Statistical Analysis Plan

Open-label, Multicenter Phase 1/2 Study of Mogamulizumab in Combination with Nivolumab in Subjects with Locally Advanced or Metastatic Solid Tumors

Protocol Number: 0761-014

US IND Number: 126,887

Date: Final 2018-12-06

Statistical Analysis Plan Signature Page

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Abbreviations/Acroynms

ADA	anti-drug antibody
AE	adverse event
ALK	anaplastic lymphoma kinase
ATC	anatomical therapeutic chemical
BLQ	below the lower limit of quantification
BOR	best overall response
CI	confidence interval
C_{min}	observed minimum concentration
C_{max}	observed peak concentration
CR	complete response
CRC	colorectal carcinoma
CSR	clinical study report
CTCAE	Common Terminology Criteria for Adverse Events
DLT	dose-limiting toxicity
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report forms
EGFR	epidermal growth factor receptor
FNR	false negative rate
FPR	false positive rate
HCC	hepatocellular carcinoma

Abbreviations/Acroynms

HPV	human papillomavirus
ICH	international conference on harmonization
IMP	Investigational medicinal product
irRECIST v1.1	immune-related response evaluation criteria in solid tumors version 1.1
IV	intravenous
KKD(US)	Kyowa Kirin Pharmaceutical Development, Inc.
KM	Kaplan-Meier
Max	maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min	minimum
MSI	microsatellite instability
MTD	maximum tolerated dose
NSCLC	non-small-cell lung cancer
NSQ	non-squamous cell
ORR	overall response rate
OS	overall survival
PD	progressive disease
PD-L1	programmed cell death-ligand 1
PFS	progression-free survival
PR	partial response
PS	Performance status
PT	preferred term
QTcB	QT interval corrected using Bazett's formula

Abbreviations/Acroynms

QTcF	QT interval corrected using Fridericia's formula
RECIST v1.1	Response Evaluation Criteria in Solid Tumors version 1.1
SAE	serious adverse event
SCCHN	squamous cell carcinoma of the head and neck
SD	stable disease
Std Dev	standard deviation
SOC	system organ class
SQ	squamous cell
TEAE	treatment-emergent adverse event
TLF	tables, data listings, figures
TMTB	total measured tumor burden
TTR	time to response
WHO	World Health Organization

1 INTRODUCTION

This Statistical Analysis Plan (SAP) has been developed after review of Kyowa Kirin Pharmaceutical Development, Inc. Protocol 0761-014 (Amendment 2, dated 05 Dec 2016), along with the corresponding electronic case report forms (eCRF). This SAP describes the analysis sets and specific details for the statistical methods to be used for the analysis and reporting of all efficacy, safety, pharmacokinetic parameters, and immunogenicity data collected during the conduct of Protocol 0761-014. This SAP supersedes the statistical considerations identified in Protocol 0761-014 with regards to details of the analyses; where considerations are substantially different, they will be identified as such in this document. In the event that the protocol has amendment(s) that do not have an impact on the statistical analysis methodology, this SAP will not require an amendment. This SAP has been developed and finalized prior to database lock of the clinical database for Protocol 0761-014. If additional analyses are required to supplement the planned analyses described in this SAP, they may be performed and will be identified in the Clinical Study Report (CSR).

This SAP is being written with consideration of the recommendations outlined in the International Conference on Harmonization (ICH) E9 Guideline entitled "Guidance for Industry: Statistical Principles for Clinical Trials" and the most recent ICH E3 Guideline, entitled "Guidance for Industry: Structure and Content of Clinical Study Reports."

2 OBJECTIVES

The objectives of this study are as follows:

2.1 Primary Objective

The primary objective of this study is to characterize the safety and tolerability and determine the maximum tolerated dose (MTD) or the highest protocol-defined dose in the absence of exceeding the MTD, of the combination regimen of mogamulizumab and nivolumab in subjects with locally advanced or metastatic solid tumors

2.2 Secondary Objectives

The secondary objective of this study is to evaluate the anti-tumor activity of the combination of mogamulizumab and nivolumab based on the Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1). Anti-tumor activity will be assessed as overall response rate (ORR), time to response (TTR), duration of response (DOR), progression-free survival (PFS), and overall survival (OS).

2.3 Exploratory Objectives

The exploratory objectives of this study are:

1) To assess serum concentrations of mogamulizumab and nivolumab when administered in combination.
2) To evaluate the immunogenicity of mogamulizumab and nivolumab when administered in combination.
3) To evaluate the pharmacodynamic profile of the combination of mogamulizumab and nivolumab and determine which biomarkers may correlate with safety and/or anti-tumor activity.
4) To evaluate the ORR of the combination of mogamulizumab and nivolumab based on the immune-related RECIST (irRECIST) v1.1.

3 OVERALL STUDY DESIGN AND TREATMENT PLAN

This is a multicenter, Phase 1/2, open-label, dose-finding, cohort-expansion study of the anti-CCR4 antibody mogamulizumab in combination therapy with the anti-programmed death receptor-1 (PD-1) antibody nivolumab in adult subjects with locally advanced or metastatic solid tumors. The study includes a Phase 1 dose finding and a Phase 2 cohort expansion:

- Phase 1 dose finding has a 3+3 design that will identify the MTD or the highest protocol-defined dose, in the absence of exceeding the MTD, for the combination regimen and will enroll up to 12 subjects (3 to 6 subjects per cohort).
- Phase 2 cohort expansion will explore the safety, pharmacokinetic (PK), PD, and anti-tumor activity of the highest tolerated dose of the combination regimen and will enroll up to 184 subjects (21 to 36 per tumor type) in up to 7 tumor-specific expansion cohorts.

Phase 1: Dose-finding: The dose levels and schedules are described below:

	Dosage of Mogamulizumab		**Dosage of Nivolumab**
Dose Level	**Cycle 1 (Days 1, 8, 15, 22)**	**Subsequent Cycles (Days 1, 15)**	**All Cycles (Days 1, 15)**
1	1.0 mg/kg	1.0 mg/kg	240 mg
Optional[a]	0.3 mg/kg	0.3 mg/kg	240 mg

a: This dose level may be enrolled if > 1 subject experiences dose-limiting toxicity at Dose Level 1.

Phase 2: Cohort expansion

Up to 184 subjects (21 to 36 subjects per tumor type) with locally advanced or metastatic disease in the following tumor types will be enrolled: squamous cell non-small cell lung cancer (NSCLC); programmed cell death ligand 1 (PD-L1)-non-expressing non-squamous cell NSCLC; squamous cell carcinoma of the head and neck (SCCHN); colorectal carcinoma, non-microsatellite instability (non-MSI) high; ovarian cancer, hepatocellular carcinoma (HCC), and pancreatic adenocarcinoma. PD-L1 expressing is defined as membrane staining

observed in ≥ 1% tumor cells among a minimum of 100 evaluable tumor cells. Subjects will be treated with the highest dose of the combination regimen that was considered tolerable in Phase 1. The safety and tolerability of the dosing regimen used in each expansion cohort will be monitored. The SRC will review cumulative safety data from all subjects approximately every 2 months during the enrollment period. Clinical safety in the expansion cohorts will be monitored continually.

4 STATISTICAL METHODOLOGY

This plan describes methods planned for the analysis and display of efficacy, safety, pharmacokinetic parameters, and immunogenicity endpoints. Separate plans will document exploratory analyses of pharmacokinetic/pharmacodynamic data, pharmacodynamic relationships with safety and/or efficacy results, and the effects of immunogenicity on safety, efficacy, pharmacokinetic and pharmacodynamic.

The specific endpoints are as follows.

Primary Endpoints:

- Safety and tolerability will be evaluated by assessing adverse events (AEs), changes in physical examination findings, vital sign measurements, 12-lead electrocardiogram (ECG) readings, and clinical laboratory evaluations.

Secondary Endpoints:

- Overall response will be evaluated using RECIST v1.1. Overall response rate is calculated based on the best overall response (BOR), defined as the best response designation recorded between the date of first dose of investigational medical product (IMP) and the date of subsequent anti-cancer therapy (excluding on-treatment palliative radiotherapy of non-target bone or CNS lesions). Note: Continuation of nivolumab after discontinuing combination therapy does not count as start of new therapy for this definition. A BOR of either complete response (CR) or partial response (PR) requires confirmation of the assessment at least 4 weeks later. In addition, as a sensitivity analysis, BOR will also be defined as the best response designation recorded between the date of first dose of IMP and the date of first objectively documented progression (i.e. radiographic progression) or the date of subsequent anti-cancer therapy (excluding on-treatment palliative radiotherapy of non-target bone or CNS lesions), whichever occurs first.
- Time to response (TTR): Days from Cycle 1 Day 1 to the first assessment date of confirmed CR/PR using RECIST v1.1.
- Duration of response (DOR): Days from the first assessment date of confirmed CR/PR to the date of death or progressive disease (PD), whichever is earlier, using RECIST v1.1.

For subjects who neither progress nor die, the duration of objective response will be censored at the same time they will be censored for the primary definition of PFS. DOR will be evaluated for responders (i.e. subjects with confirmed CR or PR) only.

- Progression-free survival (PFS): Days from Cycle 1 Day 1 to the date of death or PD using RECIST v1.1, whichever is earlier. Clinical deterioration in the absence of objectively documented progression per RECIST 1.1 is not considered progression for the purpose of determining PFS. Subjects who die without a reported progression will be considered to have progressed on the date of their death. Subjects who did not progress or die will be censored on the date of their last evaluable tumor assessment. Subjects who did not have any on study tumor assessments and did not die will be censored on the date of first dose. Subjects who started any subsequent anti-cancer therapy, including tumor-directed radiotherapy and tumor-directed surgery, without a prior reported progression will be censored at the last evaluable tumor assessment prior to initiation of the subsequent anti-cancer therapy. For subjects whose BOR is PR or CR using RECIST v1.1, the date of first documented objective tumor progression or death that occurs after the last documented PR or CR will be used as the PFS event date.
- Overall survival (OS): Days from Cycle 1 Day 1 to the date of death. For subjects without documentation of death, OS will be censored on the last date the subject was known to be alive.

Exploratory Endpoints

- Pharmacokinetic parameters:
  - Mogamulizumab: observed minimum serum concentration at the end of a dosing interval (C_{min}) and corresponding C_{max}; and
  - Nivolumab: C_{min}.
- Immunogenicity: Anti-mogamulizumab antibody and anti-nivolumab antibody;
- Pharmacodynamic parameters: biomarkers may include, but are not limited to, immune cell subsets and factors such as cytokines and chemokines in tumor and/or blood;
- Immune-related overall response evaluated using irRECIST v1.1.

4.1 General Statistical Considerations

All data collected for the dose finding phase (Phase 1) and the cohort-expansion phase (Phase 2) will be listed. Phase 2 data will be summarized by tumor type and overall (all subjects) if appropriate. All subjects from Phase 1 will be summarized as an independent cohort with all cancer types combined.

Descriptive statistics (mean, standard deviation [Std Dev], median, minimum [Min], and maximum [Max]) will be used for continuous variables; number and percentage of subjects will be used for discrete variables. For change-from-baseline calculations, the last measurement prior to the first dose of IMP will be used as the baseline value.

For summary statistics, the mean and median will be displayed to one decimal place greater than the original values; the standard deviation will be displayed to two decimal places greater than the original values.

All tabulations of summary statistics, graphical presentations, and statistical analyses will be performed using SAS® Version 9.4 or higher.

4.2 Determination of Sample Size

The sample size for the dose-finding phase of the study is based on a standard 3+3 dose-finding design and depends on observed toxicity. With 2 doses under consideration, a maximum of 12 subjects will be required.

The Simon's 2-stage optimal design is used for the expansion cohorts. A cohort may be considered for termination due to lack of efficacy if the observed number of tumor responses (either confirmed or unconfirmed) in the first stage is too small. The characteristics of this design depend on 2 probabilities: the false positive rate (FPR), the probability of declaring the experimental treatment to be superior when in fact it is no better than the historical standard, and the false negative rate (FNR), the probability of concluding the experimental treatment to be no better than the historical standard, when in fact it is superior. Table 1 below presents operating characteristics of the Simon's 2-stage design with 15% FPR and 10% FNR for various expansion cohorts and their historical and target objective response rates. For example, an initial evaluation of efficacy may be performed after 16 treated subjects with squamous cell NSCLC have evaluable tumor response data. Guided by the Futility Boundary as shown, the decision to terminate the cohort or to allow it to continue will be made after taking into consideration other relevant observations such as duration and depth of response and risk/benefit profile. The number of subjects receiving treatment at the time of the Stage 1 efficacy evaluation may exceed the specified Stage 1 sample size depending on accrual rate, response lag, and other factors.

Upon completion of Stage 1 enrollment for a given cohort, the safety review committee (SRC) will review available efficacy and safety data and determine whether enrollment into Stage 2 may continue, even if not all response data are yet available to determine whether the Stage 1 criteria have been met. The SRC may decide that enrollment may continue if the benefit risk assessment is perceived to be positive.

With FPR (or one-sided alpha) being 15% and FNR (or 1-power) being 10%, the following table shows sample size required for each tumor type.

Table 1 Sample Size Estimation by Tumor Type

Tumor Type	Response Assumption		Simon 2-Stage Sample Sizes[a]		Probability of Early Stopping due to Futility (%) if true response rate = Lower Bound
	Lower Bound Historical Response Rate (%)	Target Response Rate (%)	Stage 1 (n1)/ Total (N)	Stage 1 Response Futility Boundary (≤): Stop if this many responses or fewer	
NSCLC SQ	20	40	16/32	3	60
NSCLC NSQ PD-L1 non-expressing	10	30	10/21	0	35
Ovarian	10	30	10/21	0	35
CRC (non-MSI high)	5	20	12/29	0	54
SCCHN	25	45	14/36	3	52
HCC	16	36	12/28	1	41
Pancreatic	0	15	15/17	0	>99

a: False positive rate (FPR) or one-sided alpha=15% and false negative rate (FNR) or 1-power=10%.

CRC=colorectal carcinoma; n1=sample size in Stage 1; N=sample size; non-MSI high=non-microsatellite instability high; NSCLC=non-small-cell lung cancer; NSQ=non-squamous; PD-L1=programmed cell death-ligand 1; HCC=hepatocellular carcinoma; SCCHN=squamous cell carcinoma of the head and neck; SQ=squamous.

A maximum of 188 subjects will participate in the study. This number takes into account a total of 4 subjects that were enrolled in the dose-finding stage and a total of 184 subjects (across all tumor types) calculated for the expansion cohort.

4.3 Disposition of Subjects

The numbers of subjects enrolled, treated, discontinued from treatment (by reason), and replaced will be presented by dose cohort, including the expansion cohorts.

Note that subjects in the dose finding Phase 1 will be replaced if they do not experience a dose-limiting toxicity (DLT) and either of the following conditions hold:

- They do not receive all infusions of both IMPs in Cycle 1 within 28 days at the doses assigned to the cohort in which they are enrolled.
- They do not complete the safety follow-up through the end of the DLT evaluation period (14 days after the last dose of IMP in Cycle 1).

Subjects enrolled in the expansion cohorts may be replaced for these same reasons, at the discretion of the Sponsor.

4.4 Data Sets Analyzed

The following analysis sets will be used in the study:

- **Safety Analysis Set**: Includes all subjects who received at least one dose of IMP (even a partial dose).
- **Efficacy Analysis Set**: Includes all subjects who receive combination therapy in Cycle 1 Day 1.
- **Pharmacokinetic Analysis Set:** Includes all subjects who provide at least one post-dose concentration measurement.
- **Pharmacodynamic Analysis Set:** Includes all subjects who provide at least one post-dose sample.
- **ADA Analysis Set:** The ADA analysis set for mogamulizumab will include all subjects that have both a baseline subject ADA status and at least one on-treatment subject ADA status.

The number of subjects in the Safety Analysis, Efficacy Analysis, Pharmacokinetic Analysis, Pharmacodynamics Analysis Set, and ADA analysis set will be summarized.

4.5 Protocol Deviations

Protocol deviations (PDs) will be identified, logged, and reviewed during the course of the study. A determination of major versus minor PDs will be made according to the criteria outlined in the study protocol deviation review plan. A listing of all PDs will be provided. For purposes of CSR reporting, all important/major protocol deviations will be identified based on the following minimum criteria:

- Subjects who entered the study even though they did not satisfy the entry criteria
- Subjects who developed withdrawal criteria during the study but were not withdrawn
- Subjects who received the wrong treatment or incorrect dose

- Subjects who received an excluded concomitant treatment.

4.6 Demographic and Other Baseline Characteristics

Demographic and baseline characteristics will be summarized descriptively for both the Safety Analysis Set and the Efficacy Analysis Set. Gender, race, ethnicity, tobacco use, and baseline Eastern Cooperative Oncology Group (ECOG) performance status (PS) will be summarized with number and percentage presented for each category. Age, height, and weight at baseline will be described with summary statistics (n, mean, Std Dev, median, minimum, and maximum).

In addition, subject cancer history will be summarized descriptively. The characteristics include:

- Primary tumor type;
- Time from initial diagnosis of tumor to first dose day (in months);
- Time from locally advanced/metastatic disease to first dose day (in months);
- Stage at enrollment (locally advanced, metastatic);
- Metastatic sites (if applicable);
- EGFR mutation (positive, negative, other, not done), ALK rearrangement (positive, negative, other, not done), HPV infection (positive, negative, unequivocal, other, not done) and MSI (type of assay, PCR: MSI-high, MSI-low, MSI-stable, other, not done; IHC: positive, negative, other, not done); Oncogene assessment: KRAS, ROS1, BRAF,…etc.

4.6.1 Medical History

Medical history data will be presented in data listings for individual subjects.

4.7 Prior/Concomitant Cancer and Non-Cancer Therapies/Procedures

4.7.1 Prior Cancer Therapy

The number of cancer therapy regimens that subjects received prior to enrollment will be summarized by frequency counts. The best response to the most recent line of therapy will be provided. This will be performed on the Safety Analysis Set.

4.7.2 Prior Cancer Surgery, Radiation Therapy, and Other Therapy

The number and percentage of subjects who underwent prior cancer surgery, radiation therapy, and other types of cancer therapy will be summarized separately for each of these categories. This will be performed on the Safety Analysis Set.

