Official Title: A Phase 1b/2, Open-Label, Multicenter Study to Evaluate the Safety and Pharmacokinetics of a Modified Tafasitamab IV Dosing Regimen Combined With Lenalidomide (LEN) in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) [MINDway]

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Statistical Analysis Plan

MOR208C115

A Phase 1b/2, Open-Label, Multicenter Study to Evaluate the Safety and Pharmacokinetics of a Modified Tafasitamab IV Dosing Regimen Combined With Lenalidomide (LEN) in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) [MINDway]

IND Number:	**145,009**
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Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803 USA**
Protocol Version:	**Protocol v7.0 dated 11 APR 2024**
CRF Approval Date:	**10 JUL 2024**
SAP Version:	**Amendment 1**
SAP Author:	[redacted] **PSR Biostatistician, Biostatistics**
Date of Plan:	**24 OCT 2024**

This study is being conducted in compliance with Good Clinical Practice, including the archiving of essential documents.

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LIST OF ABBREVIATIONS

Abbreviation	Term
ADA	antidrug antibody
AE	adverse event
AESI	adverse events of special interest
ASCT	autologous stem cell transplantation
[redacted]	[redacted]
BQL	below the quantification limit
CI	confidence interval
C_{max}	maximum observed plasma or serum concentration
COVID-19	coronavirus disease 2019
CR	complete response
CRF	case report form
CRS	cytokine release syndrome
CSR	Clinical Study Report
CT	computed tomography
CTCAE	Common Terminology Criteria for Adverse Events
[redacted]	[redacted]
C_{trough}	minimum concentration
CV	coefficient of variation
DLBCL	diffuse large B-cell lymphoma
DoR	duration of response
DSMC	Data Safety Monitoring Committee
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
EMA	European Medicines Agency
ENR	Enrolled Participant Set
EOS	end of study
EOT	end of treatment
FAS	Full Analysis Set
FDA	Food and Drug Administration
G-CSF	granulocyte colony-stimulating factor
hIgG1	human immunoglobulin G1
hIgG1/2a	human immunoglobulin G1/2a
IAS	Immunogenicity Analysis Set

Abbreviation	Term
ICF	informed consent form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
INV	investigator
IPI	International Prognostic Index
IRR	infusion-related reaction
IV	intravenous(ly)
IWG	International Working Group
LEN	lenalidomide
MedDRA	Medical Dictionary for Regulatory Activities
[redacted]	[redacted]
MRI	magnetic resonance imaging
NA	not applicable
nAb	neutralizing antibody assay
NALT	nonstudy antilymphoma treatment
NCI	National Cancer Institute
NE	not evaluable
NHL	non-Hodgkin lymphoma
[redacted]	[redacted]
[redacted]	[redacted]
ORR	objective response rate
PAS	Primary Analysis Set
PD	progressive disease
PET	positron emission tomography
PFS	progression-free survival
PK	pharmacokinetic(s)
PKAS	Pharmacokinetic Analysis Set
PPS	Per-Protocol Set
PR	partial response
PT	preferred term
Q2W	once every 2 weeks
Q4W	once every 4 weeks
QTcB	QT interval corrected using Bazett's formula
QTcF	QT interval corrected using Fridericia's formula
R/R	relapsed/refractory
SAE	serious adverse event

Abbreviation	Term
SAF	Safety Analysis Set
SAP	Statistical Analysis Plan
SD	stable disease
SOC	system organ class
SPS	Screened Participants Set
TEAE	treatment-emergent adverse event
TLS	tumor lysis syndrome
WHO	World Health Organization

1. INTRODUCTION

This is an open-label, multicenter, Phase 1b/2 study to evaluate the safety and PK of [redacted] tafasitamab IV [redacted] combined with LEN in participants with R/R DLBCL. Section 3 of the Protocol provides a detailed description of the investigational products, target patient population, rationale for doses to be examined, and potential risks and benefits of treatment with tafasitamab and LEN.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the MOR208C115 Protocol.

The structure and content of this SAP provide sufficient details to meet the requirements identified by the FDA, EMA, and ICH Guidance on Statistical Principles in Clinical Trials. All work planned and reported from this SAP will follow internationally accepted guidelines, published by the American Statistical Association and the Royal Statistical Society, for statistical practice.

The planned analyses identified in this SAP may be included in CSRs and/or in relevant summary report documents (eg, regulatory submissions or future manuscripts). Posthoc exploratory analyses not necessarily identified in this SAP may be performed to further examine study data and will not require an update to the final SAP. Any posthoc or unplanned exploratory analyses performed will be clearly identified as such and described in the CSR.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on Protocol MOR208C115 v7.0 dated 11 APR 2024 and CRFs approved 10 JUL 2024. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol Amendments and eCRF versions.

In addition, ICH E9 (EMA 1998) and ICH E9 (R1; EMA 2020) will be the basis for the analysis strategies outlined in this SAP.

The reader of this SAP is encouraged to also read the clinical study Protocol, and other identified documents, for details on the design and planned conduct of this study. Operational aspects related to collection and timing of planned clinical assessments are not repeated in this SAP unless relevant to the planned analyses.

2.2. Study Objectives and Endpoints

Table 1 presents the objectives and endpoints.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
• To evaluate the safety and tolerability of tafasitamab administered [redacted] in combination with LEN in participants with R/R DLBCL • To determine a recommended dose for tafasitamab [redacted] administration in combination with LEN in participants with R/R DLBCL	Incidence and severity of TEAEs
Secondary	
To evaluate the PK profile of tafasitamab [redacted] doses in combination with LEN	Tafasitamab serum concentrations after 3 (C_{trough} and C_{max}) and 12 (C_{trough}) treatment cycles
To assess antitumor activity of tafasitamab [redacted] doses in combination with LEN	• Best ORR by INV assessment up to Cycle 12 based on Cheson et al (2007) • DoR by INV assessment based on Cheson et al (2007) • PFS by INV assessment based on Cheson et al (2007)
To assess the incidence of ADAs to tafasitamab	Number and percentage of participants developing anti-tafasitamab antibodies up to Cycle 12
[redacted]	

Note: Each treatment cycle is 28 days.

3. STUDY DESIGN

MOR208C115 (MINDway) is an open-label, multicenter, Phase 1b/2 study of tafasitamab combined with LEN to evaluate the safety and PK of [redacted] tafasitamab [redacted] in adult participants with R/R DLBCL.

Participants will receive LEN in combination with tafasitamab in 28-day cycles. [redacted]

- [redacted]

Lenalidomide 25 mg will be administered for a maximum of 12 cycles or until disease progression, unacceptable toxicity, withdrawal, death, or lost to follow-up, whichever occurs first. After Cycle 12 or LEN discontinuation, participants will continue with tafasitamab monotherapy [redacted] until disease progression, unacceptable toxicity, withdrawal, death, or lost to follow-up, whichever occurs first.

[redacted]

participant discontinues the study for reasons other than safety before completion of the predefined safety observation window (5 weeks), the participant may be replaced.

[redacted]

A participant is considered to have started the study and entered the screening period when they have signed the ICF.

[redacted]

A participant is considered enrolled in the study if they receive at least 1 dose of study drug (tafasitamab or LEN).

The EOS is reached for an individual participant if any of the following applies: withdrawal, lost to follow-up, death, or completion of the EOS/90-day safety follow-up visit after treatment discontinuation. Regardless of the reason for treatment discontinuation (with the exception of withdrawal of consent, death, or lost to follow-up) all participants must complete a safety follow-up visit 90 days after the last dose of study treatment.

The EOS is reached when all participants still receiving study treatment have been followed for at least 3 years, or when the final participant on study has completed their last visit, whichever occurs first.

Overall survival follow-up after EOT will not be performed in the study.

3.1. Randomization

Not applicable.

3.2. Control of Type I Error

All statistical analyses are exploratory in nature. Unless otherwise specified, all CIs provided will be at the 95% confidence level.

3.3. Sample Size Considerations

As this is a Phase 1b/2 study, primary, secondary, and exploratory endpoints will be analyzed using descriptive statistics. No formal statistical tests will be performed.

[redacted]

3.4. Schedule of Assessments

Refer to Protocol v7.0 dated 11 APR 2024 for a full description of all study procedures and assessment schedules for this study.

3.5. Analysis Timepoints

3.5.1. Dose Escalation Analyses

A DSMC, consisting of sponsor and investigator representatives, will continuously monitor the study and can recommend stopping enrollment at any time based on emerging safety data.

[redacted]. The DSMC recommendations will be guided by predefined safety criteria that apply to the 35-day safety observation window (from Cycle 1 Day 1 to Cycle 2 Day 7). Details of the predefined safety criteria can be found in Protocol Section 5.2.

Details of specific responsibilities, composition, and meeting formats and frequency of the DSMC are outlined in the DSMC charter.

[redacted]

3.5.2. Primary Completion Analysis

The primary completion analysis will be performed when all participants have either reached Cycle 3 Day 28 or discontinued study treatment prior to Cycle 3 Day 28.

Primary and secondary objectives will be analyzed at the time of the primary completion analysis. Additional analyses for safety or efficacy endpoints may be performed if needed or if requested by authorities.

3.5.3. Final Analysis

The final analysis of the study will occur approximately 3 years after the last participant is enrolled.

At the time of final analysis, analyses performed during the primary analysis will be repeated using updated data [redacted] objectives will be analyzed. Additional analyses for safety or efficacy endpoints may be performed if needed or if requested by authorities.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Start of Study

A participant is considered to have started the study and entered the screening period when they have signed the ICF.

4.1.2. Day 1

The reference start date is designated as Day 1.

The reference start date for all safety and efficacy assessments (eg, AE onset, laboratory abnormality occurrence, vital sign measurements, dose interruption) will be the earliest among start dates of study drug.

For any nonsafety screening assessments or events such as baseline disease characteristics or medical history (eg, time since diagnosis of disease) that occurred prior to the earliest start date of any study drug, the reference start date will be the earliest among start dates of study drugs.

4.1.3. Study Day

The study day describes the day of the event or assessment date, relative to the reference start date.

If a visit/reporting date is on or after Day 1, then the study day at the visit/reporting date will be calculated as

Day # = (visit/reporting date – Day 1 date + 1).

If the visit/reporting date is before Day 1, then the study day at the visit/reporting date will be calculated as

Day # = (visit/reporting date – Day 1 date).

A study day of –1 indicates 1 day before Day 1.

The study day will be displayed in the data listings.

4.1.4. Baseline Value

Baseline is the last nonmissing measurement obtained before the first administration of any study drug, unless otherwise defined.

Values from assessments specified to be performed after the first dose of any study drug (eg, vital sign assessments during and after the tafasitamab infusion) are not considered as baseline values.

When scheduled assessments and unscheduled assessments occur on the same day and the time of the assessment or time of first dose is not available, the following convention will be used to determine baseline:

- If both a scheduled and an unscheduled visit occur on the day of the first dose and the time is missing, the scheduled assessment will be used as baseline.
- If all scheduled assessments are missing on the day of the first dose and an unscheduled assessment is available, the unscheduled assessment will be used as baseline.

4.1.5. Reference End Date

The reference end date will be the date of the last administration of any study drug.

4.1.6. Date of Last Contact

The date of last contact will be derived as the latest date among the following:

- Actual assessment dates considering all assessments (laboratory sample collection, vital signs, ECOG performance status, B symptoms, ECG measurement, tumor imaging), including scheduled and unscheduled visits.
- Date of new antilymphoma treatment administered after study drug discontinuation.
- Adverse event end date. If the AE is ongoing, then the AE start date will be used.
- Date of last interaction with participant collected in the "End of Study/Early Follow-Up Discontinuation" eCRF.
- Date of death from the "Death" eCRF.
- Date of study completion or withdrawal from the "End of Study/Early Follow-Up Discontinuation" eCRF.
- Date of study treatment completion or discontinuation from the "End of Treatment/Early Discontinuation of Treatment" eCRF.

4.1.7. Analysis Visit Windows and eCRF Visit Windows

Unless otherwise specified, for parameters that will be summarized by visit, the nominal visit as recorded in the eCRF will be used. There will be no additional analysis windows based on the assessment date. In order to summarize over time, parameters recorded at each visit (eg, ECOG performance status, vital signs) and assessments (including unscheduled ones) will be time-slotted if indicated.

