STATISTICAL ANALYSIS PLAN

VERSION 1.0

CLINICAL STUDY PROCOTOL: CP-MGA271-06

ORIGINAL PROTOCOL (01 OCTOBER 2020)

A Phase 2 Open-Label Trial to Evaluate Enoblituzumab in Combination with Retifanlimab or Tebotelimab in the First-Line Treatment of Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

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LIST OF ABBREVIATIONS

ADA	Anti-drug antibodies
ADaM	Analysis Data Model
AE	Adverse event
AESI	Adverse event of special interest
B7-H3	B 7 homolog 3
BOR	Best overall response
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
C_{max}	Maximum concentration
CPS	Combined positive score
CR	Complete response
CRF	Case report form
CSR	Clinical Study Report
NCI-CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
C_{trough}	Trough concentration
DCR	Disease control rate
DoR	Duration of response
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
HPV	Human papilloma virus
ICF	Informed consent form
IHC	Immunohistochemistry
MedDRA	Medical dictionary for regulatory activities
NE	Not evaluable
ORR	Objective response rate
OS	Overall survival
PD	Progressive disease
PD-L1	Programmed death ligand 1

PFS	Progression-free survival
PK	Pharmacokinetics
PPK	Population PK
PR	Partial response
Q3W	Every 3 weeks
QTcF	QT interval corrected by Fridericia method
RECIST v1.1	Response Evaluation Criteria in Solid Tumours version 1.1
SAE	Serious adverse event
SAP	Statistical analysis plan
SCCHN	Squamous cell carcinoma of the head and neck
SPP	Statistical programming plan
SD	Stable disease
SDTM	Study Data Tabulation Model
SOC	System organ class
TEAE	Treatment-emergent adverse event

1 INTRODUCTION

This statistical analysis plan (SAP) provides a detailed and comprehensive description for the analysis of the study CP-MGA271-06 entitled "A Phase 2 Open-Label Trial to Evaluate Enoblituzumab in Combination with Retifanlimab or Tebotelimab in the First-Line Treatment of Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)". This SAP Version 1.0 applies to the original protocol of this study and describes in detail the statistical methods to be used for analysis of the primary and secondary efficacy endpoints, the safety endpoints, the pharmacokinetics (PK) and pharmacodynamics parameters to be collected from this study.

2 STUDY OBJECTIVES

2.1 Primary Objectives

Retifanlimab Cohort

- To assess the efficacy of the combination of enoblituzumab + retifanlimab, based primarily upon evaluation of Investigator-assessed objective response rate (ORR) in the response evaluable patient population, in patients with recurrent or metastatic SCCHN not curable by local therapy, with no prior systemic therapy for SCCHN in the recurrent or metastatic setting (with the exception of systemic therapy completed > 6 months prior if given as part of multimodal treatment for locally advanced disease).

Tebotelimab Cohort

- To assess the safety, tolerability, and preliminary efficacy of the combination of enoblituzumab + tebotelimab, based primarily upon evaluation of Investigator-assessed ORR in the response evaluable patient population, in patients with recurrent or metastatic SCCHN not curable by local therapy, with no prior systemic therapy for SCCHN in the recurrent or metastatic setting (with the exception of systemic therapy completed > 6 months prior if given as part of multimodal treatment for locally advanced disease).

2.2 Secondary Objectives

Retifanlimab Cohort

- To evaluate the Investigator-assessed progression-free survival (PFS), disease control rate (DCR), duration of response (DoR), and overall survival (OS).
- To evaluate safety and tolerability.
- To assess the PK of enoblituzumab + retifanlimab.
- To evaluate the immunogenicity of enoblituzumab + retifanlimab.

Tebotelimab Cohort

- To evaluate the Investigator-assessed PFS, DCR, DoR, and OS.
- To assess the PK of enoblituzumab + tebotelimab.
- To evaluate the immunogenicity of enoblituzumab + tebotelimab.