4.7.3 Post Treatment Cancer Therapy

The number and percentage of subjects who received any post-treatment cancer therapy will be summarized for the Safety Analysis Set.

4.7.4 Other Prior/Concomitant Medications

Prior and concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary (version September 2015). Prior medications include medications that were taken within 30 days prior to the first dose of IMP. Concomitant medications during the treatment period include medications that started at any time and were taken at any time after the start of IMP until 30 days after the last dose of IMP.

The number and percentage of subjects taking prior medications or concomitant medications during the treatment period will be summarized by anatomical therapeutic chemical (ATC) and preferred term (PT) for the Safety Analysis Set. If a subject takes more than one medication in the same ATC class, the subject will be counted only once within that classification. The same subject may contribute to two or more preferred terms within the same ATC classification.

4.8 Study Drug Exposure and Compliance

The maximum number of cycles initiated, cycles that a subject initiated, extent of exposure (defined as Last Dose Date – First Dose Date + 1), and the number of infusions administered (mogamulizumab: Days 1, 8, 15, 22 of the first cycle and Days 1 and 15 of each subsequent cycle; nivolumab: Days 1 and 15 of each cycle) per subject will be summarized for each medication. Infusion time (in minutes) per administration (overall, at 1st – 4th infusion, and later for mogamulizumab; at 1st and 2nd infusions, and later for nivolumab) will also be presented. These parameters will be summarized for the Safety Analysis Set.

Cumulative dose statistics will be calculated for mogamulizumab as follows.

- Cumulative actual dose (mg/kg): Sum of {Actual dose administered (mg)/Body weight (kg)};
- Cumulative assigned dose (mg/kg): Sum of {Planned dose (mg/kg)};
- Relative dose intensity (%):

$$\frac{Number\ of\ doses\ administered\ in\ Cycle\ 1 + Number\ of\ doses\ administered\ in\ Subsequent\ Cycles\ x2}{[(Number\ of\ cycles\ initiated) \times 4]} \times \frac{Number\ of\ cycle\ initiated \times 28}{Last\ dose\ date + n^{*} - First\ dose\ date} \times 100$$

where n* = 7 when the patient was only treated for 1 cycle, otherwise, n* = 14.

Note that body weight for each infusion is defined as weight entered at the visit for calculation of the dose level.

Similarly, cumulative actual dose (mg), cumulative assigned dose (mg), and relative dose intensity (%) will be calculated for nivolumab as well. Note that the assigned dose for nivolumab is 240 mg per administration.

- Cumulative actual dose (mg): Sum of {Actual dose administered (mg)};
- Cumulative assigned dose (mg): Sum of {Planned dose (mg)} = (Last nivolumab dose date – First nivolumab dose date) × 240/14;
- Relative dose intensity (%): Cumulative actual dose/Cumulative assigned dose × 100.

4.9 Efficacy Analysis

The efficacy analysis is based on disease response assessments. Assessment of disease response will be performed by investigators using both the RECIST v1.1 and the irRECIST v1.1. Responses for each disease evaluation assessment will be recorded in eCRFs.

4.9.1 Analysis of Efficacy Variables

Tumor response is determined by the investigator at each timepoint when tumor imaging is performed. All response-related endpoints (BOR, TTR, DOR, and PFS) will be based on RECIST v1.1 and derived programmatically using the investigator's assessments of tumor response at each timepoint. In addition, BOR of CR/PR will be assessed using irRECIST v1.1 criteria. The date of response is based on the image dates. In the event that there are images taken on different days, the latest date among all images taken will be used for the response date if the overall response is non-PD. If the overall response is PD, then the earliest date of all images taken will be used for the progression date.

All analyses will be conducted for the Efficacy Analysis Set.

Best Overall Response (BOR)

The number and percentage of subjects in each BOR category (i.e., CR, PR, SD, PD, and inevaluable) will be summarized. Subjects who do not meet CR/PR will be classified as stable disease if assessed as SD (or better) at least 9 weeks after first dose of IMP. The percentage of subjects with BORs of either CR or PR, taking into account any requirement for confirmation, will be calculated. The rates will be presented along with two-sided 95% exact confidence intervals. The 95% CIs will be derived using the Clopper-Pearson (Hollander, 1973) exact binomial confidence interval method.

The following Table 2 describes the derivation of BOR from overall response assessments at each visit. Note that BOR categories referenced in this table can be based on RECIST v1.1 or irRECIST v1.1 overall responses. For RECIST v1.1, BOR will be derived based on both

definitions as described in Section 4, secondary endpoints. For irRECIST v1.1 overall response, the analysis focuses on whether the subjects were responding (i.e., CR or PR) or not (i.e., not CR/PR).

Table 2 Best Overall Response When Confirmation of Complete Response and Partial Response is Required

Overall Response First Timepoint	Overall Response Subsequent Timepoint	Best Overall Response
CR	CR	CR
CR	PR	SD, PD or PR[a]
CR	SD	SD provided minimum criteria for SD duration was met, otherwise, PD
CR	PD	SD provided minimum criteria for SD duration was met, otherwise, PD
CR	NE	SD provided minimum criteria for SD duration was met, otherwise, NE
PR	CR	PR
PR	PR	PR
PR	SD	SD
PR	PD	SD provided minimum criteria for SD duration was met, otherwise, PD
PR	NE	SD provided minimum criteria for SD duration was met, otherwise, NE
NE	NE	NE

a: If a CR is truly met at first time point, then any disease seen at a subsequent time point, even disease meeting PR criteria relative to baseline, makes the disease PD at that point (since disease must have reappeared after CR). Best response would depend on whether minimum duration for SD was met. However, sometimes 'CR' may be claimed when subsequent scans suggest small lesions were likely still present and in fact the patient had PR, not CR at the first time point. Under these circumstances, the original CR should be changed to PR and the best response is PR.

CR=complete response; NE=not evaluable; PD=progressive disease; PR=partial response; SD=stable disease.

Time to Response (TTR)

Time to response will only be summarized descriptively for responders (i.e., CR or PR).

Duration of Response (DOR)

Duration of response will be calculated from the first date of confirmed CR/PR to the date of death or the date of first documented tumor progression (PD), whichever is earlier, using RECIST v1.1. Subjects who remain alive and do not progress will be censored on the date of their last tumor assessment. Subjects who start subsequent therapy without a prior PD will be censored at the last tumor assessment prior to initiation of the subsequent anticancer therapy. Response duration will only be evaluated in subjects with a BOR of CR or PR.

The median DOR, along with its two-sided 95% CI (Brookmeyer, 1982), will be estimated using the Kaplan-Meier (KM) method.

Progression-Free Survival (PFS)

PFS will be calculated as the number of days from the first dose of IMP to the date of death or PD, whichever is earlier. For subjects whose BOR is PR or CR using RECIST v1.1, the date of first documented objective tumor progression or death that occurs after the last documented PR or CR, and prior to the start of post-treatment anti-cancer therapy will be used as the PFS event date. Subjects who die without a reported prior progression will be considered to have progressed on the date of their death. Subjects who remain alive and do not progress will be censored on the last tumor assessment date. Subjects who start subsequent therapy without a prior reported progression will be censored on the date of last tumor assessment prior to initiation of subsequent anticancer therapy. Subjects who have no post-baseline tumor assessments and do not die will be censored on Day 1.

The median PFS time, along with its two-sided 95% CI, will be estimated using the KM method. In addition, two-sided 95% CIs for the PFS rate will be constructed at pre-specified time intervals (such as 3 months, 6 months, …, etc.), using the log-log transformation methodology of Kalbfleisch and Prentice (Kalbfleisch, 1980) where the estimated variance of $\log(-\log(\hat{S}(t)))$ is:

$$\tau^2(t) = \sigma^2[\hat{S}(t)\log(\hat{S}(t))]^2$$

The 100 x (1-α)% CI for S(t) is given by:

$$\left[\hat{S}(t)\right]^{\exp(z_{\alpha/2}\tau(t))} \le S(t) \le \left[\hat{S}(t)\right]^{\exp(-z_{\alpha/2}\tau(t))}$$

Overall Survival (OS)

Overall survival is defined as the time from the first dose of IMP to the date of death due to any cause. For subjects who do not die, the OS time will be censored on the date when the subject was last known to be alive. The date "last known to be alive" will be defined as the latest date of contact with the subject based on the following: non-imputed AE start and stop dates, visit/collection dates (including unscheduled visits) of pharmacokinetic/pharmacodynamic/Biomarker/ADA assessments, serum/urine pregnancy tests, safety laboratory collection (i.e., hematology, serum chemistry, coagulation profiles, thyroid function, and urinalysis), vital signs, pulse oximetry, physical exams, ECG assessments, tumor biopsy or tumor assessments, concomitant medication/post treatment

cancer therapy, and extended survival follow-up contact dates where the subject's status is "alive". The analysis methodology for OS will be similar to that used for PFS.

4.9.2 Statistical / Analytical Issues

4.9.2.1 Handling of Dropouts or Missing Data

Missing values will not be substituted by estimated values, but treated as missing in the statistical evaluation. All data from all subjects dosed in the study will be included in all listings, plots, summary tables, and statistical analyses when appropriate.

4.9.2.2 Interim Analyses and Data Monitoring

Safety information will be monitored on a continuing basis to support decisions regarding dose finding in Phase 1 and cohort expansion in Phase 2. Guided by Simon's 2-stage design, tumor response rates together with other relevant observations such as duration and depth of response will be evaluated after Stage 1 enrollment is complete; these results will be reviewed by the SRC as a basis for benefit risk assessment and decisions regarding Stage 2 enrollment. The assumed historic and target response rates at the time of protocol finalization may have been changed over time and may need to be adjusted by the time of the data evaluation.

4.10 Pharmacokinetic Analysis

Pharmacokinetic parameters of C_{min} and C_{max} for mogamulizumab and C_{min} for nivolumab will be summarized at each infusion for the Pharmacokinetic Analysis Set. Descriptive summary statistics including mean, standard deviation, coefficient of variation (CV), median, range, geometric mean, and coefficient of variation based on geometric mean will be presented. Individual serum C_{min} or C_{max} for mogamulizumab will be shown to one decimal place. If a C_{min} or C_{max} for mogamulizumab is below the lower limit of quantification (BLQ, <12.5 ng/mL), the concentration will be shown as "BLQ" in a listing, and the data will be handled as 0 ng/mL when calculating descriptive statistics. If the mean, minimum, median, or maximum is calculated to be below the lower limit of quantification, it will be shown as "BLQ" in a table. If the mean is below the lower limit of quantification, standard deviation will be shown as dash ('-') in the table.

4.11 Pharmacodynamic Analysis

Pharmacodynamic data will be summarized in a separate stand alone report according to a dedicated biomarker analytical plan.

4.12 Immunogenicity Analysis

4.12.1 Sample Anti-Mogamulizumab Antibody (ADA) Status

For a given sample, the ADA status for anti-mogamulizumab antibody will be determined using the anti-mogamulizumab antibody assay results (both screening and confirmatory), along with the serum mogamulizumab concentration at the same time point as follows.

- ADA-positive: The sample is positive in the confirmatory assay.
- ADA-negative: The sample is negative in the screening assay and the serum mogamulizumab concentration at the same time point is equal to or less than the drug tolerance limit (16000 ng/mL), or the sample is positive in the screening assay and negative in the confirmatory assay.
- ADA-inconclusive: The sample is negative in the screening assay and the serum KW-0761 concentration at the same time point is above the drug tolerance limit (16000 ng/mL).
- ADA-unknown: The sample is negative in the screening assay and the serum KW-0761 concentration at the same timepoint is unknown.

4.12.2 Sample Anti-Mogamulizumab Neutralizing Antibody (NAb) Status

For a given sample, the anti-mogamulizumab neutralizing antibody (NAb) status will be determined using the NAb assay result as follows.

- NAb-positive: The sample is positive in the NAb assay.
- NAb-negative: The sample is negative in the NAb assay.

4.12.3 Subject ADA Status

Each subject will be assigned a “subject ADA status” at baseline and at each subsequent time point during mogamulizumab administration.

A subject whose baseline (before administration of mogamulizumab) sample ADA status is ADA-positive will be classified as “Baseline-positive”.

During mogamulizumab administration, a subject ADA status will be determined as follows:

- ADA-positive: The subject’s samples meet either of the following criteria.
    - Treatment-induced ADA: The assay result of the sample before administration of KW-0761 is negative and one or more assay results of the samples after administration of mogamulizumab are positive.
    - Treatment-boosted ADA: The assay result of the sample before administration of mogamulizumab is positive and one or more titer values of the samples

after administration of mogamulizumab are ≥16-fold of the titer value in the sample before administration of mogamulizumab.

- ADA-negative: Subject ADA status is not defined as "ADA-positive" at any time point and the sample ADA status at the last time point is not "ADA-inconclusive".
- ADA-inconclusive: Subject ADA status is not defined as "ADA-positive" at any time point and the sample ADA status at the last time point is "ADA-inconclusive".

4.12.4 Subject NAb Status

The subject ADA status of a subject who has one or more "NAb-positive" sample ADA statuses as defined in 4.12.2 will be defined as "NAb-positive".

4.12.5 Determination of Anti-Mogamulizumab Antibody Incidence

The ADA analysis set for mogamulizumab will include all subjects that have both a baseline subject ADA status and at least one on-treatment subject ADA status.

The following percentage will be determined using baseline samples:

- Pre-existing ADA incidence: The number of the subjects whose ADA status is "Baseline-positive" (as defined in 4.12.3) as a percentage of the total number of subjects in the ADA Analysis Set.

The following percentages will be determined using on-treatment samples:

- Overall ADA incidence: The number of subjects whose subject ADA status is "ADA-positive" (as defined in 4.12.3) as a percentage of the total number of subjects in the ADA Analysis Set.
    - Treatment-induced ADA incidence: The number of subjects who have "Treatment-induced ADA" (as defined in 4.12.3) as a percentage of the number of subjects whose sample ADA status before administration of mogamulizumab is "ADA-negative" (as defined in 4.12.3).
    - Treatment-boosted ADA incidence: The number of the subjects who have "Treatment-boosted ADA" (as defined in 4.12.3) as a percentage of the number of subjects whose subject ADA status is "Baseline-positive" (as defined in 4.12.3).
    - Neutralizing ADA incidence: The number of subjects whose subject ADA status is "NAb-positive" (as defined in 4.12.3) as a percentage the number of subjects in the ADA Analysis Set.

4.13 Safety Analysis

The safety and tolerability of the investigational products will be determined by reported AEs, physical examinations, ECGs, vital signs, and laboratory test results.

All safety summaries will be based on the Safety Analysis Set.

4.13.1 Adverse Events

All subjects will be assessed regularly for the potential occurrence of adverse events (AEs) from the date of informed consent to 100 days after the last dose of IMP. The incidence of treatment-emergent AEs (TEAEs) will be summarized and tabulated using MedDRA (version 18.1), by System Organ Class (SOC) and Preferred Term (PT). A TEAE is defined as an AE that first occurs or worsens in severity on or after the first dose of any IMP and within 100 days after the last dose of IMP.

The National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) (Version 4.03) will be used to grade both clinical and laboratory AEs. A subject with several occurrences of the same AE will be counted once and classified by the most severe occurrence. AEs with missing severity ratings will be classified as having unknown severity, but will be assigned Grade 3 severity for analysis and summarization.

The relationship of each AE to the IMP will be classified as related or unrelated. Any AE with an eCRF description of related will be considered related. A subject with several occurrences of the same AE will be counted once and classified as related if at least one of them is classified as related. An AE with a missing relationship to IMP will be assumed to be related to IMP for the purpose of analysis and summarization. Relationship of AEs to mogamulizumab and nivolumab will be separately recorded and analyzed.

An overview of adverse events for the Safety Analysis Set will be provided, summarizing the incidence of the following:

- Any TEAEs; Mogamulizumab-related TEAEs; Nivolumab-related TEAEs;
- Any NCI/CTCAE Grade 3/4/5 TEAEs; Mogamulizumab-related NCI/CTCAE Grade 3/4/5 TEAEs; Nivolumab-related NCI/CTCAE Grade 3/4/5 TEAEs;
- Any Treatment-emergent SAEs; Mogamulizumab-related treatment-emergent SAEs; Nivolumab-related treatment-emergent SAEs;
- Any discontinuation of study drug due to TEAEs; discontinuation of Mogamulizumab due to Mogamulizumab-related TEAEs; discontinuation of Nivolumab due to Nivolumab-related TEAEs;
- Any NCI/CTCAE Grade 5 TEAEs; Mogamulizumab-related NCI/CTCAE Grade 5 TEAEs; Nivolumab-related NCI/CTCAE Grade 5 TEAEs;

The number and percentage of subjects with TEAEs will be summarized by SOC and PT for Cycle 1 and for all cycles. A TEAE for Cycle 1 is defined as any event new or worsening prior to the Cycle 2 start date. Mogamulizumab-related TEAEs, nivolumab-related TEAEs, any IMP-related TEAEs, ≥ Grade 3 TEAEs, mogamulizumab-related ≥ Grade 3 TEAEs, nivolumab-related ≥ Grade 3 TEAEs, any IMP-related ≥ Grade 3 TEAEs, TEAEs leading to discontinuation of any IMP, any IMP-related TEAEs leading to any IMP-discontinuation, TEAEs leading to discontinuation of mogamulizumab, mogamulizumab-related TEAEs leading to discontinuation of mogamulizumab, TEAEs leading to discontinuation of nivolumab, nivolumab-related TEAEs leading to discontinuation of nivolumab, treatment-emergent SAEs, mogamulizumab-related treatment-emergent SAEs, nivolumab-related treatment-emergent SAEs, any IMP-related treatment-emergent SAEs, and fatal TEAEs will be summarized in the same manner. For these summaries, subjects with multiple AEs will be counted only once per SOC and PT.

In addition, summaries will be provided for the number and percentage of subjects with TEAEs, mogamulizumab-related TEAEs, nivolumab-related TEAEs, any IMP-related TEAEs by SOC and preferred term and by the highest NCI CTCAE grade. For these summaries, subjects with multiple adverse events will be counted only once by the highest NCI CTCAE grade within an SOC and preferred term.

As with any antibody, allergic reactions to dose administration are possible. Therefore, infusion-related acute reactions will be identified and summarized.