4.1.8. Unscheduled Visits

In this study, unscheduled visits, as recorded in the "Unscheduled Visit Date of Visit" eCRF, are timepoints not planned in the Protocol.

Unscheduled visits will be listed and ordered chronologically by date.

Unscheduled visits will be incorporated in the baseline calculation and overall postbaseline summary. If the date is incomplete but it can be determined that values were measured during the treatment phase, the unscheduled visit will be incorporated in the overall postbaseline summaries. Unscheduled visits will be excluded from the per timepoint/visit presentation.

4.1.9. Handling of Missing and Incomplete Dates

In general, values for missing dates will not be handled unless methods for handling missing dates are specified in this section or relevant sections. The original reported dates collected in the eCRF should be used in all relevant listings. The following rules will be used for handling partial dates for analyses requiring dates.

When the date of the last dose is used in deriving variables such as duration of treatment or TEAE flag, a missing or partial date of the last dose will be handled as follows:

- If only the day is missing, then the earlier date of the last day of the month or the date that the participant discontinued treatment will be used.
- If both the month and day are missing, then the earlier date of 31 DEC of the year or the date that the participant discontinued treatment will be used.
- Otherwise, the date that the participant discontinued treatment will be used as the date of the last dose.

For relevant efficacy endpoints, a partial date of the death date will be handled as follows in the calculation:

- If mmyyyy for the last known alive date = mmyyyy for the death date, then the death date will be set to the day after the last known alive date.
- If mmyyyy for the last known alive date < mmyyyy for the death date, then the death date will be set to the first day of the death month.
- Otherwise, the partial death date will not be imputed.

4.2. Study Drug Administration

4.2.1. Study Drug and Study Treatment

Study drug refers to the individual drug, tafasitamab or LEN. Study treatment refers to tafasitamab in combination with LEN.

4.2.2. Date of First Administration of Study Drugs

The date of first administration of a study drug ("start date of study drug") is the first date when a nonzero dose of a study drug is administered. Start date of study drug is defined for each drug that is part of the study treatment.

4.2.3. Date of Last Administration of Study Drugs

The date of last administration of study drug ("last date of study drug") is the last date when a nonzero dose of study drug is administered. Last date of study drug is defined for each drug that is part of the study treatment. For tafasitamab, this date defines the EOT.

4.2.4. Date of First Administration of Study Treatment

The date of first administration of study treatment ("start date of study treatment") is the first date when a nonzero dose of any component of the study treatment is administered. For example, if the first dose of tafasitamab is taken on 03 JAN 2022, and the first dose of LEN is taken on 05 JAN 2022, then the "start date of study treatment" is 03 JAN 2022. In case of exposure to only 1 component of the study treatment, the date of first administration of study drug will be used.

4.2.5. Date of Last Administration of Study Treatment

The date of last administration of study treatment ("last date of study treatment") is the last date when a nonzero dose of any component of the study treatment is administered. For example, if the last dose of tafasitamab is taken on 13 APR 2022, and last dose of LEN is taken on 20 APR 2022, then the "last date of study treatment" is 20 APR 2022. In case of exposure to only 1 component of the study treatment, the date of last administration of study drug will be used.

4.3. Other Definitions

4.3.1. Study Cohorts

Participants will receive tafasitamab in combination with LEN in 28-day cycles. [redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

4.3.2. Screen Failures

Screen failures are defined as participants who consent to participate in the clinical study but are not subsequently entered into the treatment period.

4.3.3. Time Units

A month-length is 30.4375 days (365.25 / 12). If duration is to be reported in months, the duration in days will be divided by 30.4375. If duration is to be reported in years, the duration in days will be divided by 365.25.

4.3.4. Change From Baseline Calculation

The absolute change from baseline will be calculated as

change from baseline = visit value – baseline value.

The percentage change from baseline will be calculated as

percentage change from baseline = [(visit value – baseline value) / baseline value] × 100.

4.3.5. End of Study

The EOS is reached when all participants still receiving study treatment have been followed for at least 3 years, or when the last participant on study has completed their last visit, whichever occurs first.

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; v9 or later) will be used for the generation of all tables, graphs, and statistical analyses. Descriptive summaries for continuous variables will include but not be limited to the number of observations, mean, standard deviation, median, minimum, and maximum. Descriptive summaries for categorical variables will include the number and percentage of participants in each category.

5.2. Treatment Groups

Data will be summarized overall and by treatment group [redacted]

5.3. Analysis Sets

5.3.1. Screened Participants Set

The SPS will consist of all participants who signed the ICF and completed the "Informed Consent" eCRF. Participants who signed the ICF and fulfilled screening criteria but never started any study drug will be listed. Screen failures will not be included in any of the summary tables (except in the screened participants disposition table).

5.3.2. Analysis Set for the Primary Estimand: Primary Analysis Set

A detailed description of the primary estimand for this study can be found in Protocol Section 4.1.1.

The PAS will include all participants who receive at least 1 of the higher tafasitamab doses at either 24 or 30 mg/kg and who had at least 1 postbaseline safety assessment.

A valid safety assessment includes death.

5.3.3. Enrolled Participant Set

The ENR will consist of all participants who received at least 1 dose of study drug (tafasitamab OR LEN).

5.3.4. Full Analysis Set

The FAS will include all participants who received at least 1 dose of study treatment (tafasitamab AND LEN).

Participants will be analyzed according to the dose group to which they were initially assigned.

5.3.5. Safety Analysis Set

The SAF will include all participants who received at least 1 dose of study drug (tafasitamab or LEN) and had at least 1 postbaseline safety assessment. A valid safety assessment includes death. Treatment groups for this set will be determined according to the actual treatment the participant received regardless of assigned study treatment.

All safety analyses will be conducted using the SAF.

5.3.6. Per-Protocol Set

Participants included in FAS with at least 1 valid postbaseline assessment for ORR and without any important Protocol deviations that would confound efficacy analysis will be included in the PPS. There may be other conditions leading to exclusion from the PPS, such as ineligibility per central pathology assessment.

Sensitivity analyses for efficacy endpoints may be performed using the PPS.

[redacted]

5.3.8. Pharmacokinetic Analysis Set

The PKAS will include all participants who received at least 1 dose of tafasitamab and have at least 1 quantifiable serum tafasitamab concentration.

5.3.9. Immunogenicity Analysis Set

The IAS will include all participants who received at least 1 dose of tafasitamab and have at least 1 valid anti-tafasitamab antibody assessment.

5.3.10. Reason of Exclusion From Analysis Sets

Participants may be excluded from the analysis sets for the reasons presented in Table 2.

Table 2: Reasons for Exclusion From Analysis Sets

Analysis Set	Reason for Exclusion From Analysis Set
SPS	Not applicable
PAS	1. No tafasitamab dose of [redacted] 2. No postbaseline safety assessment
ENR	No dose of any study drug
FAS	No dose of any component of study treatment
SAF	1. No dose of any study drug 2. No postbaseline safety assessment
PPS	1. No dose of any component of study treatment 2. Central pathology diagnosis different from investigator diagnosis 3. No postbaseline ORR assessment 4. Important Protocol deviations or other conditions that influence efficacy
[redacted]	
PKAS	1. No dose of tafasitamab 2. No quantifiable serum tafasitamab concentration
IAS	1. No dose of tafasitamab 2. No anti-tafasitamab antibody assessment

Note: If a participant has more than 1 reason for exclusion from any analysis set, then only the highest-ranking reason will be considered. For example, for the PPS, if a participant is excluded because of "no dose of any component of study treatment" and "no postbaseline response assessment," then only "no dose of any component of study treatment" will be counted when summarizing the reasons for exclusion from the PPS.

5.3.11. Withdrawal of Consent

Refer to Protocol Section 8.1 for details regarding withdrawal of consent. The date on which a participant withdraws consent will be recorded in the "End of Study/Early Follow-Up Discontinuation" eCRF.

6. BASELINE, EXPOSURE, AND DISPOSITION

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

6.1. Demographics, Baseline Characteristics, and Disease History

6.1.1. Demographics and Baseline Characteristics

The following demographics and baseline characteristics will be summarized for the ENR, FAS, PAS, and SAF:

- Age (as continuous variable [years])
- Age (as categorical variable) with the following subgroups:
  - < 60 versus ≥ 60 years of age
  - < 65 versus ≥ 65 years of age
  - < 70 versus ≥ 70 years of age
  - < 75 versus ≥ 75 years of age
- Height (cm)
- Weight (kg)
- ECOG status (categorical variable)
- Sex
- Race
- Ethnicity

Listings for demographic data will be produced for the ENR with inclusion in FAS, PAS, and SAF noted.

6.1.2. Baseline Disease Characteristics

The following baseline disease characteristics will be summarized for the FAS and PAS:

- Date of initial diagnosis of DLBCL
- Stage of DLBCL at initial diagnosis
- Current stage (Ann Arbor staging classification) and dichotomized (I and II vs III and IV)
- Diagnosis of DLBCL (NHL subtype) as per INV
- Number of prior systemic DLBCL treatment lines (categorical variable)
- Number of participants with 1 vs ≥ 2 prior systemic DLBCL treatment lines
- Prior ASCT (yes vs no)
- Rituximab refractoriness (yes vs no)

- Refractoriness to last prior therapy (yes vs no)
- Relapse ≤ 12 months after initial DLBCL diagnosis (early relapse) versus relapse > 12 months after initial DLBCL diagnosis (late relapse)
- Bulky disease present versus absent (defined as having a longest lesion diameter of ≥ 7.5 cm as assessed by local radiological assessment)
- IPI Risk Group (as per IPI score/age-adjusted IPI score)
- Diagnosis of DLBCL (NHL subtype) as per central pathology
- PET result at screening
- Cell of origin by Hans Algorithm

The following coded terms (among prior anti-lymphoma surgeries/procedures) are considered prior ASCT: ASCT, SCT, AUTO SCT, autologous transplant, autologous stem cell transplant, stem cell transplant, transplant.

For PET, in case of multiple assessments at screening (eg, due to multiple lesions), the latest before Cycle 1 Day 1 will be considered.

All data for the ENR will be listed with inclusion in the PAS and FAS noted.

6.1.3. Bone Marrow Involvement at Screening/Baseline

Data on bone marrow aspiration and/or biopsies as recorded at baseline/screening or within the 4 weeks prior to the date of informed consent include the following information:

- Date and type of examination
- Type of diagnosis of DLBCL at baseline
- Bone marrow involvement by DLBCL

All summaries will include the type of examination and bone marrow involvement by DLBCL and will be presented for the PAS and FAS. All data for the ENR will be listed with inclusion in the PAS and FAS noted.

6.1.4. Definitions, Derivations, and Imputation Rules for Variables Related to Disease Characteristics

6.1.4.1. Early Versus Late Relapse After DLBCL Diagnosis

The "date of initial diagnosis of DLBCL" and the "date of first progression/relapse" can be found in the "Diagnosis of DLBCL" eCRF.

The imputation rules in Table 3 will be applied in the situation of partially completed dates.

Table 3: Imputation Rules Used to Derive the Time Between Date of Initial DLBCL Diagnosis and Date of First Progression/Relapse

Component of the Date			Variable	
DD	**MMM**	**YYYY**	**Start Date**	**End Date**
Present	Present	Present	No imputation	No imputation
Missing	Present	Present	Last day of the month	Last day of the month
Missing	Missing	Present	No imputation	No imputation
Missing	Missing	Missing	No imputation	No imputation

If the day and month are missing, and the year is present for both variables required, the participant will be assigned to the category "late relapse after initial DLBCL diagnosis" if the difference between the year for the "date of initial diagnosis of DLBCL" and the year for the "date of first progression/relapse" is 2 years or more. If the difference between the years is only 1 year, the relapse category after initial DLBCL diagnosis will be considered as "unknown." If the year is the same for both variables, the participant will be assigned to the category "early relapse after initial DLBCL diagnosis." If the relapse category cannot be determined, the participant will be assigned to the category "unknown."

6.1.4.2. Refractoriness to Prior Antilymphoma Therapies

The following 2 subgroups for treatment refractoriness in prior therapy lines will be defined using information regarding prior antilymphoma medications collected in the eCRF:

- Refractoriness to the last prior treatment line
- Rituximab refractoriness

6.1.4.2.1. Refractoriness to the Last Prior Antilymphoma Treatment Line

Refractoriness to the last prior treatment is defined as having less than a PR (ie, SD or PD) as the best overall response to the most recent therapy.