2.3 Exploratory Objectives

Retifanlimab and Tebotelimab Cohorts

- To explore the relationships between PK, pharmacodynamics, patient safety, and antitumor activity.
- To explore population PK (PPK) and exposure-response analyses.
- To explore the relationships between PD-1, PD-L1, B7-H3, and LAG-3 expression on tumor cells and response.
- To investigate the immune-regulatory activity in vivo, including various measures of T-cell and NK-cell activation/exhaustion in peripheral blood and/or tumor biopsy specimens.
- To assess circulating immune cells and effect of treatment.
- To evaluate peripheral biomarkers and correlate with potential clinical response.
- To explore gene expression profiles and Fc receptor polymorphism in PBMCs and/or pre-treatment tumor biopsies and correlate with clinical response (when applicable).

The results of the exploratory objectives may not be included in the Clinical Study Report or database lock unless they represent meaningful findings.

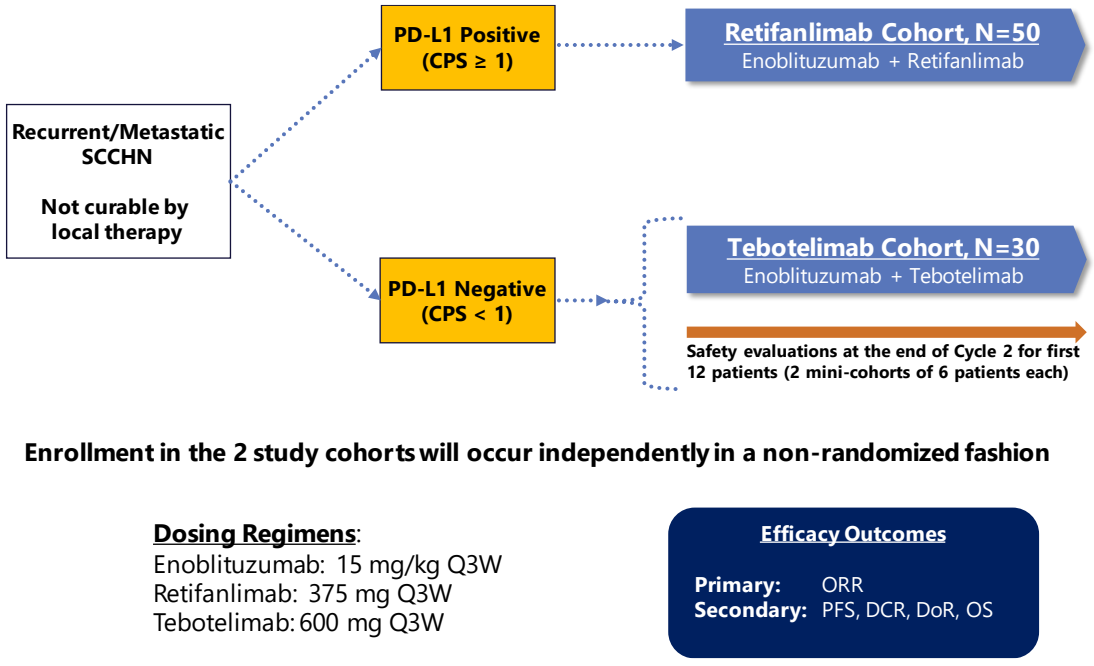
3 STUDY DESIGN AND PLAN

3.1 Overall Study Design and Plan

This is a Phase 2, open label, non-randomized study in the first-line treatment of patients with recurrent or metastatic SCCHN not curable by local therapy, with no prior systemic therapy for SCCHN in the recurrent or metastatic setting (with the exception of systemic therapy completed > 6 months prior if given as part of multimodal treatment for locally advanced disease).