4.13.2 Clinical Laboratory Evaluation

For chemistry, coagulation and hematology parameters, laboratory measurements (including actual values at the visit and their changes from baseline during the treatment period) will be summarized. In addition, the maximum and minimum post-treatment values will be presented.

Shift tables from baseline to the worst post-baseline values during the treatment period will be provided for chemistry parameters and hematology parameters that have NCI-CTCAE v4.03 toxicity grades. Both scheduled and unscheduled post baseline values during the treatment period will be considered. Additionally, the number and percentage of subjects with Grade ≥ 3 will be presented for each CTCAE gradable laboratory test.

All clinical laboratory data will be listed by subject. Values outside the normal ranges will be flagged and toxicity grades will be displayed for relevant parameters.

4.13.3 Vital Signs

Vital signs measurements include pulse rate, temperature, systolic blood pressure, and diastolic blood pressure. Measures at baseline and changes from baseline to the end of

treatment will be summarized. In addition, the maximum and minimum post-treatment values and their changes from baseline will be summarized.

4.13.4 12-Lead Electrocardiogram (ECG)

The QTc intervals are to be determined using the Fridericia correction (QTcF) and the Bazett correction (QTcB). The QTcF and QTcB intervals of the ECG measurements and changes from baseline to end of treatment will be summarized. In addition, the maximum and minimum post-treatment values will be summarized. The mean of triplicate values at the visit will be used for this summary.

The number and percentage of subjects with elevated QTcF or QTcB values (> 450 msec, > 480 msec, and > 500 msec) at baseline and end of treatment will be presented. In addition, the number and percentage of subjects with QTcF or QTcB values that increase by > 30 msec and > 60 msec from baseline to end of treatment will be presented.

A shift table from baseline to the worst post-baseline values during the treatment period will be provided for QTcF and QTcB intervals. The following categories will be used: ≤ 450 msec, > 450 and ≤ 480 msec, > 480 and ≤ 500 msec, and > 500 msec.

4.13.5 Physical Examinations

Weight collected during physical examinations will be summarized for baseline, end of treatment, minimum and maximum post-treatment values, as well as the changes from baseline. Physical examination findings will also be listed by subject.

4.13.6 ECOG Performance Status

The worst ECOG performance status result during the treatment period will be provided, along with the number and percentage of subjects in each score.

5 REFERENCES

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Hollander M, Wolfe DA. Nonparametric statistical methods. John Wiley & Sons, Inc. 1973.

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

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonised Tripartite Guideline, Structure and Content of Clinical Study Reports (E3), 30 November 1995.

Kalbfleisch JD, Prentice RL. The statistical analysis of failure time data. John Wiley & Sons, Inc. 1980.

6 PROGRAMMING CONSIDERATIONS

All tables, data listings, figures (TLFs), and statistical analyses will be generated using SAS® Version 9.4 (or higher). Generated outputs will adhere to the following specifications.

6.1 Table, Listing, and Figure Format

6.1.1 General

1) All TLFs will be produced in landscape format.
2) All TLFs will be produced using the Times New Roman font, size 9.
3) The data displays for all TLFs will have a 1.5-inch binding margin on top of a landscape oriented page and a minimum 1-inch margin on the other 3 sides.
4) Headers and footers for figures will be in Times New Roman font, size 9.
5) Legends will be used for all figures with more than 1 variable, group, or item displayed.
6) TLFs will be in black and white (no color).
7) Specialized text styles, such as bolding, italics, borders, shading, and superscripted and subscripted text, will not be used in the TLFs. On some occasions, superscripts 1, 2, or 3 may be used (see below).
8) Only standard keyboard characters will be used in the TLFs. Special characters, such as non-printable control characters, printer-specific, or font-specific characters, will not be used. Hexadecimal-derived characters will be used, where possible, if they are appropriate to help display math symbols (e.g., μ). Certain superscripts (e.g., cm^2) will be employed on a case-by-case basis.
9) Mixed case will be used for all titles, footnotes, column headers, and programmer-supplied formats.

6.1.2 Headers

All output will have the following header at the top of the page:

Kyowa Kirin Pharmaceutical Development, Inc. Page n of N

Study: 0761-014

All output will have page numbers. TLFs will be internally paginated in relation to the total length (i.e., the page number will appear sequentially as page n of N, where N is the total number of pages in the table).

6.1.3 Display Titles

Each TLF will be identified by a numeral, and the designation (i.e., Table 1) will be centered above the title. A decimal system (14.x-y.z, 14.x.y-z, and 16.2.x-y) will be used to identify TLFs with related contents. The title will be centered in initial capital characters. The analysis set will be identified on the line immediately following the title. The title and table designation will be single spaced. A solid line spanning the margins will separate the titles from the column headers. There will be 1 blank line between the last title line and the solid line.

Table 14.x.y-z

First Line of Title

Second Line of Title if Needed

Safety Analysis Set

6.1.4 Column Headers

1) Column headings will be displayed immediately below the solid line described above, in initial upper-case characters.
2) For numeric variables, units will be included in column or row heading when appropriate.
3) Analysis set sizes will be provided for each treatment group in the column heading as (N=xx) (or in the row headings if applicable). This is distinct from the 'n' used for the descriptive statistics representing the number of subjects in the analysis set.
4) The treatment in the tables and listings will be: Mogamulizumab 1 mg/kg + Nivolumab 240 mg, Mogamulizumab 0.3 mg/kg + Nivolumab 240 mg (if applicable), and Total (if applicable).

6.1.5 Body of the Data Display

1) Listings will be sorted for presentation in order of cohort (Phase 1, Phase 2: NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, and Pancreatic), subject ID, collection day, and collection time.
2) If the categories of a parameter are ordered, then all categories between the maximum and minimum category will be provided in the table, even if n=0 for all treatment groups in a given category that is between the minimum and maximum level for that parameter. For example, the frequency distribution for symptom severity would appear as:

Severity	n

Rating	
severe	0
moderate	8
mild	3

Where percentages are provided in these tables, any counts of 0 will appear as 0, not as 0 (0%).

3) If the categories are not ordered (e.g., Medical History, Reasons for Discontinuation from the Study, etc.), then only those categories for which there is at least 1 subject represented in 1 or more groups will be included.

4) An Unknown or Missing category will be added to the summary of any categorical parameter for which information is not available for 1 or more subjects.

5) Unless otherwise specified, the estimated mean and median for a set of values will be presented to 1 more significant digit than the original values, and standard deviations will be presented to 2 more significant digits than the original values. The minimum and maximum will be presented with the same number of significant digits as the original values. For example, for systolic blood pressure:

n	XX
Mean	XXX.X
Std Dev	X.XX
Median	XXX.X
Minimum	XXX
Maximum	XXX

6) Data in columns of a table will be formatted as follows:

   - alphanumeric values left-justified;
   - whole numbers (e.g., counts) right-justified; and
   - numbers containing fractional portions decimal-aligned.

7) Percentage values will be formatted with 1 digit to the right of the decimal point in parentheses, 1 space after the count (e.g., 7 (12.8%), 13 (5.4%)). Less-than signs (e.g., "< 0.1%") will appear when values are >0.0% and <0.1% (but not equal to 0.0%). Unless otherwise noted, for all percentages, the number of subjects in the analysis set for the treatment group who have an observation will be the denominator.

8) Tabular displays of data for prior/concomitant medications and all tabular displays of adverse event data will be provided by the body system, drug class, or SOC with the highest occurrence in the overall total group, in decreasing order. Within the body system, drug class and SOC, medical history (by PT), drugs (by ATC code), and adverse events (by PT) will be displayed in decreasing order. If the incidences for multiple terms are identical, they will be sorted alphabetically.

9) Missing data will be represented on subject listings as either a hyphen ("-") with a corresponding footnote (" - = unknown or not evaluated"), or as "N/A" (footnote "N/A = not applicable"), whichever is appropriate. Missing descriptive statistics or p-values due to non-estimability will be reported as "-".

10) Dates will be formatted in SAS®ISO date format yyyy-mm-dd (e.g., "2000-07-01"). Missing portions of dates will be represented on subject listings as blank (e.g., "2000-07"). Dates that are missing because they are not applicable for the particular subject will be presented as "N/A", unless otherwise specified.

11) All observed time values will be presented using a 24-hour clock in hh:mm:ss format (e.g., "01:35:45", "21:26"). Time values will be reported only if they were measured as part of the study.

6.1.6 Footnotes

1) A solid line spanning the margins will separate the body of the data display from the footnotes.

2) All footnotes will be left justified with single-line spacing immediately below the solid line underneath the data display.

3) Informational footnote will begin with "Note:". Annotation footnotes will begin with an asterisk and other non-numeric symbol. Each new footnote will start on a new line.

4) Footnotes will appear on each page. Subject specific footnotes will be avoided.

5) Footnotes will be used sparingly, and only if they add value to the table, figure, or data listing. If a data display has more than 4 footnotes, they will all appear on a cover page for the data display; only those footnotes essential to comprehension of the data will be repeated on each page. Footnotes will not repeat definitions already provided in the SAP.

6) The last line of the footnote section will be a standard source line, indicating the data source used by the SAS program that produced the data display, the name of the SAS program, and the listing source (e.g., "Data source: xyzabc.sas7bdat Program source: myprogram.sas Listing source: 16.x.y.z").

6.2 Data-Handling Rules

This section describes naming conventions and rules for calculations common to all applicable tables. Some rules specific to a table can be found in the relevant mock-ups.

6.2.1 Unit Conversion to Months

If months are calculated for a duration, the following conversion is used.

1) Duration (months): {Duration (days)} / 30.4

6.2.2 Visits

1) Relative Study Day: The first day of any IMP is Day 1. A minus (-) sign indicates days prior to the start of IMP (e.g., Day -5 represents 5 days before start of therapy. There is no Day 0.). The relative study day for a specific visit is calculated as (Visit Date – Date of First Dose +1).
2) Baseline: For all study variables, baseline is defined as the last measurement obtained prior to the first dose of the IMP.

6.2.3 Demographics and Baseline Characteristics

1) Age = (Date of informed consent–Date of birth + 1) / 365.25 and truncated to complete years.
2) Conversion factors and calculations for height, weight and BSA:
   - Height (in cm) = height (in inches) * 2.54
   - Weight (in kg) = weight (in lbs) * 0.4536

6.2.4 Prior and Concomitant Medications

1) Prior and concomitant medications will be coded and classified using the World Health Organization (WHO) Drug Dictionary (version September 2015). The specific dictionary version will appear in the actual tables/listings.
2) Counting rules for prior/concomitant medications: Prior medications include medications that were taken within 30 days prior to study entry. Concomitant medications during the treatment period include medications that started at any time and were taken at any time after the start of IMP until 30 days after the last dose of the IMP.
3) Medications missing both start and stop dates, or having a start date prior to 30 days post the last dose of IMP and missing the stop date, or having a stop date after the start of IMP and missing the start date, will be counted as concomitant. When partial dates are present in the data, both a partial start date and/or a partial stop date will be

evaluated to determine whether it can be conclusively established that the medication either ended prior to the start of IMP or started after 30 days post the last dose of IMP. If the above cannot be conclusively established based on the partial and/or present dates, then the medication will be counted as concomitant.

6.2.5 Safety

1) Adverse events will be coded and classified using MedDRA 18.1. The specific dictionary version will appear in the actual tables/listings.
2) Counting rules for AEs: AEs with missing start dates, but with stop dates either overlapping the treatment period or missing, will be counted as treatment-emergent, taking the worst-case approach. Special care will be taken regarding partial dates, applying similar logic to that of the prior/concomitant medications.
3) For purposes of flagging individual subject data, laboratory test result abnormalities are defined as values above or below the normal range.

6.2.6 SAS® Procedures

This section provides sample SAS® code to illustrate statistical analyses specified in the statistical methods section. All computer output from SAS® statistical procedures serving as a basis for extracted results (e.g., LIFETEST) will be retained for quality control procedures and will be included in CSR appendices.

1) Exact 95% confidence interval on BOR (CR/PR):

```
proc freq;
        by trt;
        table resp / binomial;
run;
```

2) Median survival time with 95% confidence interval:

```
proc lifetest outsurv=surv;
time tte*censor(0);
strata trt;
run;
```

Note: 95% confidence intervals for time intervals (e.g., 3 months, 6 months, etc.) will be extracted from data set *SURV*.

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Table 14.1.1.1
Subject Disposition
All Subjects Enrolled in Phase 1 (Dose Finding)

	Mogamulizumab 1 mg/kg + Nivolumab 240 mg n (%)
Subjects Enrolled	xx (100.0)
Subjects Enrolled and Did Not Receive Any Study Drug	xx (xx.x)
Subjects Enrolled and Treated	xx (xx.x)
Subjects Who Were Replaced	xx (xx.x)
Subjects Who Completed Treatment Per Protocol	xx (xx.x)
Subjects Discontinued from Study Treatment Phase	xx (xx.x)
Objective disease progression	xx (xx.x)
Adverse event not related to cancer progression	xx (xx.x)
Clinical disease progression	xx (xx.x)
Subject withdrew consent	xx (xx.x)
Investigator discretion	xx (xx.x)
Lost to follow-up	xx (xx.x)
Complete treatment per protocol	xx (xx.x)
Study terminated	xx (xx.x)
Subjects with Ongoing Treatment [1]	xx (xx.x)
Subjects Discontinued from Follow-up	xx (xx.x)
Subject died	xx (xx.x)
Subject withdrew consent	xx (xx.x)
Lost to follow-up	xx (xx.x)
Study terminated	xx (xx.x)
Other	xx (xx.x)
Subjects with Ongoing Follow-up [1]	xx (xx.x)

Note: Percentage is calculated using the number of enrolled subjects as the denominator.
[1] Per Protocol Amendment 4 criteria.

Table 14.1.1.2
Subject Disposition
All Subjects Enrolled in Phase 2 (Cohort Expansion)

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg n (%)
Subjects Enrolled	xx (100.0)
Subjects Enrolled and Did Not Receive Any Study Drug	xx (xx.x)
Subjects Enrolled and Treated	xx (xx.x)
Subjects Who Were Replaced	xx (xx.x)
Subjects Who Completed Treatment Per Protocol	xx (xx.x)
Subjects Discontinued from Study Treatment Phase	xx (xx.x)
Objective disease progression	xx (xx.x)
Adverse event not related to cancer progression	xx (xx.x)
Clinical disease progression	xx (xx.x)
Subject withdrew consent	xx (xx.x)
Investigator discretion	xx (xx.x)
Lost to follow-up	xx (xx.x)
Study terminated	xx (xx.x)
Subjects Who are Ongoing with Treatment	xx (xx.x)
Subjects Discontinued from Follow-up	xx (xx.x)
Subject died	xx (xx.x)
Subject withdrew consent	xx (xx.x)
Lost to follow-up	xx (xx.x)
Study terminated	xx (xx.x)
Other	xx (xx.x)
Subjects Who are Ongoing with the Study	xx (xx.x)

Note: Percentage is calculated using the number of enrolled subjects as the denominator.

Programming note: First page of this table is for "All Cancer Types; subsequent pages are for NSCLC SQ, NSCLC NSQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately. "Ongoing" rows will be removed after DBL.

Table 14.1.1.3
Data Sets Analyzed
All Subjects Enrolled

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg n (%)
Subjects Enrolled	xx (100.0)
Safety Analysis Set	xx (xx.x)
Reason for Exclusion from Analysis Set	
Did not receive any study drug	xx (xx.x)
Efficacy Analysis Set	xx (xx.x)
Reason for Exclusion from Analysis Set	
Did not receive combination medication at cycle 1 day 1	xx (xx.x)
Did not receive Mogamulizumab at cycle 1 day 1	xx (xx.x)
Did not receive Nivolumab at cycle 1 day 1	xx (xx.x)
Pharmacokinetic Analysis Set	xx (xx.x)
Reason for Exclusion from Analysis Set	
Did not have any post baseline concentration	xx (xx.x)
ADA Analysis Set for Mogamulizumab antibody	xx (xx.x)
Reason for Exclusion from Analysis Set	
Did not have baseline sample	xx (xx.x)
Did not have any post baseline sample	xx (xx.x)

Note: Percentage is calculated using the number of enrolled subjects as the denominator.

Programming note: First page of this table is for "All Cancer Types; subsequent pages are for Phase 1 Cohort, NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.1.2.1.1
Demographic and Baseline Disease Characteristics
Safety Analysis Set

Variable Statistic/Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
Age (years) at time of informed consent	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Age Group (n, %)	
<65 years	xx (xx.x)
>=65 years	xx (xx.x)
Gender (n, %)	
Male	xx (xx.x)
Female	xx (xx.x)
Child-bearing potential	xx (xx.x)
Race (n, %)	
White	xx (xx.x)
Asian	xx (xx.x)
Black or African American	xx (xx.x)
American Indian or Alaska Native	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)
Not reported	xx (xx.x)
Other	xx (xx.x)
Ethnicity (n, %)	
Hispanic or latino	xx (xx.x)
Not hispanic or latino	xx (xx.x)
Not reported	xx (xx.x)
Unknown	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of the study drug.

[2] Time from initial diagnosis (months) is calculated as (date of the first dose – date of initial diagnosis + 1)/30.4. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation. Similar calculation and imputation rules are applied for time from local advancement/metastatic disease.
[3] Sum of packs for cigarettes and chewing tobacco.
Note: Tobacco use includes number of pack-years that is estimated, such as '>40' being considered as 40 pack-years.

Table 14.1.2.1.1
Demographic and Baseline Disease Characteristics
Safety Analysis Set

Variable Statistic/Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
ECOG Performance Status [1] (n, %)	
0	xx (xx.x)
1	xx (xx.x)
Height (cm)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Weight (kg) [1]	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Primary Tumor Type (n, %)	
NSCLC	xx (xx.x)
Pancreatic	xx (xx.x)
SCCHN	xx (xx.x)
…	

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of the study drug.
[2] Time from initial diagnosis (months) is calculated as (date of the first dose– date of initial diagnosis + 1)/30.4. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation. Similar calculation and imputation rules are applied for time from local advancement/metastatic disease.
[3] Sum of packs for cigarettes and chewing tobacco.
Note: Tobacco use includes number of pack-years that is estimated, such as '>40' being considered as 40 pack-years.