If the status for "refractoriness to the last prior treatment line" cannot be determined, the participant will be considered as having an "unknown" status.

6.1.4.2.2. Rituximab Refractoriness

Rituximab refractoriness is defined as having reached less than a PR to any rituximab-containing treatment regimen. If the status for "rituximab refractoriness" cannot be determined, the participant will be considered as having an "unknown" status.

6.1.5. Medical History and Current Medical Conditions

Medical history and current medical conditions will be summarized for the PAS and FAS by SOC, PT, and by toxicity grade according to NCI CTCAE v5.0. Coding will be performed using MedDRA v27.0 or higher.

Listings will also be provided for the ENR with inclusion in the SAF, PAS, and FAS noted.

6.2. Disposition of Participants

6.2.1. Disposition of Screened Participants

The following will be summarized for the SPS:

- Number of participants screened.
- Number and percentage of screen failures.
  - Screen failure reasons will be summarized. Percentage will be calculated based on number of participants who failed screening. A participant may fail screening due to multiple reasons.
- Number and percentage of participants enrolled.

6.2.2. Disposition of Enrolled Participants

The following summary will be provided for participants in the SPS who did not fail screening:

- Number of participants who are not screen failures.
- Number and percentage of participants who have not started treatment.
- Number and percentage of enrolled participants.
- Number and percentage of participants with ongoing treatment.
- Number and percentage of participants who completed treatment.
- Number and percentage of participants who discontinued treatment with the primary reason for discontinuation.
- Number and percentage of participants still in the study.
- Number and percentage of participants who completed the study.
- Number and percentage of participants who withdrew from the study with the primary reason for withdrawal.
- Number and percentage of participants who withdrew from the study without completing the EOS visit.
- Number and percentage of participants who withdrew from the study and completed the EOS visit.

The following summaries will be provided for the ENR:

- Number and percentage of participants by country and site.
- Number and percentage of participants who have discontinued study treatment based on components as follows:
  - Tafasitamab only, including the reason for discontinuation.
  - LEN only, including the reason for discontinuation.

  - Both study drugs (at the same time or sequentially), including the reason for discontinuation, which will include LEN discontinuation as per Protocol.

- Number and percentage of participants who discontinued both tafasitamab and LEN before completing 12 cycles, including the reason for discontinuation.
- Participant disposition by cycle, including the following:
  - Number and percentage of participants who completed combination treatment (ie, Cycles 1-12 with both study drugs).
  - Number and percentage of participants who started Cycle 13 Day 1 with:
    - Tafasitamab only.
    - LEN only (Protocol deviation).
    - Tafasitamab + LEN (Protocol deviation).
  - Number and percentage of participants in Cycles 1-12 who are ongoing with tafasitamab only, LEN only, or both study drugs.
  - Number and percentage of participants in Cycles 13 or later who are ongoing with tafasitamab only, LEN only (Protocol deviation), or both study drugs (Protocol deviation).
- Number and percentage of participants who discontinued tafasitamab at Cycle 13 or later, including the reason for discontinuation.

The date of last dose and reason for discontinuation of the study drugs will be in the "End of Treatment/Early Discontinuation of Treatment" eCRF. The date of EOS visit, indication if participant completed the follow-up period, and, when applicable, the reason for early follow-up discontinuation will be in the "End of Study/Early Follow-Up Discontinuation" eCRF.

In addition, the number of participants in the ENR, SAF, FAS, PAS, PPS, and [redacted] will be provided. Reasons for exclusion from a set will be summarized.

Listings will be presented based on the ENR.

6.2.3. Summary Statistics of Enrollment

Summary information regarding the enrollment of participants will be provided in order to describe the maturity of data and quality of follow-up for the safety and efficacy analyses. The following will be presented for the FAS and SAF:

- Duration of enrollment period (months) = (date of last participant enrolled – date of first participant enrolled + 1) / 30.4375. This will be reported for overall only.
- Date of first participant enrolled.
- Date of last participant enrolled.

6.3. Protocol Deviations

Important Protocol deviations will be identified based on reviews of the data prior to database lock.

Important Protocol deviations for the ENR will be summarized overall and tabulated according to the categories mentioned below. The number (%) of participants with at least 1 important Protocol deviation will be tabulated.

The following categories will be considered in the analysis:

- Participant enrolled and did not satisfy the entry criteria.
- Participant developed treatment discontinuation/study withdrawal criteria during the study but was not discontinued/withdrawn.
- Participant received the wrong treatment or incorrect dose.
- Participant received a prohibited concomitant treatment.
- Assessment and procedure deviation.

Listings of important Protocol deviations will be presented based on participants in the SPS who were not screen failures.

6.4. Exposure

With the exception of a summary of exposure to components of the study treatment, which will be provided for the ENR, all exposure summaries will be conducted based on the PAS, FAS, and SAF. Listings will be on the ENR with inclusion in the PAS, FAS, and SAF noted.

6.4.1. Treatment Cycles

Each treatment cycle will consist of 28 days. The treatment plan is outlined in Table 4.

Note: Each treatment cycle is 28 days.

Dose reductions of tafasitamab are not allowed during the course of the study. Unless contraindicated, tafasitamab treatment should continue even if the participant discontinues LEN.

6.4.2. Other Definitions

6.4.2.1. Duration of Exposure to Study Drug

Duration of exposure to each study drug will be calculated as

duration of exposure (months) = (date of last of dose to study drug – date of first dose of study drug + 1) / 30.4375.

6.4.2.2. Duration of Exposure to Study Treatment

Duration of exposure to the study treatment will be calculated as

duration of exposure (months) = (date of last dose of any study drug – date of first dose of any study drug + 1) / 30.4375.

6.4.2.3. Duration of Exposure to Any Study Drug

Duration of exposure to any study drug will be calculated as

duration of exposure (months) = (date of last dose of any study drug – date of first dose of any study drug + 1) / 30.4375.

6.4.2.4. Tafasitamab Infusion Rate

6.4.2.4.1. Infusion Rate

The infusion rate (per visit) will be calculated as

infusion rate (mL/h) = total volume of solution containing tafasitamab administered (mL) / total infusion time (hours).

6.4.2.4.2. Cycle Infusion Rate

For a given cycle, the infusion rate is defined as the highest infusion rate among the infusions included.

6.4.2.4.3. Standard Infusion Rate

The standard infusion rate for 12 mg/kg (Cycle 1 Days 1, 4, and 8) is defined as follows:

- 70 mL/h for the first 30 minutes
- 143 mL/h afterwards (assuming a minimum of 90 minutes)

The infusion rate upper limit will be 143 mL/h (90 minutes).

The standard infusion rate for 24 and 30 mg/kg is defined as follows:

- Cycle 1 Day 15 to Cycle 3 Day 15:
  - 62.5 mL/h (over approximately 4 hours) if the planned volume was 250 mL
  - 125 mL/h (over approximately 4 hours) if the planned volume was 500 mL
- Cycle 4 Day 1 onwards:
  - 125 mL/h (over approximately 2 hours) if the planned volume was 250 mL
  - 250 mL/h (over approximately 2 hours) if the planned volume was 500 mL

If there are interruptions or, in general, any gaps that occur with the infusion, only the actual time of infusion will be considered (ie, time gaps between infusion end and infusion restart will not be considered)

6.4.2.5. Tafasitamab Dose Administered Over Time

For a given infusion, the tafasitamab administered dose will be calculated as

administered dose over time (mg/h) = actual dose administered (mg)/ total infusion time (hours).

6.4.2.6. Dose Interruption and Skipped Doses

6.4.2.6.1. Tafasitamab

There are 2 scenarios for tafasitamab interruption. Firstly, a participant can skip a visit and thus the administration of tafasitamab at that visit. This is defined as "skipping of tafasitamab administration." Secondly, tafasitamab administration can be interrupted during the infusion, this is defined as "interruption of tafasitamab during infusion." Furthermore, a participant

interrupting tafasitamab infusion can have the following scenarios: either the participant takes the full dose after the infusion interruption or the participant does not take the full dose after the infusion interruption. Participants who interrupted or skipped tafasitamab will be indicated in the "Tafasitamab Dosage Administration" eCRF.

6.4.2.6.2. Lenalidomide

If a participant does not take a dose of LEN, that is, skips a LEN capsule for a day, this is considered as a "dose interrupted." Participants who interrupt LEN will be indicated in the "Lenalidomide Dosage Administration" eCRF. Lenalidomide interruption occurs when a participant stops LEN for example to allow for toxicity resolution before restarting the drug.

6.4.2.7. Completion

6.4.2.7.1. Tafasitamab Cycle Completion

A tafasitamab cycle will be considered complete if the participant was exposed to tafasitamab on all planned days of the cycle.

6.4.2.7.2. Tafasitamab Time Period Completion

A tafasitamab time period will be considered complete if all cycles within the period are complete (eg, completed Cycles 1-12 or eg Cycle 13 onwards).

6.4.2.7.3. Lenalidomide Cycle Completion

A LEN cycle will be considered complete if the mean compliance of the cycle is at least 80%.

6.4.2.7.4. Lenalidomide Treatment Period Completion

The LEN treatment period will be considered complete if all 12 cycles are complete.

6.4.3. Study Drug Compliance

6.4.3.1. Compliance With Tafasitamab Treatment

A participant will be considered compliant with the Protocol if the tafasitamab dose administered is 80% to 120% of the assigned dose. Intraparticipant dose reductions of tafasitamab are not permitted.

Infusion interruptions or skipped infusions due to AEs, COVID-19, or logistical or technical reasons will not be considered as noncompliance.

The following strategy will be used to derive the actual administered dose versus the planned dose to calculate compliance with tafasitamab treatment.

Actual dose administered per infusion will be derived as follows:

- Actual dose (mg/kg) = actual dose administered (mg) / weight (kg)
  - Actual dose administered will be taken from the "Tafasitamab Dosage Administration" eCRF. Weight will be taken from the "Vital Signs" eCRF.
- Skipped doses will result in an administered dose of 0 mg/kg for the particular visit

Planned dose per infusion will be derived as 12, 24, or 30 mg/kg as indicated in the "Tafasitamab Dosage Administration" eCRF.

Compliance per infusion will be derived as

compliance rate per infusion (%) = actual dose / planned dose.

Compliance per cycle will be derived as

compliance rate per cycle (%) = actual dose (considering all infusions taken by the participant in the cycle) / planned dose (considering all infusions planned in the cycle).

6.4.3.2. Compliance With Lenalidomide Treatment

Lenalidomide will be taken for the first 21 days of each cycle, and participants may reach the total daily dose by combining capsules of 2 different dose strengths.

The compliance rate per intake (ie, per each day of Days 1 to 21 in a cycle) will be calculated as

compliance rate per intake (%) = dose administered / planned dose.

Dose administered and planned dose can be found in the "Lenalidomide Dosage Administration" eCRF.

Compliance with LEN treatment will be derived and reported per cycle. A participant will be considered compliant with LEN treatment for a particular cycle if the mean compliance rate for a cycle is 80% to 120%. The following will not be considered as noncompliance:

- Participants with a transient treatment interruption (an entire cycle skipped or doses skipped on single days) due to an AE, COVID-19, or logistical or technical reasons (as indicated in the "Lenalidomide Dosage Administration" eCRF).
- Participants undergoing treatment discontinuation who took LEN for fewer than 21 days.
- Reduction of the planned dose (eg, due to an AE).

6.4.4. Summaries

6.4.4.1. Dose Reduction of Lenalidomide

The following will be summarized for LEN dose reductions in the SAF, PAS, and FAS:

- Number (%) of participants with any dose reduction.
- Number (%) of participants with a reduction to a minimum of 20, 15, 10, or 5 mg before completion of Cycle 12.
- Number (%) of participants who had no reduction at all or only a reduction to 20 mg (but not lower).