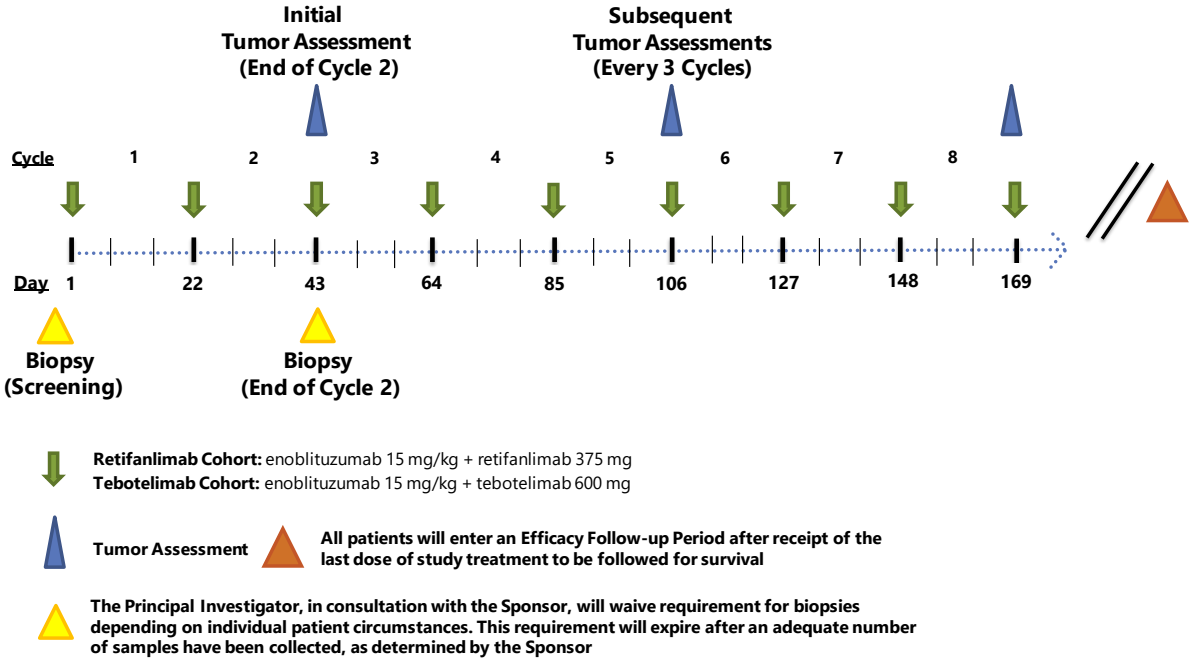
Approximately 80 patients will be enrolled in 2 cohorts, as shown in **Figure 1**, to receive enoblituzumab in combination with either retifanlimab (Retifanlimab Cohort, PD-L1 positive [CPS ≥ 1] patients, N=50) or tebotelimab (Tebotelimab Cohort, PD-L1 negative [CPS < 1] patients, N=30). Enrollment into each cohort will occur in a non-randomized fashion. Patients may not crossover between cohorts. PD-L1 expression will be prospectively collected and prospectively analyzed. B7-H3 and LAG-3 expression will be prospectively collected and retrospectively analyzed.

Figure 1 Study Schema



Patients will receive the assigned study drugs (enoblituzumab 15 mg/kg and either retifanlimab 375 mg or tebotelimab 600 mg) on a every 3 weeks (Q3W) basis, in cycles of 3 weeks duration (see **Figure 2**). The initial tumor assessment will occur at the end of Cycle 2 (i.e., after approximately 6 weeks), and at the end of every 3 cycles thereafter (i.e., approximately every 9 weeks). After receipt of the last dose of study treatment, patients will enter an Efficacy Follow-up Period and will be followed for survival.

Figure 2 Treatment Cycles



An independent Data Safety Monitor (DSM), the Sponsor, and Investigators will maintain regular oversight of patient safety throughout the trial. In the Tebotelimab Cohort, toxicity will be evaluated by monitoring the occurrence and severity of DLTs in the first 12 patients (2 mini-cohorts of 6 patients each) through Cycle 2 Day 7.

The data for each of the Retifanlimab and Tebotelimab Cohorts will be analyzed upon completion of enrollment of each cohort, and after all patients in the applicable cohort have at least one tumor assessment, to inform whether to proceed with the study and to determine any modifications to the trial design.

3.2 Sample Size

The total sample size is planned to be approximately 80 patients, with approximately 50 and approximately 30 patients in the Retifanlimab and Tebotelimab Cohorts, respectively.

Enrollment into the Retifanlimab and Tebotelimab Cohorts will occur independently in a non-randomized fashion.