Table 14.1.2.1.1
Demographic and Baseline Disease Characteristics
Safety Analysis Set

Variable Statistic/Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
Time from Initial Diagnosis to First Dose Date (months) [2]	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Time from First Recurrence or Local Advancement to First Dose Date (months) [2]	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Time from First Presentation with Distant Metastatic Disease to First Dose Date (months) [2]	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of the study drug.
[2] Time from initial diagnosis (months) is calculated as (date of the first dose– date of initial diagnosis + 1)/30.4. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation. Similar calculation and imputation rules are applied for time from local advancement/metastatic disease.
[3] Sum of packs for cigarettes and chewing tobacco.
Note: Tobacco use includes number of pack-years that is estimated, such as '>40' being considered as 40 pack-years.

Table 14.1.2.1.1
Demographic and Baseline Disease Characteristics
Safety Analysis Set

Variable Statistic/Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
Stage at Enrollment (n, %)	
Locally Advanced	xx (xx.x)
Metastatic	xx (xx.x)
EGFR mutation (n, %)	
Positive	xx (xx.x)
Negative	xx (xx.x)
Other	xx (xx.x)
Not Done	xx (xx.x)
ALK rearrangement (n, %)	
Positive	xx (xx.x)
Negative	xx (xx.x)
Other	xx (xx.x)
Not Done	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of the study drug.
[2] Time from initial diagnosis (months) is calculated as (date of the first dose- date of initial diagnosis + 1)/30.4. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation. Similar calculation and imputation rules are applied for time from local advancement/metastatic disease.
[3] Sum of packs for cigarettes and chewing tobacco.
Note: Tobacco use includes number of pack-years that is estimated, such as '>40' being considered as 40 pack-years.

Table 14.1.2.1.1
Demographic and Baseline Disease Characteristics
Safety Analysis Set

Variable Statistic/Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
HPV infection (n, %)	
Positive	xx (xx.x)
Negative	xx (xx.x)
Unequivocal	xx (xx.x)
Other	xx (xx.x)
Not Done	xx (xx.x)
Oncogene assessment (n, %)	
KRAS	xx (xx.x)
ROS1	xx (xx.x)
BRAF	xx (xx.x)
…	

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of the study drug.
[2] Time from initial diagnosis (months) is calculated as (date of the first dose– date of initial diagnosis + 1)/30.4. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation. Similar calculation and imputation rules are applied for time from local advancement/metastatic disease.
[3] Sum of packs for cigarettes and chewing tobacco.
Note: Tobacco use includes number of pack-years that is estimated, such as '>40' being considered as 40 pack-years.

Table 14.1.2.1.1
Demographic and Baseline Disease Characteristics
Safety Analysis Set

Variable Statistic/Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
MSI (n, %)	
PCR Assay	
MSI H	xx (xx.x)
MSI L	xx (xx.x)
MSS	xx (xx.x)
Other	xx (xx.x)
Not done	xx (xx.x)
IHC Assay	
Positive	xx (xx.x)
Negative	xx (xx.x)
Other	xx (xx.x)
Not done	xx (xx.x)
Tobacco use (n, %)	
No	xx (xx.x)
Yes	xx (xx.x)
Former	xx (xx.x)
Current	xx (xx.x)
Cigarettes only (pack-years)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of the study drug.
[2] Time from initial diagnosis (months) is calculated as (date of the first dose– date of initial diagnosis + 1)/30.4. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation. Similar calculation and imputation rules are applied for time from local advancement/metastatic disease.
[3] Sum of packs for cigarettes and chewing tobacco.
Note: Tobacco use includes number of pack-years that is estimated, such as '>40' being considered as 40 pack-years.

Table 14.1.2.1.1
Demographic and Baseline Disease Characteristics
Safety Analysis Set

Variable Statistic/Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
Chewing tobacco only (pack-years)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Both Cigarettes and Chewing tobacco (pack-years) [3]	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of the study drug.
[2] Time from initial diagnosis (months) is calculated as (date of the first dose– date of initial diagnosis + 1)/30.4. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation. Similar calculation and imputation rules are applied for time from local advancement/metastatic disease.
[3] Sum of packs for cigarettes and chewing tobacco.
Note: Tobacco use includes number of pack-years that is estimated, such as '>40' being considered as 40 pack-years.

Same template will be used for the following table:

Table 14.1.2.1.2
Demographic and Baseline Disease Characteristics
Efficacy Analysis Set

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately. Only the MTD group will be presented.

Table 14.1.2.2
Prior Cancer Therapy
Safety Analysis Set

All Cancer Types

Variable Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
Number of Prior Cancer Regimens (n, %)	
No prior cancer therapy	xx (xx.x)
Has prior cancer therapy [1]	xx (xx.x)
1	xx (xx.x)
2	xx (xx.x)
3	xx (xx.x)
4	xx (xx.x)
5	xx (xx.x)
≥ 6	xx (xx.x)
Best Response for the most recent cancer regimen (n, %)	
Has prior cancer therapy [1]	xx
CR	xx (xx.x)
PR	xx (xx.x)
SD	xx (xx.x)
PD	xx (xx.x)
Not applicable	xx (xx.x)
Unknown	xx (xx.x)
Radiation Therapy (n, %)	
Yes	xx (xx.x)
No	xx (xx.x)
Cancer Surgery (n, %)	
Yes	xx (xx.x)
No	xx (xx.x)
Other Type of Cancer Therapy (n, %)	
Yes	xx (xx.x)
Laser Treatment	xx (xx.x)
Intralesion Injection	xx (xx.x)
Other	xx (xx.x)
No	xx (xx.x)

[1] Number of subjects with at least one prior cancer therapy is used as the denominator for percentage calculation in the subsequent categories.
Note: Percentage is calculated using the number of subjects in the column heading as the denominator.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.1.2.3
Post Treatment Cancer Therapy
Safety Analysis Set

All Cancer Types

Variable Category	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
Number of Post Treatment Cancer Regimens (n, %)	
1	xx (xx.x)
2	xx (xx.x)
3	xx (xx.x)
>3	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.1.2.4.1
Summary of Prior Medications (Excluding Cancer Therapy)
Safety Analysis Set

All Cancer Types

ATC Classification Preferred Term	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx n (%)
Any Subjects with Prior Medication, Total	xx (xx.x)
ATC Classification 1	xx (xx.x)
Preferred Term 1	xx (xx.x)
Preferred Term 2	xx (xx.x)
Preferred Term 3	xx (xx.x)
	xx (xx.x)
ATC Classification 2	
Preferred Term 1	xx (xx.x)
Preferred Term 2	xx (xx.x)
Preferred Term 3	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. WHO Drug Dictionary (September, 2015) was used for coding.
Medications with start dates within 30 days of the first dose date of the study treatment, and ended prior to the first dose date of the study treatment are presented.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.1.2.4.2
Summary of Concomitant Medications (Excluding Cancer Therapy)
Safety Analysis Set

All Cancer Types

ATC Classification Preferred Term	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx n (%)
Any Subjects with Concomitant Medication, Total	xx (xx.x)
ATC Classification 1	xx (xx.x)
Preferred Term 1	xx (xx.x)
Preferred Term 2	xx (xx.x)
Preferred Term 3	xx (xx.x)
	xx (xx.x)
ATC Classification 2	
Preferred Term 1	xx (xx.x)
Preferred Term 2	xx (xx.x)
Preferred Term 3	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. WHO Drug Dictionary (September, 2015) was used for coding
Medications that started at any time until 30 days after the last dose date, and were taken at any time after the first dose date are presented.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Repeat for the following:

Table 14.1.2.5.1
Summary of Prior Cancer Therapy
Safety Analysis Set

Table 14.1.2.5.2
Summary of Post Treatment Cancer Therapy
Safety Analysis Set

Table 14.1.2.6.1
Summary of Prior Steroids and Immune Modulating Medications by Reason for Administration
Safety Analysis Set

[Note: Use Reasons: Medical History Condition, Prophylaxis, Adverse Event]
All Cancer Types: Reason for administration = Medical History Condition

ATC Classification Preferred Term	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx n (%)
Any Subjects with Prior Steroid and Immune Modulating Medication, Total	xx (xx.x)
ATC Classification 1	xx (xx.x)
Preferred Term 1	xx (xx.x)
Preferred Term 2	xx (xx.x)
Preferred Term 3	xx (xx.x)

Followed by
[All Cancer Types: Reason for administration = Prophylaxis]
[All Cancer Types: Reason for administration = Adverse Event]

Programming note: Add footnote "Medications with start dates within 30 days of the first dose date of the study treatment, and ended prior to the first dose date of the study treatment are presented.".

Table 14.1.2.6.2
Summary of Concomitant Steroids and Immune Modulating Medications by Reason for Administration
Safety Analysis Set

[Note: Use Reasons: Medical History Condition, Prophylaxis, Adverse Event. Add footnote: Medications that started at any time until 30 days after the last dose date, and were taken at any time after the first dose date are presented.]

Table 14.1.2.6.3
Summary of Prior Steroids and Immune Modulating Medications by Route of Administration
Safety Analysis Set

[Note: Use Systemic Use, Topical. Defined as
Systemic = (Oral, Intravenous, Injection, Intrahepatic, Nasogastric, Intramuscular, Intrapleural, INTRAMUSCULAR, Subcutaneous, Epidural)
Topical = (Topical, Intraocular, Nasal, Respiratory, Rectal, Vaginal, Transdermal, Sublingual)
Add footnote "Medications with start dates within 30 days of the first dose date of the study treatment, and ended prior to the first dose date of the study treatment are presented.".]

Table 14.1.2.6.4
Summary of Concomitant Steroids and Immune Modulating Medications by Route of Administration
Safety Analysis Set

[Note: Use Systemic Use, Topical. Defined as
Systemic = (Oral, Intravenous, Injection, Intrahepatic, Nasogastric, Intramuscular, Intrapleural, INTRAMUSCULAR, Subcutaneous, Epidural)
Topical = (Topical, Intraocular, Nasal, Respiratory, Rectal, Vaginal, Transdermal, Sublingual). Add footnote: Medications that started at any time until 30 days after the last dose date, and were taken at any time after the first dose date are presented.]]

Table 14.1.3.1.1
Summary of Extent of Exposure to Mogamulizumab
Subjects in Phase 1 (Dose Finding)

	Mogamulizumab 1 mg/kg + Nivolumab 240 mg N=xxx
Number of Cycles per Subject	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Cycle Initiated (n, %)	
Cycle 1 Day 1	xx (xx.x)
Cycle 1 Day 8	xx (xx.x)
Cycle 1 Day 15	xx (xx.x)
Cycle 1 Day 22	xx (xx.x)
Cycle 2 Day 1	xx (xx.x)
Cycle 2 Day 15	xx (xx.x)
…	xx (xx.x)
Maximum Cycle Initiated (n, %)	
1	xx (xx.x)
2	xx (xx.x)
3	xx (xx.x)
…	
Number of Infusions	
n	xx
Total [1]	xxx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx

[1] Total number of infusions among all subjects in the treatment group.
[2] Last dose infusion – First dose infusion + 1

[3] {[(Number of doses administered in cycle 1 + (Number of doses administered post cycle 1 x 2))/(Number of cycles initiated x 4)] × [Number of initiated cycles × 28/((Last dose date + n*)-First dose date)]} x 100, where n* = 7 when the patient was only treated for 1 cycle, otherwise, n* = 14.

Table 14.1.3.1.1
Summary of Extent of Exposure to Mogamulizumab
Subjects in Phase 1 (Dose Finding)

	Mogamulizumab 1 mg/kg + Nivolumab 240 mg N=xxx
Extent of Exposure (days) [2]	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Cumulative Actual Dose (mg/kg)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Cumulative Assigned Dose (mg/kg)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Relative Dose Intensity (%) [3]	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Number of Patients with Dose Intensity of	
<70%	xx (xx.x)
>=70% - <90%	xx (xx.x)

	Mogamulizumab 1 mg/kg + Nivolumab 240 mg N=xxx
>=90% - <110%	xx (xx.x)
>=110%	xx (xx.x)

[1] Total number of infusions among all subjects in the treatment group.
[2] Last dose infusion – First dose infusion + 1
[3] {Number of doses administered/[(Number of cycles initiated-1) ×2 + 4] × [Number of initiated cycles × 28/[(Last dose date + n*)-First dose date]]} x 100, where n* = 7 when the patient was only treated for 1 cycle, otherwise, n* = 14.

Same template will be used for the following table for Phase 2 subjects:

Table 14.1.3.1.2
Summary of Extent of Exposure to Mogamulizumab
Subjects in Phase 2 (Cohort Expansion)

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately. Only the MTD group will be presented.

Table 14.1.3.2.1
Summary of Extent of Exposure to Nivolumab
Subjects in Phase 1 (Dose Finding)

		Mogamulizumab 1 mg/kg + Nivolumab 240 mg N=xxx
Number of Cycles per Subject	xx	
n	xx.x	
Mean	xx.xx	
Std Dev	xx.x	
Median	xx	
Minimum	xx	
Maximum		
Cycle Initiated (n, %)		xx (xx.x)
Cycle 1 Day 1		xx (xx.x)
Cycle 1 Day 15		xx (xx.x)
Cycle 2 Day 1		xx (xx.x)
Cycle 2 Day 15		xx (xx.x)
…		xx (xx.x)
		xx (xx.x)
Maximum Cycle Initiated (n, %)		
1		
2		xx (xx.x)
3		xx (xx.x)
…		xx (xx.x)
Number of Infusions		
n		
Total [1]	xx	
Mean	xx.x	
Std Dev	xx.xx	
Median	xx.x	
Minimum	xx	
Maximum	xx	

[1] Total number of infusions among all subjects in the treatment group.
[2] Last dose infusion − First dose infusion + 1
[3] Cumulative dose (mg) / Cumulative assigned dose (mg) x 100, where cumulative assigned dose = (Last nivolumab dose date − First nivolumab dose date) × 240/14

Table 14.1.3.2.1
Summary of Extent of Exposure to Nivolumab
Subjects in Phase 1 (Dose Finding)

	Mogamulizumab 1 mg/kg + Nivolumab 240 mg N=xxx
Extent of Exposure (days) [2]	xx
N	xx.x
Mean	xx.xx
Std Dev	xx.x
Median	xx
Minimum	xx
Maximum	
Cumulative Actual Dose (mg)	xx
N	xx.x
Mean	xx.xx
Std Dev	xx.x
Median	xx
Minimum	xx
Maximum	
Cumulative Assigned Dose (mg)	xx
n	xx.x
Mean	xx.xx
Std Dev	xx.x
Median	xx
Minimum	xx
Maximum	
Relative Dose Intensity (%) [3]	xx
n	xx.x
Mean	xx.xx
Std Dev	xx.x
Median	xx
Minimum	xx
Maximum	

[1] Total number of infusions among all subjects in the treatment group.
[2] Last dose infusion – First dose infusion + 1

[3] Cumulative dose (mg) / Cumulative assigned dose (mg) x 100, where cumulative assigned dose = (Last nivolumab dose date – First nivolumab dose date) × 240/14

Same template will be used for the following table for Phase 2 subjects:

Table 14.1.3.2.2
Summary of Extent of Exposure to Nivolumab
Subjects in Phase 2 (Cohort Expansion)

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately. Only the MTD group will be presented.

Table 14.1.3.3.1
Summary of Mogamulizumab Infusion Time
Subjects in Phase 1 (Dose Finding)

	Mogamulizumab 1 mg/kg + Nivolumab 240 mg N=xxx
Overall (minutes)	
n (number of infusions)	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
First Infusion (minutes)(Cycle 1, Day 1)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Repeats for Second Infusion (Cycle 1, Day 8), Third Infusion (Cycle 1, Day 15), and Forth Infusion (Cycle 1, Day 22)	
Fifth Infusion or Later (minute)	
n (number of infusions)	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx

Same template will be used for the following table:

Table 14.1.3.3.2
Summary of Mogamulizumab Infusion Time
Subjects in Phase 2 (Cohort Expansion)

Programming note: This table is for all cancer types only. Display: "All Cancer Types". Only the MTD group will be presented.

Table 14.1.3.4.1
Summary of Nivolumab Infusion Time
Subjects in Phase 1 (Dose Finding)

	Mogamulizumab 1 mg/kg + Nivolumab 240 mg N=xxx
Overall (minutes)	
n (number of infusions)	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
First Infusion (minutes) (Cycle 1, Day 1)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Second Infusion (minutes) (Cycle 1, Day 15)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
Third Infusion or Later (minutes)	
n (number of infusions)	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx

Same template will be used for the following table:

Table 14.1.3.4.2
Summary of Nivolumab Infusion Time
Subjects in Phase 2 (Cohort Expansion)

Programming note: This table is for all cancer types. Display: "All Cancer Types". Only the MTD group will be presented.