6.4.4.2. Over-Infusion Rate of Tafasitamab

The following will be summarized for tafasitamab in the SAF, PAS, and FAS:

- Number (%) of participants who had at least 1 infusion rate at a given visit greater than the standard infusion rate
- For each cycle, number (%) of participants who had at least 1 infusion rate among visits in a cycle greater than the standard infusion rate

6.4.4.3. Tafasitamab Dose Administered Over Time

Tafasitamab dose administered over time by infusion will be summarized for the SAF, PAS, and FAS.

6.4.4.4. Dose Interruption and Skipped Doses

The following will be summarized for the SAF, PAS, and FAS:

- Number (%) of participants who skipped at least 1 tafasitamab dose
- Number (%) of participants who skipped tafasitamab by cycle and by number of skipped doses
- Number (%) of participants who interrupted at least 1 tafasitamab infusion
- Number (%) of participants who interrupted tafasitamab by cycle and by number of interruptions
- Number (%) of participants who interrupted at least 1 LEN dose
- Number (%) of participants who interrupted LEN by cycle and by number of interrupted doses

6.4.4.5. Study Treatment Exposure

The following will be summarized for the ENR:

- Number (%) of participants who were treated with study drug, split by:
  - any study drug
  - both study drugs
  - any tafasitamab dose
  - at least 1 dose of tafasitamab 24 or 30 mg/kg
  - [redacted]
  - any LEN dose

6.4.4.6. Compliance

6.4.4.6.1. Compliance With Tafasitamab

The compliance rate will be summarized and the number (%) of compliant and noncompliant participants will be reported by visit for the SAF, PAS, and FAS.

For visits in which no infusion was planned (eg, EOT), compliance will not be reported.

A listing of tafasitamab dose administration will be provided for the ENR with inclusion in the SAF, PAS, and FAS noted.

6.4.4.6.2. Compliance With Lenalidomide

The compliance rate will be summarized and the number (%) of compliant and noncompliant participants will be reported by cycle (Cycles 1-21) for the SAF, PAS, and FAS.

A listings of LEN dose administration will be provided for the ENR with inclusion in the SAF, PAS, and FAS noted.

6.5. Prior and Concomitant Medication and Nondrug Therapies

6.5.1. Coding

Prior and concomitant medications and preinfusion medications for tafasitamab will be recorded and coded using the WHO Drug Dictionary and grouped by WHO drug class and WHO drug term. Surgical and medical procedures (nondrug therapies) will be coded using MedDRA and summarized by SOC and PT.

6.5.2. Definitions

6.5.2.1. Preinfusion Medication for Tafasitamab

Preinfusion medication for tafasitamab is defined as medication given prior to tafasitamab infusion to mitigate potential IRRs. Premedication encompasses antipyretics, histamine receptor blockers, glucocorticosteroids, and meperidine.

6.5.2.2. Prior Medication/Nondrug Therapies

If the medication/nondrug therapy start and stop dates are both before the start date of study treatment, the medication/nondrug therapy will be classified as prior medication/nondrug therapy.

6.5.2.3. Concomitant Medication/Nondrug Therapies

If the medication/nondrug therapy start date is after start of study treatment, the medication/nondrug therapy will be considered as concomitant medication/nondrug therapy. If the medication stop date is incomplete, the following algorithm will apply:

- If stop day is missing but month is complete, the medication/nondrug therapy will only be excluded from concomitant medication/nondrug therapy if stop month is before month of treatment start.
- If stop day and month are missing but year is complete, the medication/nondrug therapy will only be excluded from the concomitant medication/nondrug therapy if stop year is before year of treatment start.
- If stop date is completely missing, the medication/nondrug therapy will not be excluded.

6.5.2.4. Prior and Concomitant Medication/Nondrug Therapies

If the medication/nondrug therapy start date is before the start date of study treatment but is ongoing or has a stop date after the start of study treatment, it will be considered as both prior and concomitant medication/nondrug therapy.

6.5.3. Prior Lines of Antilymphoma Therapy

Prior antilymphoma therapies (drug or nondrug) will be summarized for the PAS and FAS as follows:

- Prior antilymphoma medications
  - Number (%) of participants by number of prior therapy lines (as categorical variable)
  - Number (%) of participants with 0, 1, or ≥ 2 prior antilymphoma medications
- Prior radiation therapy
  - Number (%) of participants with at least 1 prior antilymphoma radiotherapy
- Prior surgery
  - Number (%) of participants with at least 1 prior antilymphoma surgery/procedure
- Prior ASCT
  - Number (%) of participants with prior ASCT

All data will be listed for the ENR with inclusion in the PAS and FAS noted. Listings for individual antilymphoma-specific treatments will include the following:

- Best overall response and date
- Reason for therapy discontinuation
- Therapy start date
- Therapy end date

- Therapy type
- Medication name
- Number of the particular therapy line

6.5.3.1. Time Since Last Antilymphoma Treatment

The time since last antilymphoma treatment will be calculated as

time since last antilymphoma treatment (months) = (date of first dose of study drug – EOT date for last prior antilymphoma treatment [medication/radiation therapy/surgery] + 1) / 30.4375.

6.5.4. Summaries of Non-Antilymphoma Therapies

The following summary tables will be presented for the PAS and FAS:

- Preinfusion medications for tafasitamab
- Prior non-antilymphoma medications
- Concomitant non-antilymphoma medications
- Prior non-antilymphoma nondrug therapies
- Concomitant non-antilymphoma nondrug therapies

All data will be listed based on the ENR with inclusion in the PAS and FAS noted.

6.5.5. Nonstudy Antilymphoma Treatment

Receipt of NALT on or after the start date of study drug will be provided (based on the "Non-Study Lines of Anti-Lymphoma Treatment," "Non-Study Lines of Anti-Lymphoma Treatment: Drug Treatment," "Non-Study Lines of Anti-Lymphoma Treatment: Radiotherapy Treatment," and "Non-Study Lines of Anti-Lymphoma Treatment: Surgeries/Procedures" eCRFs).

The following will be summarized for the PAS and FAS:

- Number (%) of participants who received NALT prior to permanent discontinuation of tafasitamab: any NALT, drug NALT, radiotherapy NALT, surgery/procedure NALT
- Number (%) of participants who received NALT before a documented radiological progression as per IWG Criteria (Cheson et al 2007): any NALT, drug NALT, radiotherapy NALT, surgery/procedure NALT
- Number (%) of participants who received NALT anytime on or after the start date of study treatment: any NALT, drug NALT, radiotherapy NALT, surgery/procedure NALT

In addition, a summary of drug NALT (by WHO drug class and WHO drug term) received anytime on or after start of study treatment will be presented for the PAS and FAS.

Listings of drug NALT, radiotherapy NALT, and surgery/procedure NALT will be presented for the ENR with inclusion in the PAS and FAS noted. Listings will include NALT received any time on or after the start date of study drug, if prior to permanent discontinuation of tafasitamab and before a documented radiological progression as per IWG Criteria (Cheson et al 2007). Listings will include the following:

- Cohort
- Tafasitamab/LEN start and stop dates
- Date of disease progression as per IWG criteria
- If drug NALT, WHO drug class and WHO drug term
- NALT start and stop dates
- Reason for stopping NALT (only if prior treatment)

7. EFFICACY

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

7.1. General Considerations

Response assessment per INV will be based on the response criteria according to Cheson et al (2007; described in Protocol Section 12.4). The outcome of a tumor response assessment will be documented in the "Disease Response Assessment" eCRF (in the "overall response based on Cheson 2007 criteria" field).

The following efficacy endpoints will be analyzed: ORR, DoR, and PFS. Summaries will be presented by treatment group and overall.

7.2. Efficacy Hypotheses

Not applicable.

7.3. Analysis of the Secondary Efficacy Parameter(s)

7.3.1. Endpoint: Objective Response Rate

The ORR is defined as the proportion of participants with CR or PR as the best response achieved at any time during the study. Only responses of CR or PR that were documented before the initiation of NALT will be considered. The denominator will be the total number of participants included in the analysis set.

7.3.1.1. Main Estimand Analysis

The estimand of ORR, with its 5 attributes and the strategies for addressing the defined intercurrent events, is presented in Table 5.

Table 5: Estimand of Objective Response Rate

Estimand Attribute	Definition		
Treatment	Tafasitamab in combination with LEN administered for up to 12 cycles in total, after which participants can continue with tafasitamab as monotherapy.		
Population	All participants with R/R DLBCL as per eligibility criteria who received at least 1 dose of tafasitamab and 1 dose of LEN		
Variable	ORR		
Intercurrent events	**Event**	**Strategy**	**Rationale (if needed)**
	No postbaseline response assessment or not adequately assessed (eg, NE)	Hypothetical strategy	Participant will be considered as nonresponder
	Treatment discontinuation due to any reason	Treatment policy	All responses will be considered regardless of treatment discontinuation
	Death without postbaseline assessment or not adequately assessed (eg, NE)	Hypothetical strategy	Participant will be considered as nonresponder
	Start of any NALT	While on treatment strategy	Only response prior to the start of any new antilymphoma therapies will be considered
	Study withdrawal due to any reason during the post-treatment disease follow-up	While on treatment strategy	All responses will be considered up to study withdrawal
Population-level summary	Percentage and 95% CI using the Clopper-Pearson method		

7.3.1.2. Summaries

The number and percentage of participants with CR, PR, SD, PD, or NE as the best response will be summarized.

Analysis of ORR will be conducted on the FAS, based on INV assessment according to the IWG treatment response criteria for malignant lymphoma (Cheson et al 2007). The following rules will apply:

- Participants with a best response of NE will be summarized by reason for having a nonevaluable status. The following reasons will be used:
  - No postbaseline assessment available.
  - All postbaseline assessments have overall response NE as indicated by the INV.
  - NALT started before first evaluable postbaseline assessment.
- No formal hypothesis testing will be conducted.

Listings for tumor response assessments will be generated based on the ENR with inclusion in the FAS and PPS noted.

Swimmer plots will be generated showing per participant disease response assessments including disposition events (eg, EOT, AEs, death), best overall response, prior lines of therapy, refractoriness, and NALTs in the same graph.

7.3.1.3. Sensitivity Analysis

The ORR endpoint will be analyzed using the PPS as a sensitivity analysis to the FAS.

7.3.2. Endpoint: Progression-Free Survival

Progression-free survival is defined as the time (in months) from the date of the first administration of any study drug to the date of tumor progression or death from any cause. The date of progression will be the first date for which PD was assessed as the objective response. The analysis will be based on tumor assessments by the INVs according to the IWG treatment response criteria for malignant lymphoma (Cheson et al 2007).

7.3.2.1. Disease Assessments

Disease assessments will be performed with PET-CT, PET-MRI, CT, or MRI scans as per the schedule in Table 3 of the Protocol.

7.3.2.2. Censoring Rules

If a participant is alive and progression-free at the date of the analysis (ie, data cutoff date), the participant will be censored, and the reason for censoring will be provided as per Table 6.

The date of last adequate tumor assessment is the date of the last tumor assessment with an overall response different from NE and not missing before an event or censoring occurred.

Table 6: Censoring Rules for the Progression-Free Survival Estimand

Situation	Date of Progression or Censoring	Outcome	Censoring Reason
Ongoing and no event at data cutoff date	Date of last adequate tumor assessment (ie, not NE and not missing) prior to data cutoff date	Censored	Ongoing
No baseline tumor assessment	Date of Cycle 1 Day 1	Censored	No baseline tumor assessment
No valid postbaseline assessments	Date of Cycle 1 Day 1	Censored	No postbaseline assessments
Progression documented between scheduled response assessments	Date of first response of PD	Progressed	NA
Study withdrawal without documented progression	Date of last adequate tumor assessment (ie, not NE and not missing) prior to data cutoff date	Censored	Study withdrawal
Participant received NALT	Date of last adequate tumor assessment (ie, not NE and not missing) with no documented progression on/before start of NALT	Censored	NALT started

Table 6: Censoring Rules for the Progression-Free Survival Estimand (Continued)

Situation	Date of Progression or Censoring	Outcome	Censoring Reason
Death without prior PD response assessment	Date of death	Progressed	NA
Death between response assessments	Date of death	Progressed	NA
PD with missing assessment date	Date of last adequate tumor assessment (ie, not NE and not missing)	Censored	Date of disease progression missing
Death or progression after 2 or more missed assessments	Date of last tumor assessment with documented nonprogression (ie, CR, PR, or SD)	Censored	Event documented after 2 or more consecutive missed/inadequate tumor assessments

The censoring reasons indicated in Table 6 will be summarized for all time-to-event endpoints. The reason of study withdrawal will be further summarized according to the reasons reported in the "End of Study/Early Follow-Up Discontinuation" eCRF.