The sample size for each cohort is primarily based on providing preliminary estimation of ORR. **Table 1** provides 2-sided 95% confidence intervals (CI) for a number of potential responses.

Table 1 Response Rates and 95% Confidence Intervals

Sample Size	Number of Responses	Response Rate (%)	95% Confidence Interval (%)
30	2	6.7	0.8 – 22.1
30	3	10.0	2.1 – 26.5
30	4	13.3	3.8 – 30.7
50	10	20.0	10.0 – 33.7
50	14	28.0	16.2 – 42.5
50	16	32.0	19.5 – 46.7

ORRs of 19% and 5% were observed in first-line SCCHN patients with CPS ≥ 1 and CPS < 1, respectively, in pembrolizumab monotherapy. In the Retifanlimab Cohort, based on an exact binomial test, 50 patients will distinguish a favorable true ORR of 36% from an unfavorable rate of 19% with 91% power and a 1-sided type 1 error rate of 0.079. Thus, at least 14 responses out of 50 patients are to be achieved. In the Tebotelimab Cohort, 3 responses out of 30 patients will have 80% confidence that the true ORR is > 5% (the lower limit of 1-sided 80% CI for the response rate is > 5%).

4 ANALYSIS POPULATIONS

The study analyses will be performed on the following populations:

- **Safety Population:** All patients who received at least one dose of any study drug. This population will be used for analyses of safety, PK, pharmacodynamics, and immunogenicity. It will also be used for summary of baseline data and analyses of PFS and OS.
- **Response Evaluable Population:** All patients who received at least one dose of any study drug and had baseline radiographic tumor assessment. This population will be used for summary of tumor assessment data and analyses of responses.

5 ENDPOINTS

5.1 Efficacy Endpoints

5.1.1 Primary Efficacy Endpoints

The primary efficacy endpoint is the Investigator-assessed ORR per Response Evaluation Criteria in Solid Tumours version 1.1 (RECIST v1.1), defined as the proportion of patients in the response evaluable population who achieve the best overall response (BOR) of complete response (CR) or partial response (PR) (called responders) per RECIST v1.1. The BOR will be categorized as CR, PR, stable disease (SD), progressive disease (PD), or not evaluable (NE). To be qualified as an objective response, CR and PR require confirmation at least 4 weeks after initial observation of such response, and SD requires an observation at least once after 6 weeks. BOR will be evaluated from the start of study treatment.

5.1.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints are:

- PFS assessed by Investigator, defined as the time from the first dose date to the date of first documented progression or death from any cause, whichever occurs first. The documented progression is determined by objective assessment of disease per RECIST v1.1. For patients who are not known to be dead or progressed at time of data cut-off for PFS analysis, the PFS will be censored at the date of the last tumor assessment. Specifically, the following censoring rules will be applied (**Table 2**).
    - PFS (months) = (date of event [documented progression or death] or date of censoring – date of first dose + 1) / (365.25/12)

Table 2 Censoring Rules for PFS Analysis

Situation	Date	Outcome
No baseline tumor assessments	First dose date	Censored
Death prior to first scheduled tumor assessment	Date of death	Progressed
No post-baseline tumor assessments in absence of death prior to first scheduled tumor assessment	First dose date	Censored
Documented progression	Date of progression	Progressed
Initiation of alternative anti-cancer treatments in absence of documented progression	Date of last tumor assessment prior to initiation of such treatment	Censored
Death or documented progression immediately after missing 2 or more consecutive scheduled tumor assessments	Date of last tumor assessment prior to missed assessments	Censored

- DoR, defined as the time from the date of initial response (CR or PR) to the date of first documented progression per RECIST v1.1 or death from any cause, whichever occurs first. The DoR is calculated only for the responders. For responders who are not known to be dead or progressed at the time of data cut-off for DoR analysis, the DoR will be censored at the date of the last tumor assessment. Specifically, the last 3 situations described in **Table 2** will be applied. The DoR analyses will be performed only if there are enough responders to render the analyses meaningful.
    - DoR (months) = (date of event [documented progression or death] or date of censoring – date of initial response + 1) / (365.25/12)
- DCR, defined as the percentage of response evaluable patients who experienced response of CR, PR, or SD for at least 3 months.
- OS, defined as the time from the first dose date to the date of death from any cause. For patients who are not known to be dead at the time of data cut-off for OS analysis, the OS will be censored at the time they are last known to be alive.
    - OS (months) = (date of death or date of censoring – date of first dose + 1) / (365.25/12)

5.1.3 Other Efficacy Endpoints

Tumor size change over time will be calculated. The tumor size is defined as the sum of diameters of the target lesions.