Table 14.2.1.1
Summary of Best Overall Response
Efficacy Analysis Set

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx n (%)
By RECIST v1.1	
Number of Subjects with CR or PR (n, %, 95% CI [1])	xx (xx.x) [xx.x, xx.x]
Complete response [CR]	xx (xx.x)
Partial response [PR]	xx (xx.x)
Stable disease [SD]	xx (xx.x)
Progressive disease [PD]	xx (xx.x)
Inevaluable [NE]	xx (xx.x)
By **irRECIST v1.1**	
Number of Subjects with CR or PR (n, %, 95% CI [1])	xx (xx.x) [xx.x, xx.x]
Complete response [CR]	xx (xx.x)
Partial response [PR]	xx (xx.x)
Non-CR/PR	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. Best overall response is defined as the best response designation recorded between the date of first dose of investigational medical product (IMP) and the date of subsequent anti-cancer therapy (excluding on-treatment palliative radiotherapy of non-target bone or CNS lesions). Subjects who do not meet CR/PR will be classified as stable disease (SD) if assessed as SD (or better) at least 9 weeks after first dose of IMP.
[1] Exact 2-sided 95% confidence intervals using Clopper-Pearson method.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.2.1.2
Sensitivity Summary of Best Overall Response
Efficacy Analysis Set

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx n (%)
By RECIST v1.1	
Number of Subjects with CR or PR (n, %, 95% CI [1])	xx (xx.x) [xx.x, xx.x]
Complete response [CR]	xx (xx.x)
Partial response [PR]	xx (xx.x)
Stable disease [SD]	xx (xx.x)
Progressive disease [PD]	xx (xx.x)
Inevaluable [NE]	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. Best overall response is defined as the best response designation recorded between the date of first dose of investigational medical product (IMP) to the first radiological disease progression or initiation of subsequent therapy, whichever occurred earlier. Subjects who do not meet CR/PR will be classified as stable disease (SD) if assessed as SD (or better) at least 9 weeks after first dose of IMP.
[1] Exact 2-sided 95% confidence intervals using Clopper-Pearson method.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.2.2.1
Summary of Time to Response for Subjects with Best Overall Response of CR or PR
Efficacy Analysis Set

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
By RECIST v1.1 (Primary Method [1])	
Time to Response (months)	
N	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx
By RECIST v1.1 (Sensitivity Analysis [2])	
Time to Response (months)	
n	xx
Mean	xx.x
Std Dev	xx.xx
Median	xx.x
Minimum	xx
Maximum	xx

Note: Time to response is calculated from the date of first dose of IMP to the first confirmed Complete Response [CR] or Partial Response [PR] using RECIST v1.1.
[1] The primary method is based on all tumor assessments until the start of subsequent anti-cancer therapy, regardless of progressive disease.
[2] The sensitivity analysis is based on all tumor assessments until the date of progressive disease or the start of subsequent anti-cancer therapy.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.2.3.1
Summary of Duration of Response for Subjects with Best Overall Response of CR or PR
Efficacy Analysis Set

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
By RECIST v1.1 (Primary Method [1])	
Number of Subjects with CR or PR	N'=xx
Subjects with Progressive Disease/Died (n, %)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)
Duration of Response (months)	
Kaplan-Meier Estimate	
25th Quartile (95% CI)	xx.x (xx.x, xx.x)
Median (95% CI)	xx.x (xx.x, xx.x)
75th Quartile (95% CI)	xx.x (xx.x, xx.x)
By RECIST v1.1 (Sensitivity Analysis [2])	
Number of Subjects with CR or PR	N'=xx
Subjects with Progressive Disease/Died (n, %)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)
Duration of Response (months)	
Kaplan-Meier Estimate	
25th Quartile (95% CI)	xx.x (xx.x, xx.x)
Median (95% CI)	xx.x (xx.x, xx.x)
75th Quartile (95% CI)	xx.x (xx.x, xx.x)

Note: Percentage is calculated using N' as the denominator. CR = complete response, PR = partial response. - = Not estimable.
Duration of response is calculated from the first date of confirmed CR/PR to the date of death or the date of first documented tumor progression, whichever is earlier, using RECIST v1.1.
[1] The primary method is based on all tumor assessments until the start of subsequent anti-cancer therapy, regardless of progressive disease.
[2] The sensitivity analysis is based on all tumor assessments until the date of progressive disease or the start of subsequent anti-cancer therapy.
Results for individual cancer types are not presented due to the limited number of subjects with Best Overall Response of CR or PR.

Programming note: First page of the table is for "All Cancer Types".

Table 14.2.4.1
Summary of Progression-Free Survival (PFS)
Efficacy Analysis Set

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
By RECIST v1.1	
Number of Subjects with PFS Event (n, %)	xx (xx.x)
Earliest Contributing Event:	
Progressive Disease	xx (xx.x)
Death	xx (xx.x)
Number of Subjects Censored (n, %)	xx (xx.x)
Progression-Free Survival (months)	
Kaplan-Meier Estimate of PFS	
25th Quartile (95% CI)	xx.x (xx.x, xx.x)
Median (95% CI)	xx.x (xx.x, xx.x)
75th Quartile (95% CI)	xx.x (xx.x, xx.x)
Rate (%) of Being Alive without Progression for at Least [1]	
3 months (95% CI)	xx.x (xx.x, xx.x)
6 months (95% CI)	xx.x (xx.x, xx.x)
9 months (95% CI)	xx.x (xx.x, xx.x)
12 months (95% CI)	xx.x (xx.x, xx.x)
Etc.	

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Kaplan-Meier estimate using Kalbfleisch and Prentice method.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.2.5.1
Summary of Overall Survival (OS)
Efficacy Analysis Set

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
Subjects Died (n, %)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)
Overall Survival (months)	
Kaplan-Meier Estimate of OS	
25th Quartile (95% CI)	xx.x (xx.x, xx.x)
Median (95% CI)	xx.x (xx.x, xx.x)
75th Quartile (95% CI)	xx.x (xx.x, xx.x)
Rate (%) of Being Alive for at Least [1]	
3 months (95% CI)	xx.x (xx.x, xx.x)
6 months (95% CI)	xx.x (xx.x, xx.x)
9 months (95% CI)	xx.x (xx.x, xx.x)
12 months (95% CI)	xx.x (xx.x, xx.x)
Etc.	

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Kaplan-Meier estimate using Kalbfleisch and Prentice method.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.3.1.1
Overview of Adverse Events
Safety Analysis Set

	Mogamulizumab x mg/kg + Nivolumab 240 mg	
	Cycle 1 N=xxx	Any Cycle N=xxx
Adverse Event Category	n (%)	n (%)
Any TEAEs	xx (xx.x)	xx (xx.x)
Any IMP-related	xx (xx.x)	xx (xx.x)
Mogamulizumab-related	xx (xx.x)	xx (xx.x)
Nivolumab-related	xx (xx.x)	xx (xx.x)
Any Grade >=3 TEAEs	xx (xx.x)	xx (xx.x)
Any IMP-related Grade >=3	xx (xx.x)	xx (xx.x)
Mogamulizumab-related Grade >=3	xx (xx.x)	xx (xx.x)
Nivolumab-related Grade >=3	xx (xx.x)	xx (xx.x)
Any Serious TEAEs	xx (xx.x)	xx (xx.x)
Any Serious Related	xx (xx.x)	xx (xx.x)
Serious Mogamulizumab-related	xx (xx.x)	xx (xx.x)
Serious Nivolumab-related	xx (xx.x)	xx (xx.x)
Discontinuation Due to TEAEs	xx (xx.x)	xx (xx.x)
TEAE led to Mogamulizumab discontinuation	xx (xx.x)	xx (xx.x)
TEAE led to Nivolumab discontinuation	xx (xx.x)	xx (xx.x)
Discontinuation Due to Related TEAEs	xx (xx.x)	xx (xx.x)
Mogamulizumab-related TEAE led to Mogamulizumab discontinuation	xx (xx.x)	xx (xx.x)
Nivolumab-related TEAE led to Nivolumab discontinuation	xx (xx.x)	xx (xx.x)
TEAEs with Fatal Outcome	xx (xx.x)	xx (xx.x)
Any IMP-related	xx (xx.x)	xx (xx.x)
Mogamulizumab-related	xx (xx.x)	xx (xx.x)
Nivolumab-related	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately. Only the MTD group will be presented.

Table 14.3.1.2
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Analysis Set

	Mogamulizumab x mg/kg + Nivolumab 240 mg	
	Cycle 1 N=xxx	Any Cycle N=xxx
System Organ Class Preferred Term	n (%)	n (%)
Subjects with Any TEAEs	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Etc. …		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. MedDRA Version 18.1 was used for coding.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately. Only the MTD group will be presented.

Same template as 14.3.1.2 will also be used for the following table:

Table 14.3.1.3.1
Number (%) of Subjects with Mogamulizumab-Related Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.3.2
Number (%) of Subjects with Nivolumab-Related Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.3.3
Number (%) of Subjects with Any IMP-Related Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.4
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class, Preferred Term, and Highest CTCAE Grade
Safety Analysis Set

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg	
System Organ Class Preferred Term Highest CTCAE Grade	Cycle 1 N=xxx n (%)	Any Cycle N=xxx n (%)
Subjects with Any TEAE	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)
Grade 5	xx (xx.x)	xx (xx.x)
Grade >=3	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)
Grade 5	xx (xx.x)	xx (xx.x)
Grade >=3	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)
Grade 5	xx (xx.x)	xx (xx.x)
Grade >=3	xx (xx.x)	xx (xx.x)
Etc.		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. If a subject experienced more than one adverse event within a preferred term, the subject will be counted once in that preferred term at the highest CTCAE grade. If a subject experienced more than one adverse event within an SOC, the subject will be counted once for that SOC at the highest CTCAE grade. MedDRA Version 18.1 was used for coding.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately. Only the MTD group will be presented.

The following table will have similar layout as Table 14.3.1.4:

Table 14.3.1.5.1
Number (%) of Subjects with Mogamulizumab-Related Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class, Preferred Term, and Highest CTCAE Grade
Safety Analysis Set

Table 14.3.1.5.2
Number (%) of Subjects with Nivolumab-Related Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class, Preferred Term, and Highest CTCAE Grade
Safety Analysis Set

Table 14.3.1.5.3
Number (%) of Subjects with Any IMP-Related Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class, Preferred Term, and Highest CTCAE Grade
Safety Analysis Set

The following tables will have similar layout as Table 14.3.1.2:

Table 14.3.1.6
Number (%) of Subjects with Grade >=3 Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.7.1
Number (%) of Subjects with Mogamulizumab-Related Grade >=3 Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.7.2
Number (%) of Subjects with Nivolumab-Related Grade >=3 Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.7.3
Number (%) of Subjects with Any IMP-Related Grade >=3 Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.8
Number (%) of Subjects with Treatment-Emergent Serious Adverse Events
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.9.1
Number (%) of Subjects with Mogamulizumab-Related Treatment-Emergent Serious Adverse Events
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.9.2
Number (%) of Subjects with Nivolumab-Related Treatment-Emergent Serious Adverse Events
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.9.3
Number (%) of Subjects with Any IMP-Related Treatment-Emergent Serious Adverse Events
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.10.1
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) Leading to Discontinuation of Mogamulizumab
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.10.2
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) Leading to Discontinuation of Nivolumab
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.10.3
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) Leading to Discontinuation of Any IMP
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.11.1
Number (%) of Subjects with Mogamulizumab-Related Treatment-Emergent Adverse Events (TEAEs) Leading to Mogamulizumab Discontinuation
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.11.2
Number (%) of Subjects with Nivolumab-Related Treatment-Emergent Adverse Events (TEAEs) Leading to Nivolumab Discontinuation
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.11.3
Number (%) of Subjects with Any IMP Related Treatment-Emergent Adverse Events (TEAEs) Leading to Any IMP Discontinuation
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.12
Number (%) of Subjects with Treatment-Emergent Fatal Adverse Events
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.13.1
Number (%) of Subjects with Mogamulizumab-Related Treatment-Emergent Fatal Adverse Events
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.13.2
Number (%) of Subjects with Nivolumab-Related Treatment-Emergent Fatal Adverse Events
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.13.3
Number (%) of Subjects with Any IMP-Related Treatment-Emergent Fatal Adverse Events
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.14
Number (%) of Subjects with Treatment-Emergent Infusion Reaction Adverse Events
By Preferred Term
Safety Analysis Set

Table 14.3.2.1
Summary of Clinical Laboratory Values and Change from Baseline During Treatment Period
Safety Analysis Set

All Cancer Types

Parameter	Mogamulizumab x mg/kg + Nivolumab 240 mg (N=xxx)	
Time Point		
Statistic	Actual	Change
XXX (Unit)		
Baseline		
n	xx	
Mean	xx.x	
Std Dev	xx.xx	
Median	xx.x	
Minimum	xx	
Maximum	xx	
End of Treatment		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx
Minimum Post-baseline Value		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx
Maximum Post-baseline Value		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx

Continue with other parameters

Programming note: This table is for all cancer types. Display: "All Cancer Types". This table will include all laboratory tests, i.e., hematology, coagulation, and chemistry parameters.

Table 14.3.2.2.1
Shift Table for Laboratory Parameters with Single Direction
Safety Analysis Set

All Cancer Types

			Mogamulizumab x mg/kg + Nivolumab 240 mg (N=xxx), n (%) Highest CTCAE Grade During Treatment Period			
Parameter (Unit)	N*	Baseline	Grade 0	Grade 1-2	Grade 3-4	Total
XXX (Unit)	xx	Grade 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 1-2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 3-4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.						

Note: Percentage is calculated using N* as the denominator, where it is the number of subjects with both baseline and post baseline measurements for the specified parameter.
Grade 0 indicates values that do not satisfy CTC abnormality criteria.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.3.2.2.2
Shift Table for Laboratory Parameters with Both Low and High Directions
Safety Analysis Set

All Cancer Types

			Mogamulizumab x mg/kg + Nivolumab 240 mg (N=xxx), n (%)					
			Highest CTCAE Grade During Treatment Period					
Parameter (Unit)	N*	Baseline	Grade 3-4 (Low)	Grade 1-2 (Low)	Grade 0	Grade 1-2 (High)	Grade 3-4 (High)	Total
			Highest Value					
XXX (Unit)	xx	Grade 3-4 (Low)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 1-2 (Low)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 1-2 (High)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 3-4 (High)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Lowest Value					
Etc.								

Note: Percentage is calculated using N* as the denominator, where it is the number of subjects with both baseline and post baseline measurements for the specified parameter.
Grade 0 indicates values that do not satisfy CTC abnormality criteria.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline During Treatment Period
Safety Analysis Set

All Cancer Types

Parameter Time Point Statistic	Mogamulizumab x mg/kg + Nivolumab 240 mg (N=xxx) Actual	 Change
Pulse Rate (bpm)		
Baseline		
n	xx	
Mean	xx.x	
Std Dev	xx.xx	
Median	xx.x	
Minimum	xx	
Maximum	xx	
End of Treatment		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx
Minimum Post-baseline Value		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx
Maximum Post-baseline Value		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx

Parameter Time Point Statistic	Mogamulizumab x mg/kg + Nivolumab 240 mg (N=xxx) Actual	 Change
Continue with other parameters		

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.
Same template as Table 14.3.3.1 will be used for:

Table 14.3.4.1
Summary of ECG Evaluations and Change from Baseline During Treatment Period
Safety Analysis Set

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.3.4.2
Number (%) of Subjects with Abnormal QTcB and QTcF (msec) During Treatment Period
Safety Analysis Set

All Cancer Types

Parameters Visit Criteria	Mogamulizumab x mg/kg + Nivolumab 240 mg n (%)
QTcB (msec)	
Baseline	N*=xx
>450 msec	xx (xx.x)
>480 msec	xx (xx.x)
>500 msec	xx (xx.x)
End of Treatment Visit	N*=xx
>450 msec	xx (xx.x)
>480 msec	xx (xx.x)
>500 msec	xx (xx.x)
Increase >30 msec	xx (xx.x)
Increase >60 msec	xx (xx.x)
Overall for Post-baseline [1]	N*=xx
>450 msec	xx (xx.x)
>480 msec	xx (xx.x)
>500 msec	xx (xx.x)
Increase >30 msec	xx (xx.x)
Increase >60 msec	xx (xx.x)

Continue for QTcF (msec)

Note: Percentage is calculated using N* as the denominator, where N* is the number of subjects with valid ECG measurement at the specified visit (time point).
[1] Any post-baseline measurement including both scheduled and unscheduled measurements.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.3.4.3
Shift Table for QTcB and QTcF (msec) from Baseline During Treatment Period
Safety Analysis Set

All Cancer Types

			Mogamulizumab x mg/kg + Nivolumab 240 mg (N=xxx), n (%) Most Severe Value During Treatment Period				
Parameters	N*	Baseline	<=450	>450 and <=480	>480 and <=500	>500	Total
QTcB (msec)	xxx	<=450	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>450 and <=480	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>480 and <=500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
QTcF (msec)	xxx	<=450	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>450 and <=480	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>480 and <=500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using N* as the denominator, where N* is the number of subjects with both baseline and post baseline QTcB or QTcF measurements.

Programming note: This table is for all cancer type. Display: "All Cancer Type". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Same template as Table 14.3.3.1 will be used for:

Table 14.3.5.1
Summary of Weight and Change from Baseline During Treatment Period
Safety Analysis Set

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.3.6.1
Worst ECOG Performance Status Result During Treatment Period
Safety Analysis Set

All Cancer Types

	Mogamulizumab x mg/kg + Nivolumab 240 mg N=xxx
Worst Post-Baseline ECOG, n (%)	N'=xx
0	xx (xx.x)
1	xx (xx.x)
2	xx (xx.x)
3	xx (xx.x)
4	xx (xx.x)

Percentage is calculated using N' as the denominator, where N' is the number of subjects with valid ECOG performance status measurement during treatment period.

Programming note: This table is for all cancer types. Display: "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.4.1.1
Summary of PK Parameters (Cmax and Cmin) of Mogamulizumab
Pharmacokinetic Analysis Set

All Cancer Types

Visit Statistics	Cmin (ng/mL) N=xxx	Cmax (ng/mL) N=xxx
Cycle 1, Day 1		
n	xx	xx
Mean (Std Dev)	xx.x (xx.xx)	xx.x (xx.xx)
CV (%)	xx.x	xx.x
Median	xx.x	xx.x
Minimum, Maximum	xx, xx	xx, xx
Geo Mean	xx.x	xx.x
Geo CV (%)	xx.x	xx.x
Cycle 1, Day 15		
n	xx	xx
Mean (Std Dev)	xx.x (xx.xx)	xx.x (xx.xx)
CV (%)	xx.x	xx.x
Median	xx.x	xx.x
Minimum, Maximum	xx, xx	xx, xx
Geo Mean	xx.x	xx.x
Geo CV (%)	xx.x	xx.x

Continue with visits of Cycle 2, Day 1; Cycle 2, Day 15; Cycle 3, Day 1; Cycle 4, Day 1; etc.

BLQ=Below the lower limit of quantification.

