Statistical Analysis Plan

Protocol Title:	A Phase I/IIa, Open-Label, Multicentre, Dose-Escalation Study to Evaluate the Safety and Preliminary Efficacy of the Human Anti-CD38 Antibody MOR03087 as Monotherapy and in Combination with Standard Therapy in Subjects with Relapsed or Refractory Multiple Myeloma
Protocol Number:	MOR202C101 (Version 12.0, dated 17-JUL-2017)
Compound:	MOR03087
Phase:	I/IIa
Sponsor:	MorphoSys AG [redacted]
SAP Author:	[redacted]
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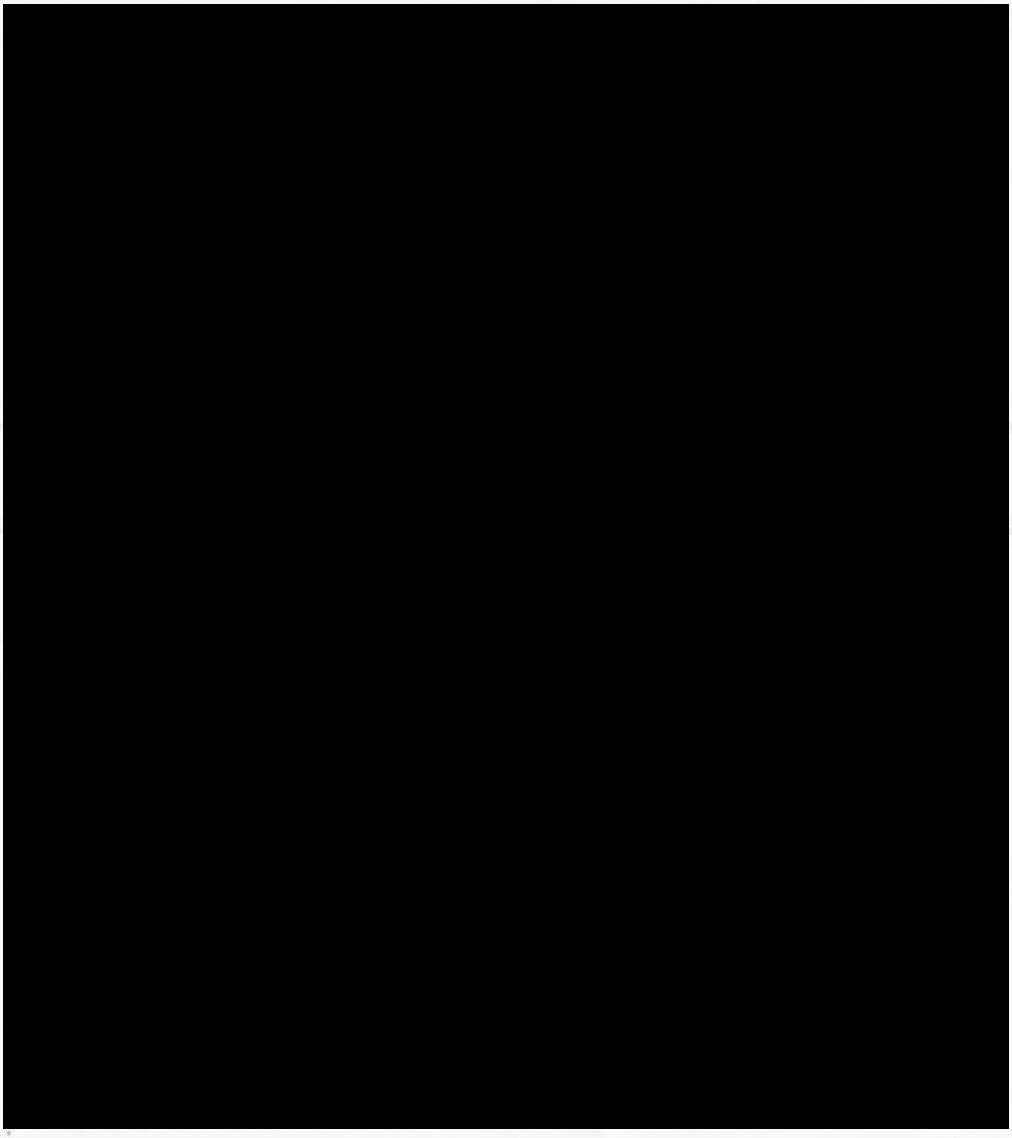