5.2 Safety Endpoints

5.2.1 Adverse Events

Safety will primarily be addressed by evaluations of the adverse events (AEs). AE is defined as any untoward medical occurrence in a patient or clinical trial patient associated with use of a drug in humans, whether or not considered drug related. An AE can be

- any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.
- any occurrence that is new in onset or aggravated in severity or frequency from baseline condition, or abnormal results of diagnostic procedures, including laboratory test abnormalities.

All AEs whether serious or non-serious, will be reported from the time a signed and dated informed consent form (ICF) is obtained until 30 days following the last dose of study drug or until the start of a subsequent systemic anti-cancer therapy, if earlier. AEs will be coded using the latest version of Medical Dictionary for Regulatory Activities (MedDRA). An assessment of severity grade will be made using NCI-CTCAE v5.0.

Both protocol-related AEs and serious adverse events (SAEs) will be collected from the time the patient has consented to study participation. AEs and SAEs reported between the time the patient signs the ICF and the administration of the first dose of study drug will be captured as concurrent medical history unless the events are attributed to protocol-specified procedures. Events attributed to protocol-specified procedures will be collected on the Adverse Event eCRFs and SAE Report form as appropriate.

Only treatment emergent adverse events (TEAEs) will be summarized as safety endpoints. A TEAE is defined as any event that is newly occurring on or after the administration of study drug or an event that existed before but increased in severity on or after study drug administration.

5.2.2 Laboratory Evaluations

Central laboratory testing should be used to determine patient eligibility and assess overall safety in the study, unless the Medical Monitor approves the use of a local laboratory in place of an unanalyzable central laboratory sample. Local laboratories will be used for clinical decision making. A laboratory abnormality is reported as an AE if any criterion for an SAE is fulfilled, or the event is associated with an intervention including, but not limited to, discontinuation or interruption of treatment, dose reduction/delay, or required initiation of concomitant therapy. Also, any laboratory abnormality may be reported as an AE at the Investigator's discretion, based on clinical significance.

5.2.3 Other Safety Endpoints

Physical examination will be performed (including weight and height) for all patients according to the schedules outlined in the protocol.

Vital signs (include temperature, pulse, blood pressure, and respiratory rate) and Eastern Cooperative Oncology Group (ECOG) performance status will be performed according to the schedules outlined in the protocol.

Twelve-lead electrocardiograms (ECGs) will be obtained according to the protocol to evaluate the potential cardiac effect. Screening and Cycle 1 Day 1 ECGs are performed in triplicate. Subsequent ECGs are obtained as clinically indicated. ECG baseline is defined as the average of the last assessment with replicates taken before first dose of study treatment.

5.3 Pharmacokinetic, Pharmacodynamic, and Immunogenicity Parameter Endpoints

PK samples, immunogenicity (ADA) samples and pharmacodynamic biomarker specimens will be collected according to the schedules outlined in the protocol.

Prospective PD-L1 testing will be performed for all patients. PD-L1 protein expression is determined by using CPS, which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS $\geq$ 1. PD-L1 expression will be assessed based on immunohistochemistry (IHC) staining using the FDA-approved 22C3 pharmDx assay.

IHC to assess B7-H3 expression will be performed in all patients. PD-1/LAG-3 testing will be performed by PD-1 and LAG-3 dual IHC staining. These biomarker assessments will be prospectively collected and retrospectively analyzed.

Local laboratory results are acceptable for evaluation of human papilloma virus (HPV) p16 status.

6 STATISTICAL METHODOLOGY

6.1 General Considerations

Safety and efficacy summaries will be provided for each cohort.