7.3.2.3. Identification of 2 or More Consecutive Missing or Inadequate Tumor Assessments

If death or progression occurs after 2 or more consecutive missed or inadequate tumor assessments, then the event will be censored on the date of the last adequate tumor assessment.

In one of the sensitivity analyses for PFS, an event occurring after 2 or more consecutive missed assessments will be back-dated to the date of the next scheduled assessment. The date of the next scheduled assessment is the date of the last adequate tumor assessment plus the Protocol-specified time interval for assessments.

The strategy to identify participants with 2 or more missed tumor response assessments after a valid tumor response assessment and the censoring rule are shown in Table 7

Table 7: Censoring Rule for Events After 2 or More Consecutive Missed or Inadequate Tumor Assessments

Valid Tumor Assessment Occurring Between	Minimum Number of Days From Last Valid Tumor Assessment	Censoring Date
Enrollment until C3D1 – 1 day	114 days	Date of last valid tumor assessment
C3D1 until C5D1 – 1 day	114 days	Date of last valid tumor assessment
C5D1 until C7D1 – 1 day	142 days	Date of last valid tumor assessment
C7D1 until C10D1 – 1 day	171 days	Date of last valid tumor assessment
C10D1 until C12D28 – 1 day	182 days	Date of last valid tumor assessment
Cycle 13 through Cycle 25 – 1 day	182 days	Date of last valid tumor assessment
After Cycle 25	730 days	Date of last valid tumor assessment

7.3.2.4. Main Estimand Analysis

Tumor assessments will be derived according to the IWG treatment response criteria for malignant lymphoma (Cheson et al 2007) by INV assessment. The estimand of PFS, with its 5 attributes and the strategies for addressing the defined intercurrent events, is presented in Table 8.

Table 8: Estimand of Progression-Free Survival

Estimand Attribute	Definition		
Treatment	Tafasitamab in combination with LEN administered for up to 12 cycles in total, after which participants can continue with tafasitamab as monotherapy.		
Population	All participants with R/R DLBCL as per eligibility criteria who received at least 1 dose of tafasitamab and 1 dose of LEN		
Variable	PFS		
Intercurrent events	**Event**	**Strategy**	**Rationale (if needed)**
	No postbaseline response assessment or not adequately assessed (eg, NE)	Hypothetical strategy	Participants will be considered as having no event; early deaths will be considered as events (see Table 6)
	Treatment discontinuation due to any reason	Treatment policy	All assessments will be considered regardless of treatment discontinuation
	Death without adequate assessment	Composite strategy	Participant will be considered as having disease progression unless they have 2 consecutive missed assessments
	Death or progression after 2 or more missed assessments	Hypothetical strategy	Participants will be censored and only responses before missed assessments will be considered
	Start of any NALT	Hypothetical strategy	Only assessments prior to the start of new therapy will be considered
	Study withdrawal due to any reason	While on treatment strategy	All assessments will be considered up to study withdrawal
Population-level summary	Kaplan-Meier estimate and 95% CI. The median PFS time and 95% CIs will be presented (Brookmeyer and Crowley 1982). The 25th and 75th percentiles will be reported.		

The PFS probabilities at specific timepoints (eg, 1, 3, 6, 12, 18, and 24 months) and the associated 95% CIs (Greenwood formula) will be summarized.

All PFS events will be described according to the type of event (death vs PD). The reasons for censoring will be tabulated.

A plot of the Kaplan-Meier curve for PFS will be provided. No formal hypothesis testing will be conducted. Analysis of PFS will be conducted on the FAS.

Listings on PFS events/censoring will be generated based on the FAS.

7.3.2.5. Sensitivity Analysis

The following sensitivity analyses for the PFS endpoint will be performed:

- A PFS event occurring after 2 or more missed assessments will be considered an event and back-dated to the date of the next scheduled assessment.
- The PPS will be used as a sensitivity analysis to the FAS.

7.3.3. Endpoint: Duration of Response

Duration of response is defined as the elapsed time between the date of first documented response (CR or PR) and the date of the first documented progression or death and will be calculated as

DoR (months) = (date of assessment of tumor progression or death – date of assessment of first documented response of CR or PR + 1) / 30.4375.

Only responders (ie, participants with PR or CR) will be considered in the analysis.

7.3.3.1. Censoring Rules

The censoring rules for DoR will be the same as those for PFS (see Table 6).

7.3.3.2. Analysis of Duration of Response

The distribution of DoR will be estimated using the Kaplan-Meier method. The median DoR and 95% CI will be presented as well as the 25th and 75th percentiles. A plot of the Kaplan-Meier curve for DoR will be provided. The DoR probabilities at specific timepoints (eg, 1, 3, 6, 12, 18, and 24 months) and the associated 95% CIs (Greenwood formula) will be summarized. A breakdown of events (death vs PD) and censoring reasons will be presented.

No formal hypothesis testing will be conducted. Analysis of DoR will be conducted on the FAS.

7.3.3.3. Sensitivity Analyses

The DoR endpoint will be analyzed using the PPS as a sensitivity analysis to the FAS.

7.3.3.4. Duration of Response for Participants With a Best Response of Complete Response

The DoR for participants with a best response of CR will be calculated as

DoR (months) = (date of assessment of tumor progression or death – date of assessment of first tumor response of CR + 1) / 30.4375.

The analysis of DoR as described in Section 7.3.3.2 will be performed based on the subset of participants in the FAS with a best response of CR.

7.3.4. Summary Statistics of Progression-Free Survival Follow-Up

Summary information regarding the follow-up of participants will be provided in order to describe the maturity of data and quality of follow-up for the efficacy analyses. The following will be presented for the FAS:

- Duration of follow-up time for PFS (months) = (date of event or censoring for PFS – study start reference date + 1) / 30.4375. Date of event or censoring is the same as defined in Section 7.3.2. This duration of follow-up will be estimated using a reverse Kaplan-Meier method to present the mean, 25th percentile, median, and 75th percentile. This will be reported based on the FAS, for the overall and recommended tafasitamab dose only.

9. PHARMACOKINETICS AND IMMUNOGENICITY

9.1. Analysis of Pharmacokinetics

Pharmacokinetic analyses will be conducted on the PKAS. Individual serum samples for the analysis of tafasitamab PK will be collected on various study days as per the schedule of assessments detailed in Section 2 of the Protocol.

Elapsed time will be calculated as

> elapsed time from the first administration of tafasitamab (days) = date/time of assessment – date/time of the first administration of tafasitamab.

For samples collected 30 minutes after the end of the tafasitamab infusion, results will be excluded from summary statistics if the actual collection time is beyond ± 15 minutes from the scheduled collection time. Such values will be flagged accordingly in the listing of PK data.

In the summary statistics and concentration-time profile graph, the value of BQL will be set to 0 for the Cycle 1 Day 1 predose assessment, to lower limit of quantification / 2 (25 ng/mL) for the first BQL value between 2 tafasitamab administrations or after the last tafasitamab administration, and will be treated as missing data in the assessments of other timepoints.

The tafasitamab serum concentration (µg/mL) data will be summarized and plotted for each treatment group and/or cohort and overall using the PKAS. Detailed analyses will be presented as follows:

- Descriptive statistics of tafasitamab concentrations will be tabulated by visit and timepoint, including n, n-missing, arithmetic mean, geometric mean, STD, CV%, geometric CV%, median, minimum, and maximum.
- Serum concentration-time profiles with the mean ± STD will be plotted across visit and timepoint. This will be performed on both the original serum concentration value and log serum concentration value.
- Listings of PK data will be generated to display the participant identifier, treatment group and/or cohort, visit, date/time of assessment, assessment timepoint, result, elapsed time, flag of collection time deviation, and reason for missing assessment. The concentration data will be presented with a maximum of 3 decimals.

9.2. Immunogenicity Analysis

Serum samples for the assessment of anti-tafasitamab antibodies will be collected as per the schedule of assessments detailed in Section 2 of the Protocol. In order to determine a participant's anti-tafasitamab antibody status, as a first step, a screening assay will be performed. Then, all screened positive samples will be tested again in a confirmatory assay. For all confirmed positive samples, the following additional assays will be performed: a semiquantitative ADA titer will be determined, the specificity toward MOR00208-hIgG1 or MOR00208-hIgG1/2a will be determined, and an nAb will be performed.

Anti-tafasitamab antibody samples will be defined as negative if they are screened or confirmed negative. Anti-tafasitamab antibody samples will be defined as positive if they are positive in

both the screening and the confirmatory assays. For all positive samples, an anti-tafasitamab antibody titer will be determined.

The immunogenicity data will be summarized for each treatment group and/or cohort and overall, using the IAS, as follows:

- Summary of the anti-tafasitamab antibody status; the number and percentage of participants will be tabulated to present the following categories:
  - Participants with pre-existing anti-tafasitamab antibodies (ie, participants who are positive for anti-tafasitamab antibodies on Cycle 1 Day 1).
  - Participants without anti-tafasitamab antibodies after treatment initiation (ie, participants who are negative for anti-tafasitamab antibodies on all occasions after Cycle 1 Day 1, irrespective of the baseline result).
  - Participants with anti-tafasitamab antibodies after treatment initiation (ie, participants who are positive for anti-tafasitamab antibodies on any occasion after Cycle 1 Day 1).
  - Participants with treatment-induced anti-tafasitamab antibodies (ie, participants who are negative for anti-tafasitamab antibodies on Cycle 1 Day 1 and positive on any other occasion).
  - Participants with treatment-boosted anti-tafasitamab antibodies (ie, participants who are positive for anti-tafasitamab antibodies on Cycle 1 Day 1 and who developed an increased titer on any other occasion).
- Summary of anti-tafasitamab antibody response per visit; the following will be tabulated:
  - Total number of participants
  - Number and percentage positive
  - Number and percentage negative
  - Number and percentage missing
- Summary of anti-tafasitamab antibody titer per visit; the following will be tabulated:
  - Number of participants with determined titers
    - Number and percentage of neutralizing anti-tafasitamab antibodies
    - Titers (summary statistics)
  - Number and percentage missing

In addition, listings of the immunogenicity data will be generated to display the participant identifier, treatment group, visit, date/time of assessment, assessment timepoint, type of assay (including specificity and nAb assay), result, and reason for missing assessment.

10. SAFETY AND TOLERABILITY

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

10.1. General Considerations

Summary tables may be replaced with listings when appropriate. For instance, an AE frequency table may be replaced with a listing if it only contains a few unique PTs reported on relatively few participants.

10.2. Adverse Events

10.2.1. Adverse Event Definitions

10.2.1.1. Adverse Event

An AE is defined as any untoward medical occurrence in a participant temporally associated with the use of study treatment, whether or not considered related to the study treatment. Therefore, an AE can be any unfavorable or unintended sign (including an abnormal laboratory finding) or symptom temporally associated with the use of study treatment. As per Protocol, any abnormal safety assessment that qualifies as an AE (eg, laboratory abnormalities, ECG abnormalities) will be documented in the eCRF as an AE. From a programming aspect, no additional derivation of AE entries will be applied.

10.2.1.2. Adverse Event Prior to Study Treatment (Pretreatment Adverse Event)

Any AE that started prior to the date of first administration of study treatment and does not increase in severity after study treatment will be classified as a pretreatment AE.

10.2.1.3. Treatment-Emergent Adverse Event

A TEAE is defined as any AE that starts or worsens after the first dose of study treatment until 90 days after the last dose of the study treatment. An AE that was present prior to study drug administration but increased in severity after treatment start will also be included as a TEAE.

Events with missing onset dates will be included as a TEAE if the end date is not before the first dose of study treatment.

If the start date and time of an AE are partially or completely missing, the AE will be assumed to be a TEAE if it cannot be proven that the AE did not occur or worsen during the treatment period (worst-case approach).

Any missing onset date of a TEAE will be handled according the following rules:

- If completely missing, then Day 1 will be used.
- If only the day is missing, then the first day of the month or Day 1, whichever is later, will be used.
- If both the month and day are missing, then 01 JAN of the year or Day 1, whichever is later, will be used.