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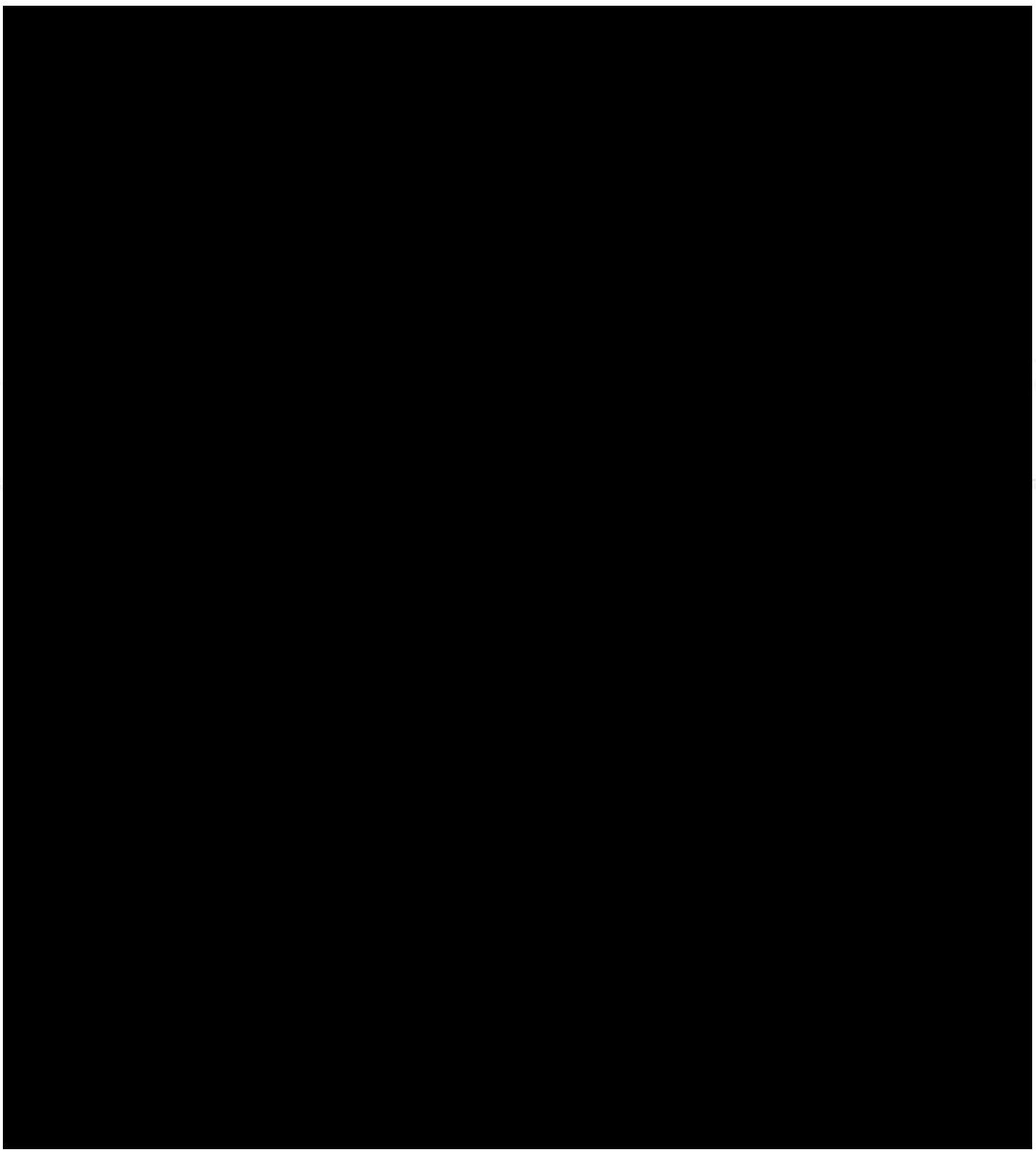

