low number of patients observed in each of the disease subtype, 95% CI for the Q1, median, and Q3 PFS time will be presented for the Overall group only using Brookmeyer-Crowley method subject to availability of adequate data.
- The number and % of patients with disease progressive events (further divided into progression or death) will be provided.
- The number and % of patients censored (further divided by reasons for censoring) will be provided.
- Kaplan-Meier curves will be produced.
- A listing of PFS data will be provided.

10.5.4 Duration of Response (DoR)

It is defined as the time when the measurement criteria are first met for PR or CR (whichever is reported first) until the date of documented disease progression or death. For subjects who neither progress nor die, the duration of response will be censored at the date of their last disease assessment.

This data will be summarized using the Kaplan-Meier method and displayed graphically per the disease subtype and overall. The following reports will be generated:

- The Q1, median, and Q3 DoR time will be provided. Due to low number of patients observed in each of the disease subtype, 95% CI for the Q1, median, and Q3 DoR time will be presented for the Overall group only using Brookmeyer-Crowley method subject to availability of adequate data.
- A plot of duration of response will be provided and include each responding patient (subject to availability of adequate data).

10.5.5 Best Overall Response

It *is the best response recorded from the start of the treatment until disease progression or discontinuation from the study.*

This data will be summarized using frequency and percentage for Complete Response (CR), Partial Response (PR), Stable Disease (SD), and Progressive Disease (PD), as captured in the CRFs, per the disease subtype and overall. This data will also be listed.

10.6 Safety Analysis

Analysis Set: Safety

The safety analyses will be reported for Overall patient data only. However, when necessary, adverse event data may be reported by disease subtype.

10.6.1 Treatment Exposure and Compliance

Analysis set: Safety

Treatment compliance and the treatment exposure will be summarized descriptively (n, mean, median, standard deviation, minimum and maximum values) and will also be listed.

- The treatment exposure to the study medication for subject will be calculated as:

  Exposure (day) = Last day of dosing – First Day of dosing + 1

  o A summary of duration of treatment (days) will be provided. In addition, a plot for duration on treatment will be provided per patient.

- The treatment compliance percentage (per patient), which is captured in the eCRF, will be summarized descriptively per Cycle. This data will be listed for individual patient.

10.6.2 Adverse Events

Analysis set: Safety

The frequency of adverse events (AEs) will be computed by counting each patient only once per MedDRA [Version 23.0 (Hierarchy)] preferred term and according to the maximum NCI CTCAE v.5.0 grade attained by the patient over the specified period. The percentage of patients with an event will be calculated using the number of patients in the safety analysis set as the denominator.

<u>Standard Summaries of Adverse Events</u>

Treatment Emergent Adverse Events are those that start on or after the date of first dose of study medication.

An overall summary of TEAEs (number and percentage of patients along with the number of events) will be presented with the following:
- Any non-TEAE
- Any TEAE
- Related TEAEs
- Serious TEAEs
- Related Serious TEAEs
- Grade 3 or Grade 4 TEAEs
- Related Grade 3 or Grade 4 TEAEs
- TEAEs leading to discontinuation
- Related TEAEs leading to discontinuation
- Serious TEAEs leading to discontinuation

- Related Serious TEAEs leading to discontinuation
- TEAEs leading to dose interruptions
- Fatal TEAEs
- Related Fatal TEAEs
- Protocol-Defined Adverse Events of Special Interest:
  - Pregnancy, abortion, birth defects/congenital anomalies
  - Overdose

Summaries showing the number of patients (n, %) along with number of events by SOC and PT will be provided for the following:
- TEAEs
- Grade 3, 4 and 5 TEAEs
- TEAE by disease subtype
- Treatment-related TEAEs
- TEAE with maximum CTCAE grade
- Treatment-Emergent SAEs
- Treatment-Related SAEs
- Treatment-related TEAEs with maximum CTCAE grade
- Deaths

The adverse events data will also be listed for individual patients.
- AEs
- Related TEAEs
- Treatment Emergent Grade 3, 4 and 5 AEs
- Treatment Related Grade 3, 4 and 5 AEs
- Treatment Emergent SAEs
- Treatment Related SAEs
- TEAE leading to discontinuation

10.6.3 Clinical Laboratory Tests

Analysis Set: Safety

Laboratory data will be presented per cycle.