10.2.1.4. Adverse Events After the Safety Follow-Up Period

If an AE occurs more than 90 days after the end of treatment, it will be defined as an AE after the safety follow-up period.

10.2.1.5. Predefined Safety Events

The following are predefined safety events according to CTCAE v5 for the safety observation window (35 days from Cycle 1 Day 1):

- Grade 4 or higher nonhematologic AE
- Grade 4 or higher neutropenia (PTs: neutropenia and neutrophil count decreased) lasting > 7 days despite standard of care treatments (eg, G-CSF)
- Grade 4 or higher anemia
- Grade 3 or higher neutropenia (PTs: neutropenia and neutrophil count decreased) with associated fever (> 38.3°C) lasting > 7 days despite standard of care treatments (eg, anti-infectives, G-CSF)
- Grade 3 or higher IRR (as per eCRF)
- Grade 3 or higher TLS (PT: tumour lysis syndrome)
- Grade 3 or higher thrombocytopenia (PTs: platelet count decreased and thrombocytopenia) with clinically significant bleeding
- Grade 2 or higher CRS (PTs: cytokine release syndrome and cytokine storm)

10.2.1.6. Hematological Adverse Events

Hematological AEs will belong to the following 4 categories: neutropenia, febrile neutropenia, anemia, thrombocytopenia. The 4 categories include the following PTs:

- PTs used to identify neutropenia: neutropenia and neutrophil count decreased
- PTs used to identify anemia: anemia and red blood cell count decreased
- PTs used to identify thrombocytopenia: platelet count decreased and thrombocytopenia
- PT used to identify febrile neutropenia: febrile neutropenia

10.2.1.7. Ranking of Safety Outcome

The following order (from best to worst) will be used to rank safety outcomes:

- Recovered/resolved
- Recovered/resolved with sequelae
- Recovering/resolving
- Not recovered/not resolved
- Unknown
- Fatal

10.2.1.8. Ranking of Action Taken With Tafasitamab

The following order (from best to worst) will be used to rank actions taken with tafasitamab:

- Dose not changed
- Drug administration delayed
- Infusion interrupted
- Infusion rate reduced
- Drug skipped
- Drug permanently discontinued

10.2.1.9. Ranking of Action Taken With Lenalidomide

The following order (from best to worst) will be used to rank actions taken with LEN:

- Dose not changed
- Dose reduced
- Drug administration delayed
- Drug skipped
- Drug permanently discontinued

10.2.2. Adverse Events of Special Interest

Information regarding AESIs that occur while on treatment will provided directly from the eCRF. The following are considered AESIs for this study:

- TLS
- IRRs and allergic reactions to study treatment ≥ Grade 3
- CRS
- Second primary malignancies
- Hepatitis B reactivation
- Progressive multifocal leukoencephalopathy
- Tumor flare reaction

10.2.3. Death

Information regarding the death date and reason will be captured in the "Death" eCRF.

Pretreatment death is defined as any death that occurs after the ICF is signed and before the first dose of study treatment.

On-treatment death is defined as any death that occurs after the first dose of study treatment and before the last dose of study treatment/EOT.

Post-treatment death is defined as any death that occurs after the last dose of study treatment/EOT.

10.2.4. Adverse Events Summaries

10.2.4.1. Summary of Treatment-Emergent Adverse Events and Deaths for the Safety Analysis Set and Primary Analysis Set

10.2.4.1.1. General Considerations

The primary safety analysis will be performed for the PAS, and a supplemental safety analysis will be performed for the SAF. The number (%) of participants who had any TEAE will be provided along with the TEAE incidence. Treatment-emergent AEs that occur after the start date of a prohibited concomitant medication will be excluded from the primary and supplemental safety analyses. No TEAE data will be collected after withdrawal of consent.

Treatment-emergent AEs will be classified into the following categories: seriousness, causality (suspected relationship to study treatment), toxicity (determined according to CTCAE v5), intensity, outcome, and action taken.

Specifically, all summaries of treatment-related TEAEs (causality) will be divided into the following 4 sections: related to any component of study treatment, related to tafasitamab only, related to LEN only, and related to both tafasitamab and LEN.

All summaries of TEAEs leading to treatment discontinuation will be divided into the following sections: discontinuation of tafasitamab, discontinuation of LEN, discontinuation of both tafasitamab and LEN.

The incidence of TEAEs will be summarized in incidence tables. If a participant experiences more than 1 occurrence of the same TEAE, the occurrence with the greatest intensity/toxicity, worst outcome, worst action taken, or the closest association with the study treatment will be counted in the summary tables.

10.2.4.1.2. Summaries

For the SAF and PAS, the following summaries will be produced by MedDRA term (if 10 or fewer participants appear in a table, a listing may be appropriate):

- TEAEs by SOC and PT
- TEAEs by SOC, PT, and CTCAE grade category
- Grade 3 or higher TEAEs by SOC and PT
- Grade 3 or higher TEAEs by PT in decreasing order of frequency
- TEAEs by SOC, PT, and highest intensity
- TEAEs by SOC, PT, and maximum severity
- TEAEs by PT in decreasing order of frequency
- Serious TEAEs by SOC and PT
- Serious TEAEs by SOC, PT, and CTCAE grade category

- Grade 3 or higher serious TEAEs by SOC and PT
- Serious TEAEs by PT in decreasing order of frequency
- Treatment-related serious TEAEs by SOC and PT
- TEAEs with a fatal outcome by SOC and PT
- Treatment-emergent AESIs by SOC and PT
- Treatment-emergent AESIs by SOC, PT, and CTCAE grade category
- Grade 3 or higher treatment-emergent AESIs by SOC and PT
- TEAEs leading to tafasitamab infusion interruption by SOC and PT
- TEAEs leading to tafasitamab infusion interruption by SOC, PT, and CTCAE grade category
- TEAEs leading to skipped tafasitamab infusion by SOC and PT
- TEAEs leading to skipped tafasitamab infusion by SOC, PT, and CTCAE grade category
- TEAEs leading to skipped LEN dose by SOC and PT
- TEAEs leading to skipped LEN dose by SOC, PT, and CTCAE grade category
- TEAEs leading to LEN dose reduction by SOC and PT
- TEAEs leading to LEN dose reduction by SOC, PT, and CTCAE grade category
- TEAEs leading to discontinuation of tafasitamab by SOC and PT
- TEAEs leading to discontinuation of LEN by SOC and PT
- Treatment-related TEAEs by SOC and PT
- Treatment-related TEAEs by SOC, PT, and CTCAE grade category
- Treatment-related TEAEs by PT in decreasing order of frequency
- Tafasitamab-related TEAEs by PT in decreasing order of frequency
- LEN-related TEAEs by PT in decreasing order of frequency
- Grade 3 or higher treatment-related TEAEs by SOC and PT
- Tafasitamab-related TEAEs by SOC and PT
- Tafasitamab-related TEAEs by SOC, PT, and CTCAE grade category
- Grade 3 or higher tafasitamab-related TEAEs by SOC and PT
- LEN-related TEAEs by SOC and PT
- LEN-related TEAEs by SOC, PT, and CTCAE grade category
- Grade 3 or higher LEN-related TEAEs by SOC and PT
- Infusion-related TEAEs by SOC and PT

- Infusion-related TEAEs by SOC, PT, and CTCAE grade category
- Grade 3 or higher infusion-related TEAEs by SOC and PT
- TEAEs by SOC, PT, and outcome
- TEAEs by SOC, PT, and action taken with tafasitamab
- TEAEs by SOC, PT, and action taken with LEN

Deaths in the SAF and PAS will be summarized if they occur pretreatment, on treatment, or post-treatment and if due to disease progression or an AE. An overall summary of deaths will be generated for the SAF and PAS. The number (%) of participants with events will be presented.

Figures summarizing the TEAEs (broken down by grade) will be presented for the following:

- All TEAEs by PT
- Hematologic TEAEs by PT
- Nonhematologic TEAEs by PT

Time to onset since Cycle 1 Day 1 of the PTs neutropenia and febrile neutropenia will be summarized.

Time to onset since the first dose of tafasitamab 24 or 30 mg/kg of the PTs neutropenia and febrile neutropenia will be summarized.

10.2.4.2. Summaries of Treatment-Emergent Adverse Events and Deaths for the Enrolled Population Set

10.2.4.2.1. Summaries

For the ENR, an overall summary of AEs by treatment group will include the same information described in Section 10.2.4.1.2.

For the ENR, the following summary tables showing the number (%) of participants will be provided by tafasitamab dose group and overall:

- TEAEs by SOC and PT
- TEAEs by SOC, PT, and CTCAE grade category
- Grade 3 or higher TEAEs by SOC and PT
- Serious TEAEs by SOC and PT
- Serious TEAEs by SOC, PT, and CTCAE grade category
- Grade 3 or higher serious TEAEs by SOC and PT
- TEAEs by SOC, PT, and initial intensity
- Treatment-emergent AESIs by SOC and PT
- Treatment-emergent AESIs by SOC, PT, and CTCAE grade category
- Grade 3 or higher treatment-emergent AESIs by SOC and PT

Deaths in the ENR will be summarized if they occur pretreatment, on treatment or post-treatment and if due to disease progression or an AE. An overall summary of deaths will be generated for the ENR. The number (%) of participants with events will be presented.

10.2.5. Adverse Event and Death Listings

All AEs/TEAEs will be listed by cohort and treatment group and sorted by participant identification number along with the start date (day) and end date (day), duration, if serious, if an AESI, if related to tafasitamab/LEN, toxicity grade (highest), action taken with tafasitamab/LEN, other actions taken, tafasitamab start/end dates, LEN start/end dates, outcome, earliest date participant received prohibited concomitant medication (if applicable), and a flag to evaluate whether predefined safety event criteria are met. Listings will be generated for the ENR, with inclusion in the SAF and PAS noted, for the following:

- All AEs recorded throughout the study to show all information captured in the "Adverse Event" eCRF. The listing will include a flag to evaluate if the AE meets the predefined safety events criteria.
- All infusion-related AEs recorded throughout the study to show all information captured in the "Adverse Event" eCRF.
- All SAEs recorded throughout the study to show all information captured in the "Adverse Event" eCRF, including criteria for SAE met.
- All AESIs recorded throughout the study to show all information captured in the "Adverse Event" eCRF, including criteria for AESI met.
- All AEs with an onset date after the start date of prohibited concomitant medication.

All deaths, with an indicator if death occurred pretreatment, on treatment, or post-treatment, will be listed by cohort and treatment group and sorted by participant identification number along with the date of death (day) and cause of death, tafasitamab start/end dates, LEN start/end dates, and if applicable, earliest date participant received prohibited concomitant medication. The listing will be generated for the ENR, with inclusion in the SAF and PAS noted, and will include all assessments/events and a flag for those that are pre- and post-treatment assessments/events.

10.3. Clinical Laboratory Tests

10.3.1. Laboratory Variables

Laboratory assessments will be performed by local laboratories for the following categories:

- Hematology
- Chemistry
- Coagulation
- Liver biochemistry
- Serology/virology
- Urinalysis
- Pregnancy

10.3.2. Laboratory Value Definitions

Baseline will be determined according to Section 4.1.4. If there are multiple values that meet the criteria for baseline, scheduled assessments will take precedence over unscheduled.

Laboratory test values will be assessed for severity based on the numerical component of NCI CTCAE v5.

For laboratory tests for which grades of severity are not defined by NCI CTCAE, results will be graded by the low/high or normal/abnormal classifications based on laboratory normal ranges.

10.3.3. Laboratory Value Summaries

Results will be presented for the SAF.

All test results and associated normal ranges will be reported in SI units. Any laboratory test results and associated normal ranges from local laboratories will be converted to SI units.

If there are multiple nonmissing laboratory values for a participant's particular test at a scheduled visit, scheduled assessments will take precedence over unscheduled.

Numeric laboratory values will be summarized descriptively in SI units, and non-numeric test values will be tabulated when necessary.

Severity grades will be assigned to laboratory test values based on the numerical component of NCI CTCAE v5. Shift tables will be presented showing change in CTCAE grade from baseline to worst grade postbaseline. Separate summaries for abnormally high and abnormally low laboratory values will be provided when the laboratory parameter has both high and low grading criteria. The denominator for the percentage calculation will be the number of participants in the baseline category. The number of participants who had worsening of laboratory abnormalities will be summarized by maximum severity. Data on absolute neutrophil count, platelets, and hemoglobin will be visually summarized using box plots.