Unless otherwise noted, the baseline value is defined as the most recent value collected prior to the date and time of the first dose of study treatment. Study Day 1 is defined as the first day of study drug administration.

Categorical data will be summarized by the number and percent of patients falling within each category. Continuous variables will be summarized by descriptive statistics, including mean, standard deviation, median, minimum, and maximum.

Time to event endpoints will be summarized by the number and percent of the event, median time and corresponding 95% confidence interval (CI), and event free rate and corresponding 95% CI at the specified time points of interest.

All data summaries and tabulations will be conducted using SAS® software Version 9.4 or higher.

6.2 Missing Data

Data that are reported as missing will be treated as missing in all data summaries. Imputation rules for partially recorded dates, where complete dates are required to carry out an analysis, will be provided in the Statistical Programming Plan (SPP). In descriptive summaries for safety, observations that are spurious (extreme relative to the majority of the data) will not be altered or removed from the summary.

6.3 Patient Disposition and Baseline Characteristics

6.3.1 Patient Disposition

For patient disposition, the number and percentage of patients who reach various study milestones are summarized. All screened patients are broken down by screen failures (with reasons if collected) and enrolled. Then the category of enrolled is broken down by never treated (with reasons if collected) and treated. The category of treated will further be broken down by treatment ongoing and treatment discontinuation (with reasons for discontinuation, which also include protocol-defined treatment completion, if any). The end of study status for all enrolled patients will also be included.

6.3.2 Patient Demographics and Baseline Characteristics

Patient demographics, baseline characteristics, disease history, medical history, prior cancer therapy, and other collected baseline data will be summarized using descriptive statistics.

6.4 Study Drug Exposure and Concomitant Medications

Study drug exposure and concomitant medications will be summarized by descriptive statistics. The summary of study drug exposure will include descriptive statistics as well as frequency counts for the number of doses or cycles received, the total dose actually administered as well as the total dose intended, and the dose intensity which is calculated as percentage of total dose actually administered divided by total dose intended during whole treatment period.

Duration of study treatment (months) will be calculated as:

- (date decided to discontinue treatment – date of first dose + 1)/(365.25/12) for patients who have discontinued treatment.
- (date of data cutoff – date of first dose + 1)/(365.25/12) for patients whose treatment is ongoing.

The summary of concomitant medications will include the number and percentage of patients who receive any concomitant medications as well as each concomitant medication by drug class.

6.5 Subsequent Anti-Cancer Therapy

Anti-cancer therapies received after study drug discontinuation may include chemotherapy, immunotherapy, radiotherapy, and surgery. Number and percentage of patients with any subsequent anti-cancer therapy will be summarized.

6.6 Protocol Deviations

Major protocol deviations will be identified prior to database lock for final analysis and will be listed and summarized.

6.7 Efficacy Endpoint Analyses

6.7.1 Primary Efficacy Endpoints Analyses

Number and percent of patients with their BOR in the response evaluable population will be summarized. The ORR and its 2-sided 95% exact binomial CI will be calculated for each cohort.

6.7.2 Secondary Efficacy Endpoints Analyses

The Kaplan-Meier method will be applied to estimate PFS, DoR and OS curves, their median times, PFS rates at 6 and 12 months, and OS rates 12 and 24 months, respectively. The method of Brookmeyer and Crowley **(1)** will be used to construct 95% CI for median time of each time-to-event endpoint. The 95% CIs for PFS and OS rates at each time point of interest will be calculated by normal approximation after log(-log) transformation.

DCR and its 2-sided 95% exact binomial CI will be calculated in the response evaluable population.

6.7.3 Other Efficacy Endpoints Analyses

The tumor size percent change from baseline over time will be summarized and presented by spider plot. The best tumor size percent change from baseline prior to the date of first PD or initiation of new anticancer therapy will be presented by waterfall plot.