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ABBREVIATIONS

ABBREVIATION	DEFINITION OR DESCRIPTION
AE	Adverse Event
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index
CBR	Clinical Benefit Rate
CD38	Cluster of Differentiation 38 (antigen expressed on malignant plasma cells)
CR	Complete Response
CRF	Case Report Form
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
CV	Coefficient of Variation
DCR	Disease Control Rate
DEX	Dexamethasone
DLT	Dose Limiting Toxicity
DMC	Data Monitoring Committee
DoCB	Duration of Clinical Benefit
DoR	Duration of Response
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
EBMT	European Group for Blood and Marrow Transplantation
EFS	Event-free Survival
EMA	European Medicines Agency
EORTC	European Organisation for Research and Treatment of Cancer
EOS	End of Study
FDA	Food and Drug Administration
FLC	Free Light Chain
ICH	International Conference on Harmonisation
IMiD	Immunomodulatory Drug
IMP	Investigational Medical Product
ISS	International Staging System Criteria
LEN	Lenalidomide
MedDRA	Medical Dictionary for Regulatory Activities
MFI	Median Fluorescence Intensity

MM	Multiple Myeloma
MR	Minimal Response
MTD	Maximum Tolerated Dose
NCI-CTC	Common Terminology Criteria of the National Cancer Institute
NCI-CTCAE	Common Terminology Criteria of the National Cancer Institute for Adverse Events
NE	Not Evaluable
NK	Natural Killer
ORR	Overall Response Rate
PD	Progressive Disease
PFS	Progression-free Survival
PI	Proteasome Inhibitor
POM	Pomalidomide
PR	Partial Response
QLQ-C30	Quality of Life Questionnaire for Cancer Subjects – 30 questions
QLQ-MY20	Quality of Life Questionnaire for Myeloma Subjects – 20 questions
QoL	Quality of Life
QTc	QT-interval for ECG corrected for heart rate
RS	Raw Score
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
sCR	Stringent Complete Response
SD	Stable Disease
SI	Standard International
SOC	System Organ Class
TEAE	Treatment-emergent Adverse Event
TTP	Time to Progression
TTNT	Time to Next Treatment
VGPR	Very Good Partial Response
WHO	World Health Organization

1. OVERVIEW

This Statistical Analysis Plan (SAP) describes the planned analysis and reporting for MorphoSys protocol MOR202C101, Version 12.0, dated 17-JUL-2017.

This phase I/IIa, open-label, multicentre, dose-escalation study is being conducted to characterize the safety profile, assess preliminary efficacy and establish the maximal tolerated dose (MTD) or recommended dose of MOR03087 as monotherapy and in combination with dexamethasone (DEX) as well as in combination with immunomodulatory drugs (IMiDs) such as Pomalidomide (POM) and Lenalidomide (LEN) (MOR03087 + POM/DEX and MOR 03087 + LEN/DEX) in adult subjects with relapsed or refractory multiple myeloma (MM).

The structure and content of this SAP provides sufficient detail to meet the requirements identified by the Food and Drug Administration (FDA), European Medicines Agency (EMA), and International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance on Statistical Principles in Clinical Trials [1]. All work planned and reported for this SAP will follow internationally accepted guidelines, published by the American Statistical Association [2] and the Royal Statistical Society [3], for statistical practice.

The planned analysis identified in this SAP may be included in clinical study reports (CSRs), regulatory submissions, or future manuscripts. Also, post-hoc exploratory analysis not necessarily identified in this SAP may be performed to further examine study data and will not require updating the final SAP. Any post-hoc, or unplanned, exploratory analysis performed will be clearly identified as such and described in the final CSR.

The following documents were reviewed in preparation of this SAP:

- Clinical Research Protocol MOR202C101, Version 12.0, dated 17-JUL-2017
- Case report forms (CRFs) for Protocol MOR202C101
- ICH Guidance on Statistical Principles for Clinical Trials (E9).

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

2. STUDY OBJECTIVES AND ENDPOINTS

2.1 Study Objectives

2.1.1 Primary Objective

The primary objectives are

1. To assess the safety profile and to establish the maximum tolerated dose (MTD) and/or recommended dose of MOR03087 in subjects with relapsed or refractory MM:
    a. As monotherapy
    b. In combination with DEX
    c. In combination with POM + DEX
    d. In combination with LEN + DEX
2. To assess the immunogenicity of MOR03087

2.1.2 Secondary Objectives

Secondary objectives are

1. To evaluate the pharmacokinetics and pharmacodynamics of MOR03087 in subjects with relapsed or refractory MM:
    a. As monotherapy
    b. In combination with DEX
    c. In combination with POM + DEX
    d. In combination with LEN + DEX
2. To evaluate the preliminary efficacy of MOR03087 in subjects with relapsed or refractory MM:
    a. As monotherapy
    b. In combination with DEX
    c. In combination with POM + DEX
    d. In combination with LEN + DEX