10.4. Vital Signs

10.4.1. Vital Signs Variables

10.4.2. Analysis of Vital Signs

Values at each scheduled visit, change, and percentage change from baseline for vital signs, including systolic blood pressure, diastolic blood pressure, pulse, temperature, respiratory rate, and weight will be summarized descriptively for the SAF.

Normal ranges for vital sign values are defined in Table 9. For participants exhibiting vital sign abnormalities, the abnormal values will be listed along with their assigned treatment group. Alert vital signs are defined as an absolute value outside the defined normal range and percentage change greater than 25%. Note that the definition of alert vital signs does not apply for body temperature and weight. The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 9: Normal Ranges for Vital Sign Values

Parameter	High Threshold	Low Threshold
Systolic blood pressure	≤ 155 mmHg	≥ 85 mmHg
Diastolic blood pressure	≤ 100 mmHg	≥ 40 mmHg
Pulse	≤ 100 bpm	≥ 45 bpm
Temperature	≤ 38°C	≥ 35.5°C
Respiratory rate	≤ 24 breaths/min	≥ 8 breaths/min

10.5. Physical Examination

Full physical examinations will be performed at screening and EOT, while limited physical examinations will be performed per individual status.

Full physical examinations should include vital signs, palpable tumor assessments, general appearance, skin, head, eyes, ears, nose, throat including Waldeyer lymphatic structures, lungs, breasts and axillae, cardiovascular system, back and spine, abdomen (including spleen size below the costal margin if applicable), extremities, infusion site, lymph nodes, and neurological examination.

Limited physical examinations will be guided by the individual participant's status and will include body systems associated with symptoms and/or the underlying DLBCL disease (eg, lymph node status, liver, spleen). Limited physical examinations may be focused on tumor response assessments (eg, lymph node status, liver, spleen) and AEs per INV discretion.

Disease involvement of the spleen/liver may be assessed as part of the full or limited physical examinations throughout the study and recorded data will be presented in a listing.

All physical examination results collected during the study will be listed by participant and body system.

10.6. Electrocardiograms

Twelve-lead ECGs including PR, RR, QT, QRS, QTcB, and QTcF intervals will be obtained for each participant during the study. Values at each scheduled visit, change, and percentage change from baseline will be summarized for each ECG parameter. Baseline will be determined as the latest of all nonmissing values before the first administration of tafasitamab or LEN.

Normal ranges for ECG values are defined in Table 10. Electrocardiogram values will also be considered abnormal if the absolute percentage change from baseline is more than 25% (30% for QRS interval). Participants exhibiting ECG abnormalities will be listed with study visit and assigned treatment group. Abnormal values for participants with alert ECG values, defined as both the absolute value and the percentage change from baseline being outside normal ranges, will be identified and listed. Outliers of QT, QTcB, and QTcF values, defined as absolute values > 450 milliseconds, > 500 milliseconds, or change from baseline > 30 milliseconds, will be summarized.

Table 10: Normal Ranges for Electrocardiogram Intervals

Parameter	High Threshold	Low Threshold
PR	≤ 220 ms	≥ 75 ms
RR	≤ 1330 ms	≥ 600 ms
QT	≤ 500 ms	≥ 300 ms
QRS	≤ 120 ms	≥ 50 ms
QTcB, QTcF	≤ 450 ms	≥ 295 ms
Heart rate	≤ 100 beats/min	≥ 45 beats/min

10.7. Analysis of B Symptoms and ECOG Status

The B symptoms and ECOG status of participants will be evaluated at each visit throughout the study. If any of the systemic symptoms (ie, weight loss, fever, or night sweats) are present, then B symptoms will be defined as present. Otherwise, B symptoms will be considered absent. For ECOG status, data will be categorized from 0 to 5.

Absolute and relative frequencies will be tabulated for B symptoms and ECOG status per visit using the SAF. Detailed information on B symptoms and ECOG status collected from the eCRF will be presented in participant data listings (based on the SAF).

11. COVID-19 PANDEMIC-SPECIFIC ANALYSES

The following summaries will be created for both the primary and final analyses of the SAF.

- Number (%) of participants with positive test of COVID-19 during the treatment period.
- Number (%) of participants with positive test of COVID-19 during the study.
- Number (%) of participants with study treatment interruption/delay/discontinuation because of COVID-19.
- Number (%) of participants whose primary cause of death is COVID-19.
- Number (%) of participants with any TEAE due to COVID-19 by SOC and PT.
- Number (%) of participants with any serious TEAE by SOC and PT

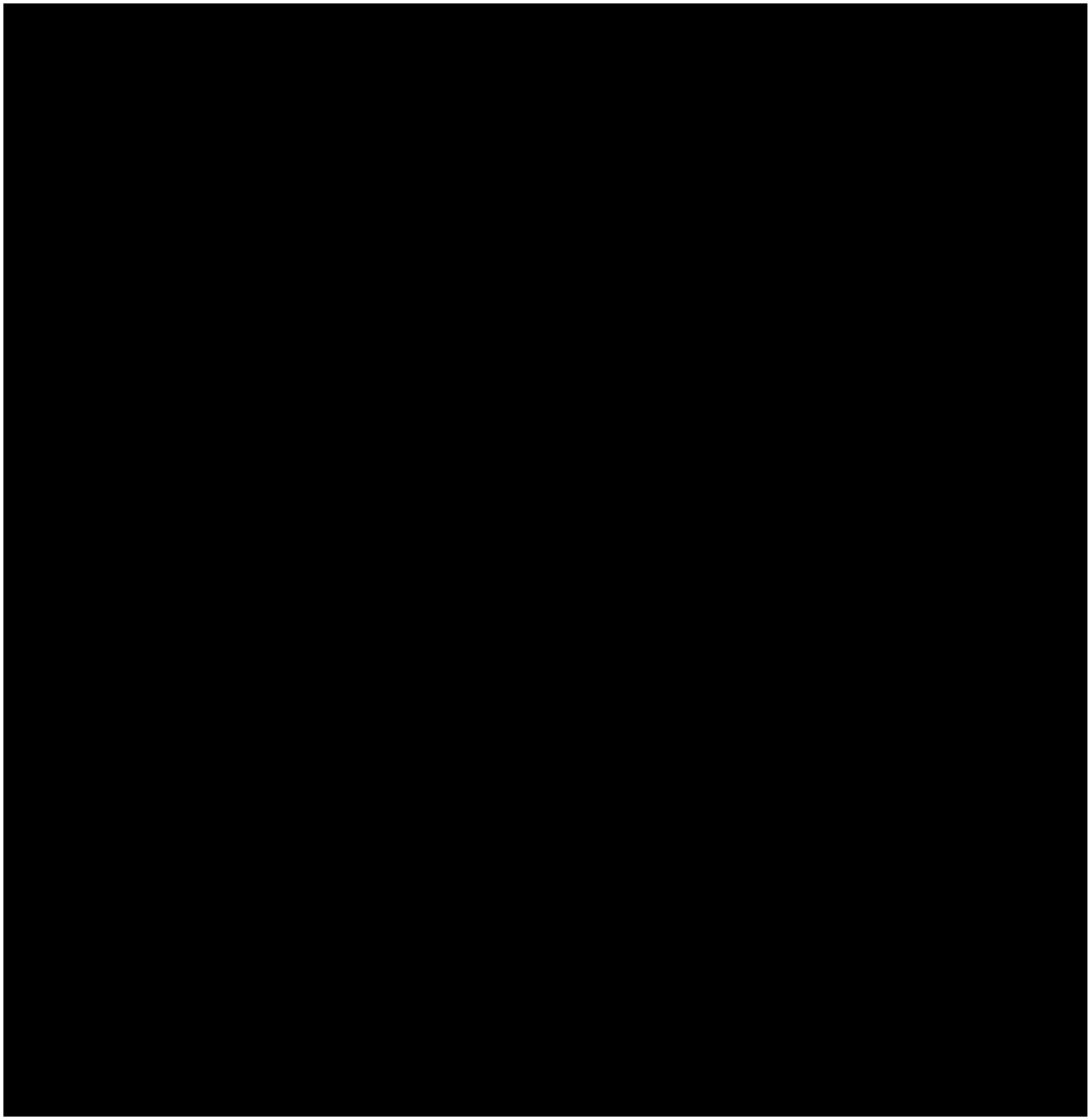
The number (%) of participants with Protocol deviations related to COVID-19 will be summarized for the ENR. Listings of COVID-19 AEs and SAEs will be generated for the ENR.

12. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 11.

Table 11: Statistical Analysis Plan Versions

SAP Version	Date
Original	18 JAN 2022
Amendment 1	24 OCT 2024



13. REFERENCES

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Cheson BD, Pfistner B, Juweid ME, et al. Revised response criteria for malignant lymphoma. J Clin Oncol 2007;25:579-586.

European Medicines Agency. ICH E9 Statistical Principles for Clinical Trials. CPMP/ICH/363/96. 1998.

European Medicines Agency. ICH E9 (R1) Addendum on Estimands and Sensitivity Analysis in Clinical Trials to the Guideline on Statistical Principles for Clinical Trials. EMA/CHMP/ICH/436221/2017. 2020.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report. Shells are provided in a separate document for tables that are not in the Standard Safety Tables v2.0.

The lists of tables, figures, and listings are to be used as guidelines. Modifications of the lists that do not otherwise affect the nature of the analysis will not warrant an amendment to the SAP.

Tables

Table No.	Title	Population	Standard
Baseline and Demographic Characteristics			
1.1.1	Analysis Sets	SPS	X
1.1.1.1	Screening Disposition	SPS	X
1.1.2.1	Summary of Participant Disposition	SPS	X
1.1.2.2	Summary of Participant Disposition by Cycle	ENR	X
1.1.3	Summary of Number of Participants Enrolled by Country and Site	ENR	X
1.1.4.1	Summary of Important Protocol Deviations	ENR	X
1.1.4.2	Summary of Protocol Deviations Related to COVID-19	ENR	X
1.1.5	Summary of Treatment Discontinuation Based on Components of Study Treatment	ENR	
1.1.5.1	Summary of Treatment Discontinuation of Both Tafasitamab and Lenalidomide Before Completing 12 Cycles	ENR	
1.1.5.2	Summary of Participants Who Discontinued Tafasitamab at Cycle 13 or Later	ENR	
1.1.6.x	Summary of Statistics of Enrollment	FAS (.1), SAF (.2)	
1.2.x	Summary of Demographics and Baseline Characteristics	ENR (.1), PAS (.2), SAF (.3), FAS (.4)	X
1.3.1.x	Summary of Baseline Disease Characteristics	PAS (.1), FAS (.2)	X
1.3.2.x	Summary of Bone Marrow Involvement at Screening	PAS (.1), FAS (.2)	
1.4.1.x	Summary of Preinfusion Medications for Tafasitamab	PAS (.1), FAS (.2)	X
1.4.2.x	Summary of Non-Antilymphoma Prior Medications	PAS (.1), FAS (.2)	X
1.4.3.x	Summary of Non-Antilymphoma Concomitant Medications	PAS (.1), FAS (.2)	X
1.4.4.x	Summary of Non-Antilymphoma Prior Nondrug Therapies	PAS (.1), FAS (.2)	
1.4.5.x	Summary of Non-Antilymphoma Concomitant Nondrug Therapies	PAS (.1), FAS (.2)	
1.4.6.x	Summary of Prior Lines of Antilymphoma Treatment	PAS (.1), FAS (.2)	
1.4.7.x	Summary of Nonstudy Antilymphoma Treatment	PAS (.1), FAS (.2)	
1.4.8	Summary of Nonstudy Antilymphoma Treatments: Drug Treatments	PAS	X
1.5.x	Summary of General Medical History and Current Medical Conditions	PAS (.1), FAS (.2)	X
Efficacy			
2.1	Summary of Objective Response Rate by Investigator Assessment	FAS	
2.1.2	Sensitivity Analysis for Summary of Objective Response Rate by Investigator Assessment	PPS	
2.2.1	Summary of Progression-Free Survival by Investigator Assessment	FAS	