Programming note: First page of the table is for "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.5.1.1
Number (%) of Subjects with Positive Anti-Drug Antibody Response to Mogamulizumab
ADA Analysis Set

All Cancer Types

Visit	Mogamulizumab x mg/kg (N=xxx)	
	Anti-Mogamulizumab Antibody	Anti-Mogamulizumab Neutralizing Antibody
	n/N1 (%)	n/N2 (%)
Cycle 1/Day 1 (Baseline)	x/xx (xx.x)	x/xx (xx.x)
Overall	x/xx (xx.x)	x/xx (xx.x)
Cycle 2/Day 1	x/xx (xx.x)	x/xx (xx.x)
Cycle 3/Day 1	x/xx (xx.x)	x/xx (xx.x)
Cycle 4/Day 1	x/xx (xx.x)	x/xx (xx.x)
Cycle 8/Day 1	x/xx (xx.x)	x/xx (xx.x)
Cycle 12/Day 1	x/xx (xx.x)	x/xx (xx.x)
100-110 Days after Last Dose	x/xx (xx.x)	x/xx (xx.x)
During an Infusion-related Reaction	x/xx (xx.x)	x/xx (xx.x)

N1: Number of subjects with valid measurements for anti-mogamulizumab antibody at the specified visit
N2: Number of subjects who were positive for anti-mogamulizumab antibody at the specified visit
Overall is positive if at least one post-baseline assessment is positive, including unscheduled ADA assessments.

Programming note: This table is for all cancer types. Display: "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.5.2.1
Summary of Anti-Mogamulizumab Antibody Incidence
ADA Analysis Set

All Cancer Types

ADA Incidence				
Pre-existing n/N (%)	Anytime n/N (%)	Treatment-induced n/N1 (%)	Treatment-boosted n/N2 (%)	Neutralizing ADA Incidence n/N (%)
x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)

n: The number of subjects who were categorized at each item.
N1 : Number of subjects whose sample ADA status at pre-infusion in Cycle 1 Day 1 was "ADA-negative".
N2 : Number of subjects whose sample ADA status at pre-infusion in Cycle 1 Day 1 was "ADA-positive".

Programming note: This table is for all cancer types. Display: "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Table 14.5.3.1
Summary of Positive Anti-Mogamulizumab Antibody Response at Post-Baseline and Infusion Reaction
Safety Analysis Set

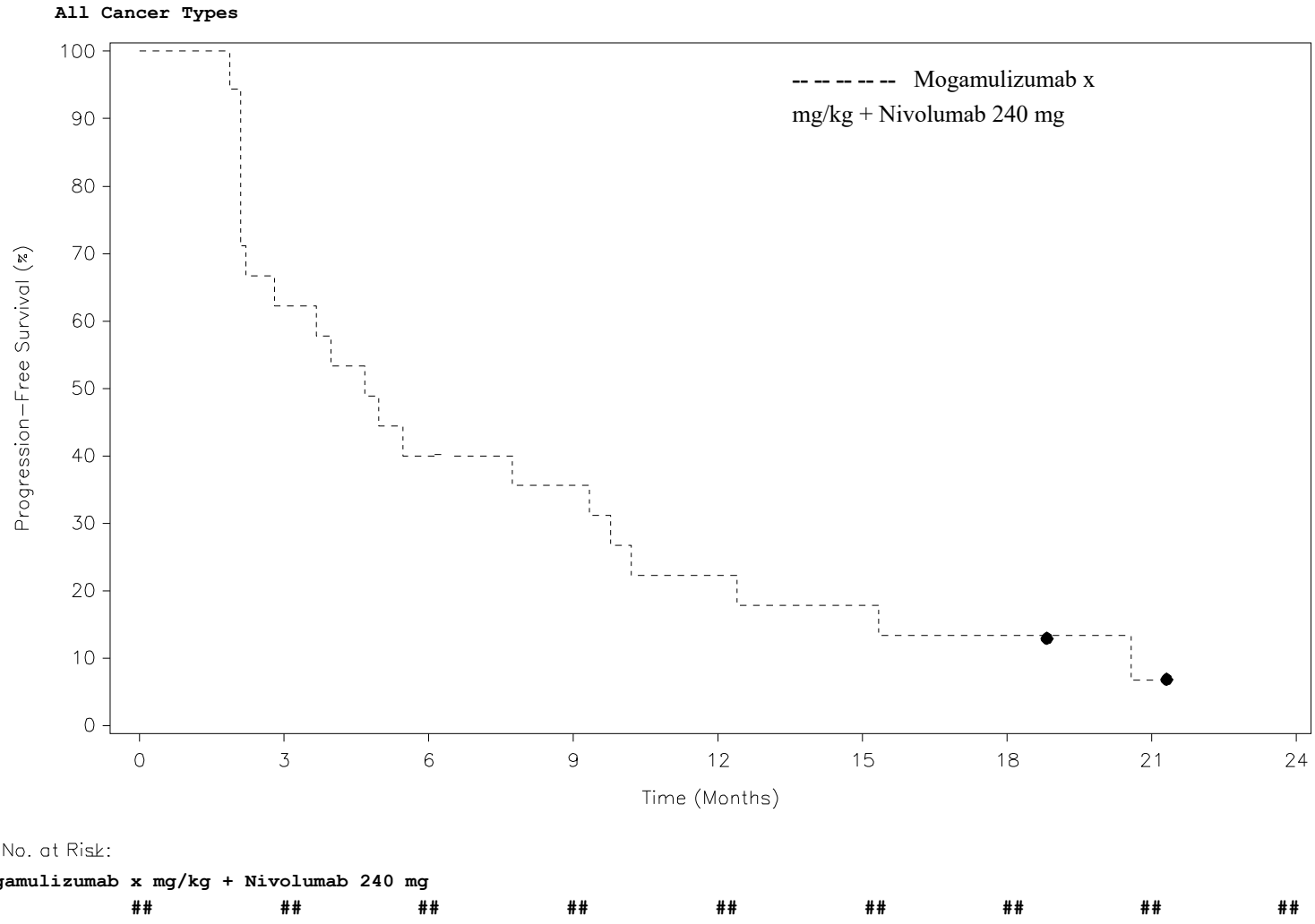
All Cancer Types

	All Subjects Exposed to Mogamulizumab N = xx n (%)
Number of Infusion Reactions (events)	xx
Number of Subjects who experienced Infusion Reactions	xx (xx.x)
Subjects who experienced Infusion Reaction and who had a positive overall assay at any time post-baseline	xx (xx.x)
Anti-Mogamulizumab antibody	xx (xx.x)
Neutralizing	xx (xx.x)

Note: Percentage is calculated using the number of subjects exposed to Mogamulizumab as the denominator.
Overall assay is positive if at least one of the two assays (Anti-Mogamulizumab antibody or neutralizing) is positive.

Programming note: This table is for all cancer types. Display: "All Cancer Types". Subsequent pages are for NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types separately.

Figure 14.2.1
Kaplan-Meier Curve of Progression-Free Survival
Efficacy Analysis Set



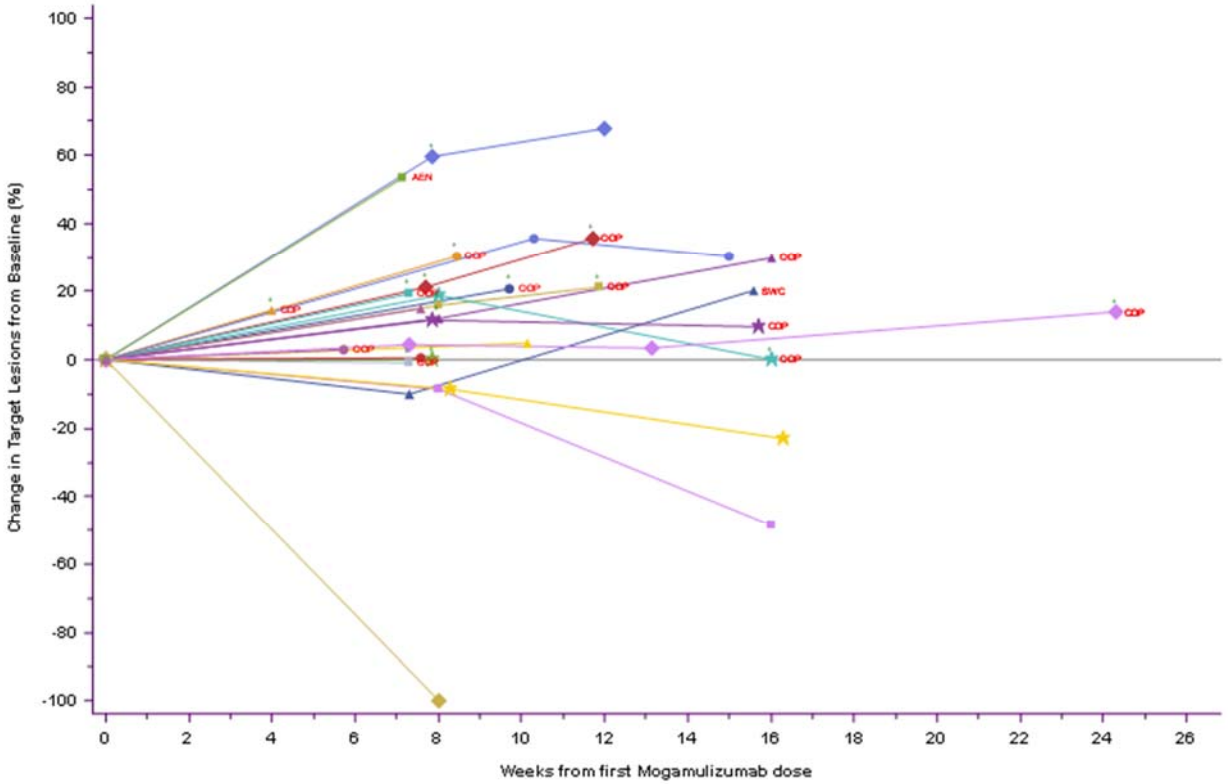
Programming note: includes all Phase 2 subjects separated by tumor type: NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types. An additional category for 'all cancer types' will be added to the graph as well. The "all cancer types" line weight needs to be higher than individual cancer type. The plot only includes groups that have >10 patients. Add footnote: "Note: All cancer type includes all patients in the study; for other groups, only groups where number of subjects >10 are included."

The following figures will have similar layout as Figure 14.2.1:

Figure 14.2.2
Kaplan-Meier Curve of Overall Survival
Efficacy Analysis Set

Programming note: includes all Phase 2 subjects separated by tumor types: NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types. An additional category for 'all cancer types' will be added to the graph as well. The plot only includes groups that have >10 patients. Add footnote: "Note: All cancer type includes all patients in the study; for other groups, only groups where number of subjects >10 are included."

Figure 14.2.3.1
Percent Change in Tumor Burden (RECIST v1.1)
Efficacy Analysis Set



Tumor burden is based on the sum of longest diameters in target lesions at each visit.
+ indicates new lesions.
Treatment discontinuation: AEN=Adverse Event Not Related to Cancer Progression, CDP=Clinical Disease Progression, ODP=Objective Disease Progression, SWC=Subject Withdrew Consent.

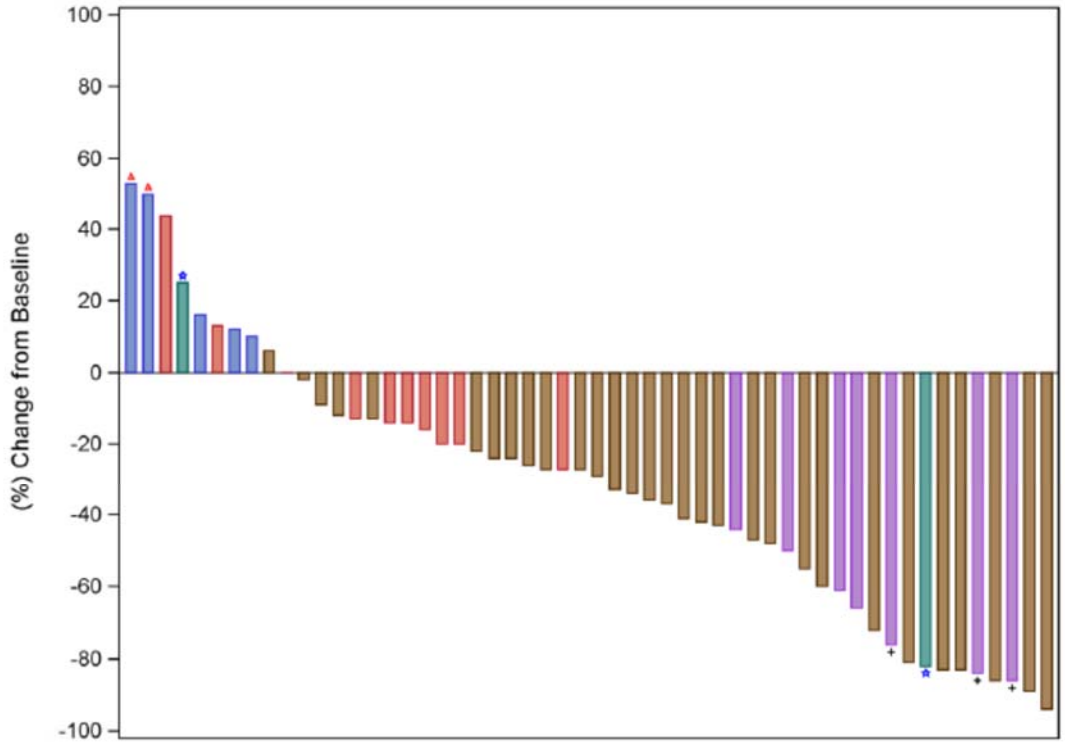
Programming note: includes all Phase 2 subjects, separated by tumor types: NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types. One cancer type is plotted on one page.

The following figures will have similar layout as Figure 14.2.3.1:

Figure 14.2.3.2
Percent Change in Tumor Burden (irRECIST v1.1)
Efficacy Analysis Set

[Note: the first footnote will be changed to
Tumor burden is based on the sum of longest diameters in target lesions at each visit. Target lesions include baseline-selected target lesion measurements and new measurable lesions.]

Figure 14.2.4.1.1
Maximum Percent Change in Tumor Burden by Best Overall Response(RECIST v1.1)
Efficacy Analysis Set



Programming note: includes all Phase 2 subjects, separated by tumor types: NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types. One cancer type is plotted on one page. For each cancer type, calculate the maximum % change of tumor burden from baseline, different color bar indicates patient's best overall response of CR, PR, SD, PD or NE. Additional symbols may be added to indicate threshold of increase/decrease (e.g., decrease >75%, increase >50%, etc.) if deemed meaningful.

[Note that, the BOR is defined the best response from first dose of IMP to the initiation of anti-cancer therapy.]

The following figures will have similar layout as Figure 14.2.4.1.1:

Figure 14.2.4.1.2
Sensitivity Analysis of Maximum Percent Change in Tumor Burden by Best Overall Response(RECIST v1.1)
Efficacy Analysis Set

[Note that, this sensitivity analysis considering BOR as from first dose of IMP to the first radiologic progressive disease or initiation of anti-cancer therapy.]

Figure 14.2.4.2
Maximum Percent Change in Tumor Burden by Best Overall Response(irRECIST v1.1)
Efficacy Analysis Set

Programming note: includes all Phase 2 subjects, separated by tumor types: NSCLC SQ, NSCLC NSQ PD-L1 non-expressing, Ovarian, CRC, SCCHN, HCC, Pancreatic cancer types. One cancer type is plotted on one page. For each cancer type, calculate the maximum % change of tumor burden from baseline, different color bar indicates patient's best overall response of CR, PR, or Non CR/PR. Additional symbols may be added to indicate threshold of increase/decrease (e.g., decrease >75%, increase >50%, etc.) if deemed meaningful.

Listing 16.2.1.1
Disposition - End of Treatment

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Informed Consent Date	Cancer Type	First Dose Date/ Last Dose Date [1]	End of Treatment Date	Reason for Study Drug Discontinuation
xxx-xxx	YYYY-MM-DD	Liver	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD	Subject withdrawal of consent: withdrew from study
xxx-xxx	YYYY-MM-DD	Renal Cell	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD	Objective disease progression
xxx-xxx	YYYY-MM-DD	Sarcoma	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD	Clinical disease progression
xxx-xxx	YYYY-MM-DD	Other: xxxx	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD	Investigator discretion: Subject was non-compliant
xxx-xxx	YYYY-MM-DD	Thyroid	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD	

…

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] First dose date/last dose date of the study drug.

Listing 16.2.1.2
Disposition - End of Study

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Date of Study Termination	Reason for Study Termination	Date of Death
xxx-xxx	Liver	YYYY-MM-DD	Subject withdrawal of consent	
xxx-xxx	Renal Cell	YYYY-MM-DD	Lost to Follow-up	
xxx-xxx	Sarcoma	YYYY-MM-DD	Subject died: [Cause of death]	YYYY-MM-DD
xxx-xxx	Other: xxxx	YYYY-MM-DD	Lost to Follow-up	
xxx-xxx	Thyroid	YYYY-MM-DD	Lost to Follow-up	
Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).				

Listing 16.2.1.3
Disposition – Screen Failure

Subject	Reason for Screen Failure
	[Did not meet inclusion/exclusion criteria]
	[Withdrew consent]
xxx-xxx	[Other: xxx]
xxx-xxx	
xxx-xxx	
xxx-xxx	
xxx-xxx	

Listing 16.2.2.1
Protocol Deviations

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Category	Description	Type	Occurrence Date	Action Taken
xxx-xxx	Liver	xxxxxxxxxxx	xxxxxxxxxxx	Minor	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxx
	Renal	xxxxxxxxxxx	xxxxxxxxxxx	Major	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxx
xxx-xxx	Cell					
xxx-xxx	Sarcoma	xxxxxxxxxxx	xxxxxxxxxxx	xxxxx	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxx
	Other:	xxxxxxxxxxx	xxxxxxxxxxx		YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxx					
xxx-xxx	Thyroid	xxxxxxxxxxx	xxxxxxxxxxx		YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxx

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Listing 16.2.2.2
Inclusion/Exclusion Criteria

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Protocol Amendment	Inc. Criteria Not Met	Exc. Criteria Met
xxx-xxx	aaa		
xxx-xxx			
xxx-xxx		xx, xx	
xxx-xxx			
xxx-xxx			

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Programming note: Print a cover page for this listing where all inclusion and exclusion criteria (Full text) will be printed. In the body of the listing, only the numbers for the criteria will be displayed. The cover page for the listing contains the following information with the following template.

Protocol Version	Additional No.	Additional Criteria Description	Category	No.	Criteria
Amendment 1			INCLUSION	I01	Subject is age 18 years or older

Listing 16.2.3
Analysis Population

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Excluded from Analysis Set	Reasons for Exclusion from Analysis Set
xxx-xxx	Liver	Safety	xxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	Renal Cell	Efficacy	xxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	Sarcoma	Pharmacokinetic	xxxxxxxxxxxxxxxxxxxxxxxxxxxx

Continue Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Note: all enrolled subjects were treated and included in both safety analysis set and efficacy analysis set.