2.2 Safety, Efficacy, and Pharmacokinetic/Pharmacodynamic Endpoints

2.2.1 Primary Endpoints

The primary endpoints are

1. Determination of the MTD and/or recommended dose of MOR03087 as monotherapy, in combination with DEX, and in combination with POM + DEX and LEN + DEX
2. Determination of the recommended dosing regimen of MOR03087
3. Incidence and severity of adverse events (AEs)
4. Immunogenicity of MOR03087 based on both absolute (number and percentage of subjects who develop anti-MOR03087 antibodies) and semi-quantitative (anti-MOR03087 antibody titer determination of confirmed positive samples) assessments

2.2.2 Secondary Endpoints

Secondary endpoints are

1. Pharmacokinetics of MOR03087 +/- LEN or POM
2. Absolute and percent change from baseline in measurements of B, T, and natural killer (NK) cell populations
3. Overall response rate (stringent complete response [sCR], complete response [CR], very good partial response [VGPR], partial response [PR]), further tumor response rates (CR, sCR, PR, minimal response [MR], VGPR), and stable disease (SD) rate
4. Duration of response (DoR), time to progression (TTP), and progression-free survival (PFS)
5. Absolute and percent change from baseline in serum and urine M-protein levels
6. Absolute and percent change from baseline in serum free light chain (FLC) levels and serum FLC ratio
7. Absolute changes from baseline in laboratory parameters (serum chemistry, haematology, urinalysis) and clinically relevant abnormal values
8. Absolute change from baseline in overall quality of life scores
9. Change in cytokines from baseline

3. STUDY METHODS

3.1 Overall Study Design and Plan

This is an open-label, multicentre, standard 3+3 dose-escalation study designed to characterize the safety profile and to assess the preliminary efficacy of MOR03087 in adult subjects with relapsed or refractory MM as monotherapy and in combination with DEX or standard IMiD therapy (POM and LEN). Approximately 10-15 sites will participate in this study.

The MTD and/or recommended dose and dosing regimens will be confirmed in a confirmation cohort of at least 6 subjects. A total of up to 126 subjects may participate in the study (including dose escalation and confirmation cohorts).

In each cohort, 28-day cycles will be used.

An independent Data Monitoring Committee (DMC) will review the relevant safety information before considering dose escalation for the next cohort.

Part A: ***MOR03087 dose escalation (bi-weekly treatment - q2w):***

Up to 8 dose levels of MOR03087 will be evaluated:

- Cohort 1 - Dose level 1: 0.01 mg/kg
- Cohort 2 - Dose level 2: 0.04 mg/kg
- Cohort 3 - Dose level 3: 0.15 mg/kg
- Cohort 4 - Dose level 4: 0.5 mg/kg
- Cohort 5 - Dose level 5: 1.5 mg/kg
- Cohort 6 - Dose level 6: 4.0 mg/kg
- Cohort 7 - Dose level 7: 8.0 mg/kg
- Cohort 8 - Dose level 8: 16.0 mg/kg

Each 28-day cycle will consist of:

MOR03087 infusion on Day 1 and Day 15 of the cycle. In Cycle 1, a loading dose will additionally be administered on Day 4 of the cycle.

At least 48 hours will pass between the first study drug administration to the subjects within a cohort in order to observe for AEs.

Part B: ***MOR03087 dose escalation (weekly treatment - q1w):***

- Dose level 6b: 4.0 mg/kg
- Dose level 7b: 8.0 mg/kg
- Dose level 8b: 16.0 mg/kg

Each 28-day cycle will consist of:

MOR03087 infusion on Days 1, 8, 15, and 22 of the cycle. In Cycle 1, a loading dose will additionally be administered on Day 4 of the cycle.

Part C: ***MOR03087 dose escalation (weekly/biweekly treatment - q1w/q2w) plus low dose of DEX:***

- Dose level 6c: 4.0 mg/kg
- Dose level 7c: 8.0 mg/kg
- Dose level 8c: 16.0 mg/kg

Each 28-day cycle will consist of:

MOR03087 infusion on Days 1, 8, 15, and 22 of the cycle. In Cycle 1, a loading dose will additionally be administered on Day 4 of the cycle.

Only for dose level 8c, for cycle 4 and onwards each 28-cycle will consist of: MOR03087 infusion on Day 1 and 15 of the cycle.