The baseline measurement is the last pre-treatment measurement taken on or before Cycle1 Day1.

Absolute values and change from baseline values of Laboratory parameters will be presented using descriptive statistics (n, mean, median, standard deviation, minimum and maximum values).

The laboratory data will also be listed.

A separate listing of patients with abnormal laboratory test values will also be presented.

Based on the available data which is captured in the database, the laboratory data will be summarized for the following clinical laboratory parameters:

Hematology	Chemistry Panel I	Chemistry Panel II	Urinalysis	Other
Hematocrit	Total bilirubin	Blood glucose	Blood	PT
Hemoglobin	Alkaline phosphatase (ALP)	Urea or blood urea nitrogen	Glucose	INR
CBC with differentials	Alanine aminotransferase (ALT)	Creatinine	Protein	
Platelet count	Aspartate aminotransferase (AST)	Albumin	Specific gravity	
WBC (Total and differentials)	Lactate dehydrogenase (LDH)	Total protein	Microscopic exam	
Red blood cell count	Gamma-glutamyl transferase GGT)	Total Cholesterol		
Absolute neutrophil count	Sodium	Triglyceride (TG)		
Absolute lymphocyte count	Potassium	LDL		
	Calcium	HDL		
	Phosphorous	TSH		
	Carbon Dioxide (CO2) or bicarbonate	T3 (Total or Free)		
	Chloride	T4 (free)		
	Magnesium			

10.6.4 Physical Examinations

Analysis Set: Safety

Physical examination data will be listed for Screening visit.

A separate listing of patients with abnormal findings will also be presented.

10.6.5 Vital Signs

Analysis Set: Safety

Vitals will include pulse rate, blood pressure, respiratory rate and oral temperature. Weight will also be included here.

The baseline measurement is the last pre-treatment measurement taken on or before Cycle1 Day1.

Absolute values and change from baseline values of Vital data will be summarized descriptively (n, mean, median, standard deviation, minimum and maximum) per cycle. A listing will also be provided.

A separate listing of patients with abnormal vital signs findings will also be presented.

10.6.6 Electrocardiogram

Analysis Set: Safety

- The baseline measurement is the last pre-treatment measurement taken on or before Cycle1 Day1.
- Absolute values and changes from baseline values of ECG parameters [PR Interval, HR (heart rate), QT interval, QTcF (QT interval with Fridericia's correction), QRS Duration] as collected on CRF will be presented through n, mean, median, standard deviation, minimum, and maximum per cycle.
- A summary of abnormal ECG results will also be provided per cycle including baseline visit using frequencies and percentages.
- A listing of this data will also be provided.
- A separate listing for the abnormal ECG values will also be presented.

10.6.7 ECOG

Analysis Set: Safety

ECOG performance status as captured in the eCRF will be summarized per cycle with number and percentage for each status category. This data will also be listed.

The baseline measurement is the last pre-treatment measurement taken on or before Cycle1 Day1.

11. Protocol Deviations

Analysis set: FAS

A full list of protocol deviations for the study report will be compiled prior to database closure. All deviations will be reviewed by the Medical monitor prior to database closure. Each deviation will be categorized as major and minor and a decision will be taken by medical monitor whether to include the subject in a PP analysis population.

Protocol deviations will be presented as number and percentage of patients with minor and major deviations in the study. This data will also be listed as appropriate.

12. Listings

In addition to all the listings mentioned above, separate listings will be presented for the following:

- Screened patients
- Eligibility review
- Reasons for withdrawal of patient from the study
- Analysis populations
- Prior therapy
- Baseline Serology assessment
- Cancer diagnosis
- Study drug exposure
- Study drug accountability
- Target lesion assessment
- Non-target lesion assessment
- Disease Response assessment
- Overall tumor assessment
- Pregnancy test
- Investigator Comments
- Patient visits
- Laboratory IgM levels in LPL/WM patients

13.   References

1. Brookmeyer R, Crowley JJ. A confidence interval for the median survival time. Biometrics. 38: 29-41, 1982.