Listing 16.2.4.1
Demographics

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Age (yrs)[1]	Gender	Child-bearing potential [2]	Race	Ethnicity	Height (cm)	Baseline Weight (kg) [3]	Tobacco Use	# of Pack-Years
xxx-xxx	Liver	xx	Male		xxxxxxxxx	xxxxxxx	xxx	xxx.x		
	Renal Cell	xx	Female	No	Other:	xxxxxxxx	xxx	xxx.x		
xxx-xxx					xxxxxxxxx					
xxx-xxx	Sarcoma	xx	Male		xxxxxxxxx	xxxxxxx	xxx	xxx.x		
xxx-xxx	Other: xxxx	xx	Male		xxxxxxxxx	xxxxxxx	xxx	xxx.x		
Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).										

[1] Age at informed consent.
[2] For Female only.
[3] Baseline is defined as the last measurement obtained prior to the first dose of the study drug.

Listing 16.2.4.2
Cancer Disease History

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Location of Primary Tumor	Date of Initial Diagnosis (Months [1])	Date of First Recurrence or Local Advancement (Months [1])	Date of First Presentation with Distant Metastatic Disease (Months [1])	Stage at Enrollment	ECOG	EGFR Mutation	ALK Rearrang-ement	HPV Infection	MSI (Assay: Result)
xxx-xxx	Liver	xxx	YYYY-MM-DD (xx)		YYYY-MM-DD (xx)	Metastatic	x	xxx	xxx	xxx	xxx
xxx-xxx	Renal Cell	xxx	YYYY-MM (xx*)		YYYY-MM-DD (xx)	Metastatic	x	xxx	xxx	xxx	xxx
xxx-xxx	Sarcoma	xxx	YYYY-MM-DD (xx)		YYYY-MM (xx*)	Metastatic	x	xxx	xxx	xxx	xxx
xxx-xxx	Other: xxxx	xxxx	YYYY-MM-DD (xx)	YYYY-MM-DD (xx)		Locally advanced	x	xxx	xxx	xxx	xxx
xxx-xxx	Thyroid	xxxx	YYYY-MM-DD (xx)		YYYY-MM-DD (xx)	Metastatic		xxx	xxx	xxx	xxx

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Months = (Date of the First Dose – Date of Initial Diagnosis/Date of Local Advancement/Metastatic Disease + 1)/30.4. If the month and year of the diagnosis date are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation.
* Months calculation is based on imputed diagnosis date.

Listing 16.2.4.3
Oncogene Assessment

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Date of Assessment	Assessment Type	Result
xxx-xxx	Liver	YYYY-MM-DD	KRAS	
xxx-xxx	Renal Cell	YYYY-MM		
xxx-xxx	Sarcoma	YYYY-MM-DD		
xxx-xxx	Other: xxxx	YYYY-MM-DD		
xxx-xxx	Thyroid	YYYY-MM-DD		

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Listing 16.2.4.4
Medical History

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Any Medical History?	Condition/Diagnosis	Start Date	Ongoing?
xxx-xxx	Liver	Yes	xxxxxxxxxxxxxxx	YYYY-MM	No
	Renal				
xxx-xxx	Cell	No			
xxx-xxx	Sarcoma	Yes	xxxxxxxxxxxxxxxxxx	YYYY	No
	Other:				
xxx-xxx	xxxx	Yes	xxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
xxx-xxx	Thyroid	Yes	xxxxxxxxxxxxxxxx		

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Listing 16.2.4.5
Prior Cancer Therapy

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Any Prior Cancer Therapy?	Regimen: Preferred Term (Drug)	Start Date/ Stop Date	Reason for Discontinuation	Best Response
xxx-xxx	Liver	Yes	A:xxxxxxxxxxxxxxx	YYYY-MM/ YYYY-MM	Progression	
xxx-xxx	Renal Cell	No	A:xxxxxxxxxxxxx	YYYY-MM-DD/ YYYY-MM-DD	Progression	Stable Disease
xxx-xxx	Sarcoma	Yes	A:xxxxxxxxxxxxxxxxxx	YYYY/ -	Toxicity	Stable Disease
xxx-xxx	Other: xxxx	Yes	A:xxxxxxxxxxxxxxx	YYYY-MM-DD/ YYYY-MM-DD	Completed Planned Treatment	Stable Disease
			B:xxxxxxxxxxxxxxxx	YYYY-MM-DD/ YYYY-MM-DD	Other: xxx	Not Applicable

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

- = Not available.
Note: WHO Drug Dictionary (September, 2015) was used for coding.

Listing 16.2.4.6
Prior Cancer Surgery

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Any Prior Cancer Surgery?	Surgery	Surgery Date
xxx-xxx	Liver	Yes	Biopsy	YYYY-MM-DD
xxx-xxx	Renal Cell	No		
xxx-xxx	Sarcoma	Yes	Metastatic Site Resection	YYYY-MM
xxx-xxx	Other: xxxx	Yes	Other: xxxxxx	YYYY-MM-DD
xxx-xxx	Thyroid	Yes	Primary Resection	YYYY

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Listing 16.2.4.7
Prior Cancer Radiation Therapy

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Any Prior Cancer Radiation Therapy?	Radiation Site Location	Start Date/ Stop Date
xxx-xxx	Liver	Yes	Lung	YYYY-MM/ YYYY-MM
xxx-xxx	Renal Cell	No		
xxx-xxx	Sarcoma	Yes	Peritoneal	YYYY/ -
xxx-xxx	Other: xxxx	Yes	Head and Neck	YYYY-MM-DD/ YYYY-MM-DD
xxx-xxx	Thyroid	Yes	Lung	YYYY-MM-DD/ YYYY-MM-DD
Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).				

- = Not available.

Listing 16.2.4.8
Other Prior Cancer Therapy

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Any Other Prior Cancer Therapy?	Other Type of Therapy	Therapy Site Location	Start Date/ Stop Date
xxx-xxx	Liver	Yes	Laser Treatment	Lung	YYYY-MM/ YYYY-MM
xxx-xxx	Renal Cell	No			
xxx-xxx	Sarcoma	Yes	Other: xxxxx	Peritoneal	YYYY/ -
xxx-xxx	Other: xxxx	Yes	Other: xxxxx	Head and Neck	YYYY-MM-DD/ YYYY-MM-DD
xxx-xxx	Thyroid	Yes	Intralesion Injection	Lung	YYYY-MM-DD/ YYYY-MM-DD
Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).					

- = Not available.

Listing 16.2.4.9
Post Treatment Discontinuation Cancer Therapy

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Any Post Treatment Discontinuation Cancer Therapy?	Regimen: Preferred Term (Drug)	Start Date (Days [1])
xxx-xxx	Liver	Yes	xxxxxxxxxxxxxxx	YYYY-MM-DD (xx)
xxx-xxx	Renal Cell	No		
xxx-xxx	Sarcoma	Yes	xxxxxxxxxxxxxxxxxx	YYYY-MM (xx*)
xxx-xxx	Other: xxxx	Yes	xxxxxxxxxxxxxxx	YYYY-MM-DD (xx)
xxx-xxx	Thyroid	Yes	xxxxxxxxxxxxxxxx	YYYY-MM-DD (xx)
Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).				

[1] Days = Post treatment discontinuation cancer therapy start date – date of the first dose + 1. If the month and year of the treatment start are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, no imputation shall be performed.
* Days calculation is based on imputed start date.
Note: WHO Drug Dictionary (September, 2015) was used for coding.

Listing 16.2.4.10
Prior Medication (Excluding Cancer Therapy)

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	VT: Verbatim Term PT: Preferred Term ATC: ATC Class	Indication	Start Date (Days [1])/ Stop Date (Days [1])	Total Daily Dose (Unit)	Frequency/Route
xxx-xxx	Liver	VT: xxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxx [Original: xxxx] ATC: xxxxxxxxxxxxxxxx	xxxx	YYYY-MM-DD (xx)/ YYYY-MM-DD (xx)	xxxx (xx)	xxxx
xxx-xxx	Renal Cell	VT: xxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxx ATC: xxxxxxxxxxxxxxxx	xxxx	YYYY-MM (-)/ YYYY (-)	xxxx (xx)	xxxx
xxx-xxx	Sarcoma	VT: xxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxx ATC: xxxxxxxxxxxxxxxx	xxx	YYYY-MM-DD (xx)/ YYYY-MM (-)	xxxx (xx)	xxxx

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Days = Date of Start/Stop of Medication - Date of First Dose of the Study Drug (+1 if Start/Stop Date of medication ≥ First Dose Date of the Study Drug).
- = Not available. [Original] is in reference to the coded medication preferred terms according to WHO Drug Dictionary without collapsing of terms. [PT] is presenting the collapsed terms, used for summaries.
* Medication ended prior to 30 days before the first dose date of the study drug.
Note: WHO Drug Dictionary (September, 2015) was used for coding. All medications started prior to the first dose date of the study drug are listed. Medications taken within 30 days of the first dose date of the study drug, and ended prior to the first dose date of the study drug are summarized in the table.

Listing 16.2.4.11
Concomitant Medication (Excluding Cancer Therapy)

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	VT: Verbatim Term PT: Preferred Term ATC: ATC Class	Start Date (Days [1])/ Stop Date (Days [1])	Total Daily Dose (Unit)	Frequency/Route
xxx-xxx	Liver	VT: xxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxx ATC: xxxxxxxxxxxxxxxxx	YYYY-MM-DD (xx)/ YYYY-MM-DD (xx)	xxxx (xx)	xxxx
xxx-xxx	Renal Cell	VT: xxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxx ATC: xxxxxxxxxxxxxxxxx	YYYY-MM (-)/ YYYY (-)	xxxx (xx)	xxxx
xxx-xxx	Sarcoma	VT: xxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxx ATC: xxxxxxxxxxxxxxxxx	YYYY-MM-DD (xx)/ Ongoing	xxxx (xx)	xxxx

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Days = Date of Start/Stop of Medication - Date of First Dose of the Study Drug (+1 if Start/Stop Date of medication ≥ First Dose Date of the Study Drug).
- = Not available. [Original] is in reference to the coded medication preferred terms according to WHO Drug Dictionary without collapsing of terms. [PT] is presenting the collapsed terms, used for summaries.
* Medications started more than 30 days after the last dose date of the study drug.
Note: WHO Drug Dictionary (September, 2015) was used for coding. All medications that started at any time and were taken at any time after the start of study drug until 30 days after the end of the study drug are summarized in the table.

Subject	Cancer Type	VT: Verbatim Term PT: Preferred Term ATC: ATC Class	Indication Details
xxx-xxx	Liver	VT: xxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxx ATC: xxxxxxxxxxxxxxxxx	Medical History: xxxxxxx Adverse Events: AE x - xxxxxx

Listing 16.2.4.12
Prior Steroids and Immune Modulating Medication

[Add footnote: * Medication ended prior to 30 days before the first dose date of the study drug.]

Listing 16.2.4.13
Concomitant Steroids and Immune Modulating Medication

[Add footnote: * Medications started more than 30 days after the last dose date of the study drug.]

Listing 16.2.5.1
Mogamulizumab Administration

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

			Infusion Administration				Infusion Delay	
Subject	Cancer Type	Cycle	Date/ Start Time - Stop Time	Interrupt? /Pre-vol. (mL)	Reason for Interruption	Interrupt Time/ Restart Time	Yes/No	Reason
xxx-xxx	Liver	xx	YYYY-MM-DD/ HH:MM - HH:MM	Yes	xxxxxxxx	HH:MM/HH:MM	No	
		xx	YYYY-MM-DD/ HH:MM - HH:MM					

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

* Subject was not premedicated prior to Mogamulizumab Infusion.

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

				Dose Administration				
Subject	Cancer Type	Cycle	Weight (kg)	Assigned Level (mg/kg)	Actual Dose Admin (mg)	Actual Volume (mL)	Reason for not Administering Planned Dose	Any Infusion Reaction Following the End of This Infusion?
xxx-xxx	Liver	xx	xx.x	xx.x	xxx.x	xxx.x		
		xx	xx.x	xx.x	xxx.x	xxx.x	xxxxxxxxxxxxx	
		xx	xx.x	xx.x	xxx.x	xxx.x		

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

* Subject was not premedicated prior to Mogamulizumab Infusion.

Listing 16.2.5.2
Nivolumab Administration

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

			Infusion Administration				Infusion Delay	
Subject	Cancer Type	Cycle	Date/ Start Time - Stop Time	Interrupt /Pre-vol. (mL)	Reason for Interruption	Interrupt Time/ Restart Time	Yes/No	Reason
xxx-xxx	Liver	xx	YYYY-MM-DD/ HH:MM - HH:MM	Yes	xxxxxxxx	HH:MM/HH:MM	No	
		xx	YYYY-MM-DD/ HH:MM - HH:MM					

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

				Dose Administration			
Subject	Cancer Type	Cycle	Weight (kg)	Actual Dose Admin (mg)	Actual Volume (mL)	Reason for not Administering Planned Dose	Any Infusion Reaction Following the End of This Infusion?
xxx-xxx	Liver	xx	xx.x	xxx.x	xxx.x		
		xx	xx.x	xxx.x	xxx.x	xxxxxxxxxxxxx	
		xx	xx.x	xxx.x	xxx.x		

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Listing 16.2.5.3
Extent of Exposure, Cumulative Dose and Relative Dose Intensity

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Study Drug	First Dose Infusion	Last Dose Infusion	Extent of Exposure (days)	Cumulative Assigned Dose	Cumulative Actual Dose	Relative Dose Intensity (%)
xxx-xxx	Liver	Mogamulizumab (mg/kg)	YYYY-MM-DD	YYYY-MM-DD	xxx	xx.x	xx.x	xx.x
		Nivolumab (mg)	YYYY-MM-DD	YYYY-MM-DD	xxx	xx.x	xx.x	xx.x
xxx-xxx	Renal Cell	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxx	xx.x	xx.x	xx.x
		xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxx	xx.x	xx.x	xx.x
...								

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Listing 16.2.6.1
Tumor Assessment Details

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

					Tumor Lesion			Lesion Length (mm) / Non-Target Response	Response	
Subject	Cancer Type	Cycle	Image Date (Days [1])	Lesion Type	No.	Site	Assessment Method		RECIST[2,3]	irRECIST
xxx-xxx	Liver	Baseline	YYYY-MM-DD (xx)	Target	1	xxxx	xxxx	xxx		
					2	xxxx	xxxx	xxx		
					3	xxxx	xxxx	xxx		
					Sum			**xxx**		
				Non-Target	1	xxxx	xxxx			
		Cycle 3/ Day 15	YYYY-MM-DD (xx)	Target	1	xxxx	xxxx	xxx		
					2	xxxx	xxxx	xxx		
					3	xxxx	xxxx	xxx		
					Sum			**xxx**		
				Non-Target	1	xxxx	xxxx	AAAA		
				New	No					
				Overall Response					**PR**	**PR**
		…								
		Cycle 12/ Day 1	YYYY-MM-DD (xx)	Target	1	xxxx	xxxx	xxx		
					2	xxxx	xxxx	xxx		
					3	xxxx	xxxx	xxx		
					Sum			**xxx**		
				Non-Target	1	xxxx	xxxx	AAAA		
				New	Yes	xxxx	xxxx	xxx		
					Sum#			**xxx**		
				Overall Response					**PR**	**PD**
		End of Treatment	YYYY-MM-DD (xx)	**Overall Response**					**PD**	**PD**
				Progression First					**[2]YYYY-MM-**	**YYYY-MM-DD (xx) YYYY-MM-DD**

Subject	Cancer Type	Cycle	Image Date (Days [1])	Lesion Type	Tumor Lesion No.	Tumor Lesion Site	Tumor Lesion Assessment Method	Lesion Length (mm) / Non-Target Response	Response RECIST[2,3]	Response irRECIST
				Response					**DD (xx)/PR [3]YYYY-MM-DD (xx)/PR**	**(xx)/PR**
				Best Overall Response					**[2]YYYY-MM-DD (xx)/PR [3]YYYY-MM-DD (xx)/PR**	**YYYY-MM-DD (xx)/PR**

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Days = Date of Image - Date of the First Dose (+1 if Date of Image ≥ Date of the First Dose).
[2] Best overall response is defined as the best response designation recorded between the date of first dose of investigational medical product (IMP) and the date of subsequent anti-cancer therapy (excluding on-treatment palliative radiotherapy of non-target bone or CNS lesions).
[3] Sensitivity endpoint of Best overall response is defined as the best response designation recorded between the date of first dose of investigational medical product (IMP) to the first radiological disease progression or initiation of subsequent therapy, whichever occurred earlier.
Sum of existing and new target lesions.
- = Not available.
CR = Complete response; PR = Partial response; SD = Stable disease; PD = Progressive disease; UP = Unequivocal progressive disease.
Note: The date of overall response will be determined based on the image dates. In the event that there are images taken on different days, the latest date among all images taken will be used for the response date if the overall response is non-PD. If the overall response is PD, then the earliest date of all images taken will be used for the progression date.

Listing 16.2.6.2.1
Progression-Free Survival (PFS) Per RECIST and Overall Survival (OS)

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Date of First Dose	Progressive Disease?/ Date of Progression (Days [1])	Death?/ Date of Death (Days [1])	Date of Post Treatment Anti-Cancer Therapy	Date of Last Tumor Assessment (Days [1])	PFS (Days [1])	Date Last Known Alive (Days[1])	OS (Days [1])
xxx-xxx	Liver	YYYY-MM-DD	Yes/ YYYY-MM-DD (xx)	Yes/ YYYY-MM-DD (xx)	YYYY-MM-DD	YYYY-MM-DD (xx)	xxx	YYYY-MM-DD (xx)	xxx +
xxx-xxx	Renal Cell	YYYY-MM-DD	No	No		YYYY-MM-DD	xxx +	YYYY-MM-DD (xx)	xxx
xxx-xxx	Sarcoma	YYYY-MM-DD	Yes/ YYYY-MM-DD (xx)	No	YYYY-MM-DD	YYYY-MM-DD	xxx	YYYY-MM-DD (xx)	xxx
xxx-xxx	Lung	YYYY-MM-DD	No	Yes/ YYYY-MM-DD (xx)		YYYY-MM-DD	xxx	YYYY-MM-DD (xx)	xxx

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

+ = censored observation; PFS = Progression Free Survival; OS = Overall Survival.
[1] Days = Date of specified event/assessment – Date of first dose + 1.
Note: Date of Last Tumor Assessment is the last tumor assessment prior to the start of post treatment anti-cancer therapy.