Subjects who have received treatment beyond Cycle 3 will be switched to the biweekly schedule at the next Day 1 or Day 15 visit. In exceptional cases, and after discussion between the investigator and the sponsor, the treating physician may determine that it is in the best interest of the subject to remain on the weekly MOR03087 schedule, in which case the sponsor should be informed accordingly.

The low dose of DEX is defined as a single dose of 40 mg or lower (as described in protocol section 7.1), once, to be orally administered on days of MOR03087 infusion.

For subjects in Cohort 8c who switch to biweekly MOR03087 treatment from Cycle 4 onwards, the DEX treatment schedule will remain unchanged (Day 1, 8, 15 and 22).

Following the completion of Part B dose level 6b and Part C dose level 6c, and taking into account available safety information from Part A dose level 8, the DMC will provide recommendation if some or all of the planned weekly MOR03087 monotherapy dose escalation cohorts will be tested.

Following completion of Parts A, B, and C (dose escalation of MOR03087 bi-weekly and weekly

regimen), the MTD or recommended dose and schedule will be confirmed in a minimum of 6 subjects.

Part D: ***MOR03087 (weekly/biweekly treatment) in combination with POM+DEX***

- Dose level 7d: 8.0 mg/kg
- Dose level 8d: 16.0 mg/kg

Each 28-day cycle will consist of:

MOR03087 infusion on Days 1, 8, 15, and 22 of the cycle. In Cycle 1, a loading dose will additionally be administered on Day 4 of the cycle.

Only for dose level 8d, for cycle 4 and onwards each 28-day cycle will consist of: MOR03087 infusion on Day 1 and 15 of the cycle.

Subjects who have received treatment beyond Cycle 3 will be switched to the biweekly schedule at the next Day 1 or Day 15 visit. In exceptional cases, and after discussion between the investigator and the sponsor, the treating physician may determine that it is in the best interest of the subject to remain on the weekly MOR03087 schedule, in which case the sponsor should be informed accordingly.

Oral POM 4 mg on Days 1-21 of the 28-day cycle.

Oral DEX 40 mg (≤ 75 years old) or 20 mg (> 75 years old) on Days 1, 8, 15, and 22 of the 28-day cycle.

For subjects in Cohort 8d who switch to biweekly MOR03087 treatment from Cycle 4 onwards, the DEX treatment schedule will remain unchanged (Day 1, 8, 15 and 22).

In Cycle 1 DEX is to be added to the loading dose on Day 4.

Part E: ***MOR03087 (weekly/biweekly treatment) in combination with LEN+DEX***

- Dose level 7e: 8.0 mg/kg
- Dose level 8e: 16.0 mg/kg

Each 28-day cycle will consist of:

MOR03087 infusion on Days 1, 8, 15, and 22 of the cycle. In Cycle 1, a loading dose will additionally be administered on Day 4 of the cycle.

Only for dose level 8e, for cycle 4 and onwards each 28-day cycle will consist of: MOR03087 infusion on Day 1 and 15 of the cycle.

Subjects who have received treatment beyond Cycle 3 will be switched to the biweekly schedule at the next Day 1 or Day 15 visit. In exceptional cases, and after discussion between the investigator and the sponsor, the treating physician may determine that it is in the best interest of the subject to remain on the weekly MOR03087 schedule, in which case the sponsor should be informed accordingly.

Oral LEN 25 mg on Days 1-21 of the 28-day cycle.

Oral DEX 40 mg (≤ 75 years old) or 20 mg (> 75 years old) on Days 1, 8, 15, and 22 of the

28-day cycle.

For subjects in Cohort 8e who switch to biweekly MOR03087 treatment from Cycle 4 onwards, the DEX treatment schedule will remain unchanged (Day 1, 8, 15 and 22).

In Cycle 1 DEX is to be added to the loading dose on Day 4.

Following completion of Parts D and E (dose escalation of MOR03087 in combination with POM + DEX and LEN + DEX), the MTD and/or recommended dose in each part will be confirmed in a minimum of 6 subjects.

All cohorts:

Based on the individual risk/benefit ratio, subjects who have an ongoing response of at least stable disease (SD) may continue treatment with the assigned study regimen until disease progression or until a maximum of 3 years after first treatment. In case subjects present with progressive disease or with no better status than SD after 4 treatment cycles starting with Cycle 1 Day 1, the investigator may add a low weekly dose of DEX to the regimen at his/her discretion, provided DEX is not already part of the treatment regimen.