6.8 Safety Endpoint Analyses

6.8.1 Adverse Events Analyses

Only TEAEs will be summarized. The following AEs will be provided in summary tables as well as displayed in listings:

- All AEs
- AEs with CTCAE severity ≥ Grade 3
- Study drug related AEs
- Study drug related AEs with CTCAE severity ≥ Grade 3
- SAEs
- Study drug related SAEs
- AEs that resulted in discontinuation of study treatment
- AEs that led to interruption of individual study drug
- Fatal AEs
- AEs of special interest (AESI)

All of these tables will display the number and percent of patients that experience the given event and will display events by MedDRA System Organ Class (SOC) and Preferred Term (PT). Events will be displayed alphabetically for SOC and in descending order of PT incidence within each SOC. An overall summary of AEs will display the number and percent of patients who experience at least one event of each of the above types.

6.8.2 Laboratory Values Analyses

Summaries of laboratory values will display descriptive statistics for numerically quantified labs. Summaries will be grouped by lab panel (hematology, blood chemistry, and urinalysis) and will be displayed by visit for each lab parameter. Shift tables may be produced.

6.8.3 Other Safety Endpoints Analyses

Summary of weight and baseline height will be provided.

ECGs will be collected and analyzed for evidence of cardiac toxicity, especially prolongation of QT interval. The following categories for QT interval corrected by Fridericia method (QTcF) and maximum post dose change from baseline QTcF interval (ΔQTcF) may be used in summary and shift tables:

QTcF: ≤ 450 msec, >450 to 480 msec, >480 to 500 msec, and >500 msec

ΔQTcF: ≤ 30 msec, >30 to 60 msec, and >60 msec

Vital signs and ECOG performance status will be summarized with descriptive statistics at each visit and time point where they are collected. The ECOG shift from baseline to highest score during the on-treatment period will be summarized.

6.9 Pharmacokinetic, Pharmacodynamic, and Immunogenicity Parameter Endpoints Analyses

PK Analysis
Single and multiple dose PK parameters, including but not limited to C_{max} and C_{trough}, will be derived from serum concentration versus time data. PPK analyses will be conducted using data from this study alone or combined with data from other studies. PPK and exposure-response modeling will be performed. Analysis will be conducted separately for enoblituzumab, retifanlimab, and tebotelimab.

Pharmacodynamic/Biomarker Analysis
Summary statistics for pharmacodynamic parameters will be provided and/or may be presented graphically. Possible associations between changes in pharmacodynamic measures of interest and enoblituzumab, retifanlimab, and tebotelimab dose and exposure may be explored. The distributions of PD-L1, LAG-3, and B7-H3 expression will be examined. The potential associations between the biomarkers and clinical response will be explored.

ADA Analysis
The proportion of patients who are negative for study-drug specific ADA at baseline and become positive in this assay, the proportion of patients who are negative at baseline and remain negative, and those who have positive ADA at baseline that increases or decreases in titer over the course of treatment will be summarized. Analysis will be conducted separately for enoblituzumab, retifanlimab, and tebotelimab.

6.10 Subgroup Analyses

The primary efficacy endpoint ORR will be analyzed by the following subgroups (not limited to those listed below). A particular subgroup analysis will be performed only if there are enough patients in that subgroup to render the analysis meaningful. Further, depending on the outcomes of the trial, these listed subgroup analyses may not be performed, or additional subgroups may be added, for the purpose of CSR. The SAP will not be revised for these changes.

The subgroups are defined as:

- PD-L1 expression in Retifanlimab Cohort: CPS ≥ 20, CPS < 20
- HPV p16 status: Positive, Negative
- ECOG performance status: 0, 1
- Smoking status: Current/Former, Never
- Disease status: Metastatic, Recurrent only

6.11 Data Standards

Clinical Data Interchange Standards Consortium (CDISC) standards will be used. The latest version of Study Data Tabulation Model (SDTM) will be used for data tabulations of the eCRF data. The latest version of Analysis Dataset Model (ADaM) will be used for the analysis datasets.

7 LIST OF TABLES, LISTINGS AND FIGURES

The list of tables, listings, and figures (TLFs) and associated shells planned for the CSR based on the analyses described in this SAP will be provided in a separate SPP, which will also include data reporting conventions and programming specifications for the development of these TLFs.

8 REFERENCES

1. **Brookmeyer, R and Crowley, J,** A Confidence Interval for the Median Survival Time, Biometrics, 1982. 38: p. 29-41.