Programming note: Column of "Date of Last Tumor Assessment" is only applicable for patients who did not have progressive disease or die; column of "Date Last Known Alive" is only applicable for patients who did not die.

Listing 16.2.6.3.1
Time to Response and Duration of Response Per RECIST

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Date of First Dose	First Response/ Date of Response	Progressive Disease?/ Date of Progression	Death?/ Date of Death	Date of Post Treatment Anti-Cancer Therapy	Date of Last Tumor Assessment	Days [1] TTR	Days [1] DOR
xxx-xxx	Liver	YYYY-MM-DD	CR/ YYYY-MM-DD	Yes/ YYYY-MM-DD	Yes/ YYYY-MM-DD	YYYY-MM-DD		xxx	xxx
xxx-xxx	Renal Cell	YYYY-MM-DD	SD/ YYYY-MM-DD	No	No		YYYY-MM-DD		
xxx-xxx	Sarcoma	YYYY-MM-DD	PR/ YYYY-MM-DD	No	No	YYYY-MM-DD	YYYY-MM-DD	xxx	xxx+
xxx-xxx	Lung	YYYY-MM-DD	PD/ YYYY-MM-DD	Yes/ YYYY-MM-DD	Yes/ YYYY-MM-DD				
	Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).								

+ = censored observation; TTR = Time to Response; DOR = Duration of Response.
[1] Days (TTR) = Date of first response – Date of first dose + 1; or Days (DOR) = Date of PD/Death/Last Tumor Assessment – Date of response + 1.
Note: Date of Last Tumor Assessment is the last tumor assessment prior to the start of post treatment anti-cancer therapy.

Programming note: Column of "Date of Last Tumor Assessment" is only applicable for patients who did not have progressive disease or die.
The following listings will have similar layout as Listing 16.2.6.3.1:

Listing 16.2.6.3.2
Time to Response and Duration of Response Per RECIST (Excluding Tumor Responses after First Progressive Disease)

Listing 16.2.6.4
Tumor Biopsy

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Date of First Dose	Cycle	Date of Collection (Days [1])	Accession Number	Biopsy Location	Type of Sample	Type of Procedure	Was Additional Sample Collected?
xxx-xxx	Liver	YYYY-MM-DD	Screening	YYYY-MM-DD (xx)	xxxxxx	aaaa	Archive	Resection	
			Cycle 3/Day 15	YYYY-MM-DD (xx)	xxxxxx	aaaa	Fresh	aaa	Yes
			…	YYYY-MM-DD (xx)					

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Days = Date of Collection − Date of First Dose of the Study Drug (+1 if Date of Collection ≥ First Dose Date of the Study Drug).

Listing 16.2.7.1
Adverse Events

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject (Age/Gender)	Cancer Type	VT: Verbatim Term PT: MedDRA Preferred Term SOC:System Organ Class	Start Date Time/Day [1] Stop Date Time/Day [1] Duration (days) [2]	Start Cycle/ Cycle Day [1]	Time Point	CTCAE Grade	Serious	Relationship Mogamulizumab/ Nivolumab	Action Taken Mogamulizumab/ Nivolumab/Treated?	Outcome/ DLT?
xxx-xxx (xx/F)	Lung	VT: xxxxxxxxxxxxxxx* PT: xxxxxx SOC: xxxxxx	YYYY-MM-DD/xx YYYY-MM-DD/xx xx	xx/xx	DMI	x	No	NR/ NR	NN/ NR/No	REC/ No
		VT: xxxxxxxxxxxxxxx PT: xxxxxx SOC: xxxxxx	YYYY-MM-DD/xx YYYY-MM-DD/xx xx	xx/xx	PTM	x	No	R/ NR	DR/ NN/Yes	NREC/ Yes

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Day = Start/Stop date of adverse event − First dose date of the study drug (+1 if Start/Stop Date ≥ First dose date of the study drug); Cycle Day = Start date of adverse event − closest prior cycle Day 1 + 1.
[2] Duration = Stop date of adverse event − Start date of adverse event + 1.
Time point: NOI = N/A; PNI = Pre-Nivolumab Infusion; DNI = During Nivolumab Infusion; PTN = Post Nivolumab Infusion; PMI = Pre-Mogamulizumab Infusion; DMI = During Mogamulizumab Infusion; PTM = Post Mogamulizumab Infusion; UNK = Unknown.
CTCAE Grade: 1 = Grade 1 (Mild); 2 = Grade 2 (Moderate); 3 = Grade 3 (Severe or Disabling); 4 = Grade 4 (Life-threatening); 5 = Grade 5 (Death).
Relationship: NR = Not Related; R = Related.
Action Taken: NN = None; DW = Drug Withdrawn; DR = Decrease Infusion Rate; DI = Dose Interrupted/Delayed; PA = Prior to Administration of SD/IP.
Outcome: REC = Recovered/Resolved; NREC = Not Recovered/Not Resolved; RECS = Recovered/Resolved with Sequelae; RRC = Recovering/Resolving; FAT = Fatal; UNK = Unknown.
* Non-treatment emergent event;
Note: MedDRA Version 18.1 was used for coding.

The following listings will have similar layout as Listing 16.2.7.1:

Listing 16.2.7.2
Mogamulizumab or Nivolumab-related Adverse Events

Listing 16.2.7.3
Grade >=3 Adverse Events

Listing 16.2.7.4
Serious Adverse Events (SAEs)

Listing 16.2.7.5
Adverse Events Leading to Discontinuation of Mogamulizumab or Nivolumab

Listing 16.2.7.6
Fatal Adverse Events

Listing 16.2.7.7
Infusion Reaction Adverse Events

Listing 16.2.8.1
Laboratory Assessment – Chemistry

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Lab Test (Unit)	Normal Range Low-High	Cycle	Sample Date (Days [1])	Lab Value	Flag	CTCAE Grade
xxx-xxx	Lung	xxxxxxxxxxxxxxx	xx.x – xx.x	xx	YYYY-MM-DD (xx)	xx.x [B]		
				xx	YYYY-MM-DD (xx)	xx.x	H	2
				xx	YYYY-MM-DD (xx)	xx.x		
				xx	YYYY-MM-DD (xx)	xx.x	H	3

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[B] = Baseline record; H = above upper limit of normal reference range; L = below lower limit of normal reference range.
[1] Days = Sample Date – Date of first dose (+ 1 if Sample date >= Date of first dose).
Note: CTCAE grade is assigned for parameters based on NCI CTCAE criteria (version 4.03).
Grade 0 indicates values that do not satisfy CTC abnormality criteria.
Note: For values preceded by a < or > sign, the sign is removed and the value alone is used in the summary tables

The following listings will have similar layout as Listing 16.2.8.1:

Listing 16.2.8.2
Laboratory Assessment – Hematology

Listing 16.2.8.3
Laboratory Assessment – Coagulation Profile

Listing 16.2.8.4
Laboratory Assessment – Thyroid Function Test

Listing 16.2.8.5
Laboratory Assessment – Urinalysis

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Lab Test	Cycle	Sample Date (Days [1])	Lab Value
xxx-xxx	Lung	xxxxxxxxxxxxxxx	xx	YYYY-MM-DD (xx)	xx.x
			xx	YYYY-MM-DD (xx)	xx.x
			xx	YYYY-MM-DD (xx)	xx.x
			xx	YYYY-MM-DD (xx)	xx.x

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Days = Sample Date – First dose date of the study drug (+ 1 if Sample date >= First dose date of the study drug).

Listing 16.2.8.6
Laboratory Assessment – Pregnancy Test

Treatment = Phase 1 Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Type of Test	Cycle	Sample Date (Days [1])	Lab Value
xxx-xxx	Lung	Serum	xx	YYYY-MM-DD (xx)	xx.x
		Urine	xx	YYYY-MM-DD (xx)	xx.x
		Urine	xx	YYYY-MM-DD (xx)	xx.x
		Urine	xx	YYYY-MM-DD (xx)	xx.x

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Days = Sample Date – First dose date of the study drug (+ 1 if Sample date >= First dose date of the study drug).

Programming note: Based on the data collection, there are some patients with false positive pregnancy tests. Add a footnote like "Note: Subjects xxx-xxx, xxx-xxx had positive pregnancy tests which are false positive due to central lab testing being more sensitive and certain tumor types produced higher HCG levels."

Listing 16.2.8.7
Laboratory Assessment – Virology

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Lab Test	Cycle	Sample Date (Days [1])	Lab Value
xxx-xxx	Lung	aaaa	xx	YYYY-MM-DD (xx)	Negative
		bbb	Xx	YYYY-MM-DD (xx)	
		cccccc	Xx	YYYY-MM-DD (xx)	
		ddddd	xx	YYYY-MM-DD (xx)	
Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).					

[1] Days = Sample Date – First dose date of the study drug (+ 1 if Sample date >= First dose date of the study drug).

Listing 16.2.9.1
Vital Signs

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Start/Stop (Nivolumab)	Start/Stop (Mogamulizumab)	Cycle/ Time Point	Date/Time of Collection (Days [1])	Temperature (C)	Systolic BP (mmHg)	Diastolic BP (mmHg)	Pulse Rate (beats/min)
xxx-xxx	Liver			Screening	YYYY-MM-DD (xx) HH:MM	xx[B]	xx	xx	xx
		YYYY-MM-DD HH:MM/ YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM/ YYYY-MM-DD HH:MM	Cycle 1 Day 1/ POIN	YYYY-MM-DD (xx) HH:MM	xx	xx[B]	xx[B]	xx[B]
				Cycle 1 Day 1/ EOIN	YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx
				Cycle 1 Day 1/ POIM	YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx
				Cycle 1 Day 1/ DOIM	YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx
				Cycle 1 Day 1/ EOIM	YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx
				Cycle 1 Day 1/ POIM	YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[B] = Baseline Record; PNI = Prior to Nivolumab Infusion; ENI = End of Nivolumab Infusion; PMI = Prior to Mogamulizumab Infusion; DMI = During Mogamulizumab Infusion; EMI = End of Mogamulizumab Infusion; PTM = Post Mogamulizumab Infusion.
[1] Days = Date of Collection – Date of First Dose of the Study Drug (+1 if Date of Collection ≥ First Dose Date of the Study Drug).

Listing 16.2.10.1
Electrocardiogram

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Start/Stop Study Drug	Cycle/ Time Point	Date/Time of Collection (Days [1])	RR (msec)	Heart Rate (bpm)	QT (msec)	QTcF (msec)	QTcB (msec)	Overall Interpretation
xxx-xxx	Liver		Screening	YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx	xx	Normal
				YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx	xx	Normal
				YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx	xx	Normal
				Average	xx	xx	xx	xx	xx	
		YYYY-MM-DD HH:MM/ YYYY-MM-DD HH:MM	xx/POI	YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx	xx	Abnormal, Not Clinically Significant
				YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx	xx	Abnormal, Not Clinically Significant
				YYYY-MM-DD (xx) HH:MM	xx	xx	xx	xx	xx	Abnormal, Not Clinically Significant
				Average	xx[B]	xx[B]	xx[B]	xx[B]	xx[B]	

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[B] = Baseline Record; PNI = Prior to Nivolumab Infusion; PMI = Prior to Mogamulizumab Infusion; DI = During or in-between any IMP Infusions; EMI = End of Mogamulizumab Infusion.
[1] Days = Date of Collection – Date of First Dose of the Study Drug (+1 if Date of Collection≥ First Dose Date of the Study Drug).
Note: for QTcB and QTcF: * ≥450, ** ≥480, *** ≥500 msec. CS = clinically significant, NCS = not clinically significant.

Listing 16.2.11.1
Physical Examination

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Date of First Dose	Cycle	Date of Exam (Days [1])	Weight (kg)	Findings
xxx-xxx	Liver	YYYY-MM-DD	Screening	YYYY-MM-DD (xx)	xx.x	Normal
			xx	YYYY-MM-DD (xx)	xx.x	Abnormal, Not Clinically Significant:xxxxx
			xx	YYYY-MM-DD (xx)	xx.x	Abnormal, Clinically Significant: xxxxxx
xxx-xxx	Lung	YYYY-MM-DD	Screening	YYYY-MM-DD (xx)	xx.x	Normal
Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).						

[1] Days = Date of Exam − Date of First Dose of the Study Drug (+1 if Date of Exam ≥ First Dose Date of the Study Drug).

Listing 16.2.12.1
ECOG Performance Status

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Date of First Dose	Cycle	Date of Evaluation (Days [1])	Performance Status
xxx-xxx	Liver	YYYY-MM-DD	Screening	YYYY-MM-DD (xx)	1
			aaaa	YYYY-MM-DD (xx)	2
			aaaa	YYYY-MM-DD (xx)	2
xxx-xxx	Lung	YYYY-MM-DD	Screening	YYYY-MM-DD (xx)	0

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Days = Date of Evaluation − Date of First Dose of the Study Drug (+1 if Date of Evaluation ≥ First Dose Date of the Study Drug).
Performance status: 0 - Subject is fully active and able to continue with predisease activities without restrictions. 1 - Subject is restricted from physically strenuous activity but is ambulatory and can perform light or sedentary work. 2 - Subject is ambulatory and performs self-care but is unable to work; subject is up and about for more than 50% of waking hours. 3 - Subject can perform only limited self-care; subject is confined to bed or chair for 50% or more of waking hours. 4 - Subject is completely disabled and unable to carry out any self-care; subject is totally confined to bed or chair. 5 – Dead.

Listing 16.2.13.1
PK concentrations of Mogamulizumab

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Cycle Timepoint	Mogamulizumab Dose Date and Time (Days [1])	Last Prior Mogamulizumab Dose Date (Days [1])	Time from Last Dose (Days)	PK Collection Date/Time (Days [1])	PK Concentration (ng/mL)
xxx-xxx	Liver	Cycle 1 Day 1 (Pre)	YYYY-MM-DD HH:MM – HH:MM	YYYY-MM-DD (xx)	xx	YYYY-MM-DD HH:MM (xx)	BLQ
		Cycle 1 Day 1 (Post)				YYYY-MM-DD HH:MM (xx)	xx
		Cycle 2 Day 1 (Pre)	YYYY-MM-DD HH:MM – HH:MM	YYYY-MM-DD (xx)	xx	YYYY-MM-DD HH:MM (xx)	NA
		Cycle 2 Day 1 (Post)				YYYY-MM-DD HH:MM (xx)	xx

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

BLQ(Below Limit of Quantification): Concentration <12.5 ng/mL
NA: Not applicable because of lack of the sample
[1] Days = Date of Evaluation – Date of First Dose of the Study Drug (+1 if Date of Evaluation ≥ First Dose Date of the Study Drug).
Time from last dose of study drug is calculated relative to the PK collection date.

Listing 16.2.14.1.1
Anti-Drug Antibody Response to Mogamulizumab by Collection Time

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Cycle	ADA Sample Collected?	Sample Date/Time (Days [1])	Assay				PK Concentration (ng/mL)
					Screening	Confirmatory	ADA Status [2] (Titer)	Neutralizing	
xxx-xxx	Liver	Cycle 1 Day 1	Yes	YYYY-MM-DD HH:MM (xx)	Negative	---	Inconclusive	---	17000
		Cycle 2 Day 1	No						
		Cycle x Day 1	Yes	YYYY-MM-DD HH:MM(xx)	Positive	Positive	Positive (16)	Negative	xxx
		.							
		.							
		100-110 Days Post Last Dose Follow-up	Yes	YYYY-MM-DD HH:MM (xx)	Negative	---	Unknown	---	xxx

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

BLQ = Below lower limit of quantification.
[1] Days = Sample Date – Date of First Dose of the Study Drug (+1 if Sample Date ≥ First Dose Date of the Study Drug).
[2] ADA status is positive when the sample is positive in the confirmatory assay. ADA status is negative when the sample is negative in the screening assay and the serum mogamulizumab concentration at the same time point is equal to or less than the drug tolerance limit (16000 ng/mL), or the sample is positive in the screening assay and negative in the confirmatory assay. ADA status is "Inconclusive" when screening result is "Negative" and the PK concentration of mogamulizumab at the corresponding timepoint is above the drug tolerance level of the assay (>16000 ng/mL); if screening result is "Positive", the ADA status is the same as confirmatory result regardless of the PK concentration of mogamulizumab at the corresponding timepoint. ADA status is "Unknown" when screening result is "Negative" and the PK concentration of mogamulizumab at the corresponding timepoint is unknown.

Listing 16.2.14.1.2
Subject Status of Anti-Drug Antibody Response to Mogamulizumab

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Time Point	ADA/NAb Status
xxx-xxx	Liver	Baseline	Negative
		Overall Post Baseline	Positive
		Neutralizing	Negative

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

Listing 16.2.14.2.1
Anti-Drug Antibody Response for Subjects with Infusion Reactions to Mogamulizumab

Treatment = Phase 1: Dose finding phase (Mogamulizumab 1 mg/kg + Nivolumab 240 mg)

Subject	Cancer Type	Assay Positive at Any Time			Adverse Event Reported	Grade	Onset Date and Time/ Day [1]	Duration (Days [2])	Discontinued or Dose Interrupted?
		Screening	Confirmatory	Neutralizing					
xxx-xxx	Liver	Yes	No	No	Infusion Reaction	1	YYYY-MM-DD HH:MM/xx	4	No
					xxxxxxxxx	2	YYYY-MM-DD/xx	2	Yes
xxx-xxx					Infusion Reaction	1	YYYY-MM-DD/xx	1	No

Continue with Expansion phase (Mogamulizumab x mg/kg + Nivolumab 240 mg).

[1] Day = Start date of adverse event − First dose date of the study drug (+1 if Start ≥ First dose date of the study drug)
[2] Duration = Stop date of adverse event − Start date of adverse event + 1.
Note: Infusion reactions are identified by the preferred term infusion related reaction, regardless of the investigator assessment of relationship to study drug.