Table No.	Title	Population	Standard
2.2.1.1	Sensitivity Analysis for Summary of Progression-Free Survival by Investigator Assessment	PPS	
2.2.1.2	Sensitivity Analysis for Summary of Progression-Free Survival by Investigator Assessment - Change in Censoring	FAS	
2.2.2	Summary of Progression-Free Survival Follow-Up Time	FAS	
2.3	Summary of Duration of Response by Investigator Assessment	FAS	
2.3.1	Sensitivity Analysis for Summary of Duration of Response by Investigator Assessment	PPS	
2.3.2	Sensitivity Analysis for Summary of Duration of Response by Investigator Assessment - Change in Response Requirement	FAS	
Safety			
3.1.1.1	Summary of Exposure to Components of Study Treatment	ENR	
3.1.1.2.x	Summary of Exposure and Duration of Exposure to Tafasitamab	SAF (.1), PAS (.2), FAS (.3)	X
3.1.1.3.x	Summary of Exposure and Duration of Exposure to Lenalidomide	SAF (.1), PAS (.2), FAS (.3)	X
3.1.1.4.x	Summary of Exposure and Duration of Exposure to Study Treatment (Tafasitamab and Lenalidomide)	SAF (.1), PAS (.2), FAS (.3)	X
3.1.1.5.x	Summary of Exposure and Duration of Exposure to Study Drug (Tafasitamab or Lenalidomide)	SAF (.1), PAS (.2), FAS (.3)	X
3.1.1.6.x	Summary of Over-Infusion Rate of Tafasitamab	SAF (.1), PAS (.2), FAS (.3)	
[redacted]			
3.1.2.1.x	Summary of Dose Interruption of Tafasitamab	SAF (.1), PAS (.2), FAS (.3)	
3.1.2.2.x	Summary of Dose Reduction of Lenalidomide	SAF (.1), PAS (.2), FAS (.3)	
3.1.2.3.1.x	Summary of Skipped Doses of Tafasitamab	SAF (.1), PAS (.2), FAS (.3)	
3.1.2.3.2.x	Summary of Skipped Doses of Lenalidomide	SAF (.1), PAS (.2), FAS (.3)	
3.1.2.4	Summary of Study Treatment Interruption/Delay/Discontinuation Because of COVID-19	SAF	
3.1.3.1.x	Summary of Tafasitamab Compliance	SAF (.1), PAS (.2), FAS (.3)	X
3.1.3.2.x	Summary of Lenalidomide Compliance	SAF (.1), PAS (.2), FAS (.3)	X
3.2.1.x	Overall Summary of Treatment-Emergent Adverse Events	SAF (.1), PAS (.2), ENR (.3)	X
3.2.2.1.x	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2), ENR (.3)	X
3.2.2.2	Summary of COVID-19 Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF	X
3.2.3.x	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	SAF (.1), PAS (.2)	X
3.2.4.x	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	SAF (.1), PAS (.2)	X

Table No.	Title	Population	Standard
3.2.5.x	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2), ENR (.3)	X
3.2.6.x	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2), ENR (.3)	X
3.2.7.x	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	SAF (.1), PAS (.2)	X
3.2.8.1.x	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2), ENR (.3)	X
3.2.8.2.x	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2), ENR (.3)	X
3.2.8.3	Summary of COVID-19 Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF	X
3.2.8.4.x	Summary of Grade 3 or Higher Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2), ENR (.3)	X
3.2.9.x	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	SAF (.1), PAS (.2)	X
3.2.10.1.x	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.10.2.x	Summary of Tafasitamab-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.10.3.x	Summary of Lenalidomide-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.11.1.x	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	SAF (.1), PAS (.2)	X
3.2.11.2.x	Summary of Tafasitamab-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	SAF (.1), PAS (.2)	X
3.2.11.3.x	Summary of Lenalidomide-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	SAF (.1), PAS (.2)	X
3.2.13.1.x	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2)	X
3.2.13.2.x	Summary of Tafasitamab-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2)	X
3.2.13.3.x	Summary of Lenalidomide-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2)	X
3.2.14.1.x	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.14.2.x	Summary of Grade 3 or Higher Tafasitamab-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X

Table No.	Title	Population	Standard
3.2.14.2.x	Summary of Grade 3 or Higher Lenalidomide-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.15.x	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.16	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.19.1.1.x	Summary of Treatment-Emergent Adverse Events Leading to Tafasitamab Infusion Interruption by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.19.1.2.x	Summary of Treatment-Emergent Adverse Events Leading to Tafasitamab Infusion Interruption by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2)	X
3.2.19.1.3.x	Summary of Treatment-Emergent Adverse Events Leading to Skipped Tafasitamab Infusion by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.19.1.4.x	Summary of Treatment-Emergent Adverse Events Leading to Skipped Tafasitamab Infusion by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2)	X
3.2.19.2.1.x	Summary of Treatment-Emergent Adverse Events Leading to Skipped Lenalidomide Dose by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.19.2.2.x	Summary of Treatment-Emergent Adverse Events Leading to Skipped Lenalidomide Dose by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2)	X
3.2.19.2.3.x	Summary of Treatment-Emergent Adverse Events Leading to Lenalidomide Dose Reduction by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.19.2.4.x	Summary of Treatment-Emergent Adverse Events Leading to Lenalidomide Dose Reduction by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2)	X
3.2.20.1.x	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Tafasitamab by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.20.2.x	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Lenalidomide by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.24.1.x	Summary of Deaths	SAF (.1), PAS (.2), ENR (.3)	X
3.2.24.2	Summary of Deaths Caused by COVID-19	ENR	X
3.2.25.x	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Highest Intensity	SAF (.1), PAS (.2), ENR (.3)	X
3.2.26.x	Summary of Infusion-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.27.x	Summary of Infusion-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2)	X

Table No.	Title	Population	Standard
3.2.28.x	Summary of Grade 3 or Higher Infusion-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2)	X
3.2.29.x	Summary of Treatment-Emergent Adverse Events of Special Interest by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2), ENR (.3)	X
3.2.30.x	Summary of Treatment-Emergent Adverse Events of Special Interest by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category	SAF (.1), PAS (.2), ENR (.3)	X
3.2.31.x	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events of Special Interest by MedDRA System Organ Class and Preferred Term	SAF (.1), PAS (.2), ENR (.3)	X
3.2.32.x	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Outcome	SAF (.1), PAS (.2)	
3.2.33.x	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Action Taken With Tafasitamab	SAF (.1), PAS (.2)	
3.2.34.x	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Action Taken With Lenalidomide	SAF (.1), PAS (.2)	X
3.2.35.1.x	Summary of Time to Onset of Neutropenia Since Cycle 1 Day 1	SAF (.1), PAS (.2)	
3.2.35.2.x	Summary of Time to Onset of Febrile Neutropenia Since Cycle 1 Day 1	SAF (.1), PAS (.2)	
3.2.36.1.x	Summary of Time to Onset of Neutropenia Since First Dose of Tafasitamab	SAF (.1), PAS (.2)	
3.2.36.2.x	Summary of Time to Onset of Febrile Neutropenia Since First Dose of Tafasitamab	SAF (.1), PAS (.2)	
3.3.1.1	Summary of Laboratory Values - Hematology	SAF	X
3.3.1.2	Summary of Laboratory Values - Chemistry	SAF	X
3.3.1.3	Summary of Laboratory Values - Coagulation	SAF	X
3.3.1.4	Summary of Laboratory Values - Liver Biochemistry	SAF	X
[redacted]			
3.3.2.1	Shift Summary of Hematology Values - to the Worst Abnormal Value	SAF	X
3.3.2.2	Shift Summary of Chemistry Values - to the Worst Abnormal Value	SAF	X
3.3.2.3	Shift Summary of Coagulation Values - to the Worst Abnormal Value	SAF	X
3.3.2.4	Shift Summary of Liver Biochemistry Values - to the Worst Abnormal Value	SAF	X
3.3.3.1	Shift Summary of Hematology Laboratory Values in CTCAE Grade - to the Worst Abnormal Value	SAF	X
3.3.3.2	Shift Summary of Chemistry Laboratory Values in CTCAE Grade - to the Worst Abnormal Value	SAF	X
3.3.3.3	Shift Summary of Coagulation Laboratory Values in CTCAE Grade - to the Worst Abnormal Value	SAF	X
3.3.3.4	Shift Summary of Liver Biochemistry Laboratory Values in CTCAE Grade - to the Worst Abnormal Value	SAF	X
3.3.4.1	Treatment-Emergent Worsening of Laboratory Abnormalities - Hematology	SAF	X

Table No.	Title	Population	Standard
3.3.4.2	Treatment-Emergent Worsening of Laboratory Abnormalities - Chemistry	SAF	X
3.3.4.3	Treatment-Emergent Worsening of Laboratory Abnormalities - Coagulation	SAF	X
3.3.4.4	Treatment-Emergent Worsening of Laboratory Abnormalities - Liver Biochemistry	SAF	X
3.4.1	Summary of Systolic Blood Pressure	SAF	X
3.4.2	Summary of Diastolic Blood Pressure	SAF	X
3.4.3	Summary of Pulse	SAF	X
3.4.4	Summary of Respiratory Rate	SAF	X
3.4.5	Summary of Body Temperature	SAF	X
3.4.6	Summary of Body Weight	SAF	X
3.5.1	Summary of PR Interval (ms) From 12-Lead ECG	SAF	X
3.5.2	Summary of QRS Interval (ms) From 12-Lead ECG	SAF	X
3.5.3	Summary of QT Interval (ms) From 12-Lead ECG	SAF	X
3.5.4	Summary of QTcB Interval (ms) From 12-Lead ECG	SAF	X
3.5.5	Summary of QTcF Interval (ms) From 12-Lead ECG	SAF	X
3.5.6	Summary of RR Interval (ms) From 12-Lead ECG	SAF	X
3.5.7	Summary of Heart Rate (beats/min) From 12-Lead ECG	SAF	X
3.5.8	Summary of Outliers of QT, QTcB, and QTcF Interval Values (ms) From 12-Lead ECG	SAF	X
3.6.1	Summary of ECOG Status by Visit	SAF	
3.6.2	Summary of B Symptoms by Visit	SAF	
3.2.7.1	Summary of Positive COVID-19 Test During Study Treatment	SAF	
3.2.7.2	Summary of Positive COVID-19 Test (Any Time)	SAF	

Note: Tables ending with ".x" will use the number indicated in the population.

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4.4.1.2	Swimmer Plot of Disease Response Assessments for Participants in the PPS
4.4.2	Kaplan-Meier Estimates of Progression-Free Survival
4.5.1.1	Participants in the SAF With Treatment-Emergent Adverse Events by MedDRA Preferred Term and CTCAE Grade Category
4.5.1.2	Participants in the PAS With Treatment-Emergent Adverse Events by MedDRA Preferred Term and CTCAE Grade Category
4.5.2.1	Participants in the SAF With Hematologic Treatment-Emergent Adverse Events by MedDRA Preferred Term, and CTCAE Grade Category
4.5.2.2	Participants in the PAS With Hematologic Treatment-Emergent Adverse Events by MedDRA Preferred Term and CTCAE Grade Category
4.5.3.1	Participants in the SAF With Nonhematologic Treatment-Emergent Adverse Events by MedDRA Preferred Term and CTCAE Grade Category
4.5.3.2	Participants in the PAS With Nonhematologic Treatment-Emergent Adverse Events by MedDRA Preferred Term and CTCAE Grade Category
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6.3.3.1	Box Plot of Hemoglobin

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2.4.2	Baseline Disease Characteristics
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2.4.6	Prior Antilymphoma Drug Treatment
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2.4.8	Prior Antilymphoma Surgeries/Procedures
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2.4.11	Nonstudy Antilymphoma Treatment - Surgeries/Procedures
2.4.12	Bone Marrow Involvement at Screening
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2.6.2	Overall Response Assessment by Visit per Investigator
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2.8.1.1.1	Abnormal Laboratory Values - Hematology
2.8.1.2	Clinical Laboratory Values - Chemistry
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2.8.1.3	Clinical Laboratory Values - Coagulation
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2.8.1.4	Clinical Laboratory Values - Liver Biochemistry
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Listing No.	Title
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