After study drug discontinuation due to reason other than disease progression and other than withdrawal of consent, all subjects will return for a follow-up visit 1 and follow-up visit 2. Further follow-up visits will be conducted at 4-week intervals until the subject is progressive, begins subsequent anti-myeloma therapy, or dies.

All subjects will be followed up for a maximum of 3 years after first administration of study drug.

Dose Escalation Process:

At least 3 subjects meeting all inclusion and none of the exclusion criteria, as determined at the screening visit (see sections 8.1 and 8.2 of the study protocol) will be enrolled into each cohort. Enrolment into a cohort at the next higher dose level will be based on the data generated from the previous dose level and guided by DMC review until

- the maximum planned dose has been reached, or
- the review of the safety data indicates a need to either expand the current dose level cohort to include 6 subjects or stop the dose escalation or the study, or
- the review of Part B dose level 6b and Part C dose level 6c, including available safety information from Part A dose level 8, indicates that only some of the planned weekly MOR03087 monotherapy dose escalation cohorts should be tested.

The DMC safety review will take place after the third subject enrolled into a cohort has undergone minimum safety evaluations (as defined for the "DLT Evaluable Population" in section 6). The safety assessment will take into account AEs reported from Day 1 after the start of the first infusion through Day 29 (Cycle 2 Day 1) before the start of the second cycle. The next cohort will only be started after the positive outcome of the safety assessment.
Subjects who withdraw whilst their safety assessment period is not evaluable will only be replaced during the dose-escalation phase until the applicable cohort consists of a sufficient number of evaluable subjects. However, withdrawals due to DLTs will not be replaced.

Cohort expansion up to 6 subjects will be allowed if a dose limiting toxicity (DLT) (as defined in section 8.5 of the study protocol) is observed in 1 of 3 subjects. If 2 or 3 subjects experience a DLT in cohorts 6b or 6c, the study sponsor may decide to test a lower dose. If 2 or 3 subjects of the 3 subjects in any of the other cohorts experience DLT, then the previous cohort should be expanded to 6 subjects.

Part A dose levels 1-7 will be tested sequentially, and only 1 dose level will be open for enrolment at any time. Starting with Part A dose level 8, Parts B and C will open in parallel (at dose level 6 [6b and 6c]). Following completion of dose level 7c (8.0 mg/kg MOR03087 + DEX) (and dose level 7b if the DMC recommends to open this cohort), Cohorts 7d and 7e may open in parallel with dose levels 8b (if the DMC recommends to open this cohort) and 8c. New cohorts will not start before the DMC returns a positive recommendation based on safety read-outs from prior cohorts as laid down in the DMC Charter.

3.2 Selection of Study Population

This is a phase I/IIa study in adult subjects with relapsed or refractory MM as monotherapy and in combination with standard therapy. Key inclusion criteria identified in the protocol are

1. Male or female subjects ≥ 18 years of age
2. Presence of serum M-protein ≥ 0.5 g per 100 mL (≥ 5 g/L) and/or urine M-protein ≥ 200 mg per 24-hour period
3. Life expectancy of > 3 months
4. Karnofsky performance status ≥ 60%
5. Absolute neutrophil count ≥ 1.0 (1,000/mm^3)
6. Total bilirubin ≤ 2 × the upper limit of normal (ULN)
7. Alanine transaminase and aspartate aminotransferase ≤ 2.5 × ULN
8. Hemoglobin ≥ 8 g/dL

Additional key inclusion criteria are defined differently for monotherapy and different combination therapies:

Additional Key Inclusion Criteria for Treatment With MOR03087 With/Without Dexamethasone

1. Documented diagnosis of MM; specifically, relapsed or refractory MM defined as:
   - Failure of at least 2 previous therapies; previous therapies must include an immunomodulatory agent and a proteasome inhibitor (either together or as part of different therapies)
   - All subjects must have documented progression during or after their last prior therapy for MM
2. Creatinine clearance ≥ 30 mL/min (calculated using the Cockcroft-Gault equation)
3. Platelets:
   - ≥ 80 × 10^9/L, without previous transfusion within the last 4 weeks before first study drug administration

- $\geq 50 \times 10^9$/L (for dose levels ≥4 mg/kg with or without DEX). Subjects are not allowed to have received platelet transfusion within the last 4 weeks before study drug administration.

Additional Key Inclusion Criteria for the Treatment With MOR03087, Dexamethasone and Lenalidomide

1. Documented diagnosis of MM; specifically, relapsed or refractory MM defined as:
   - Received at least 1 previous therapy
   - All subjects must have documented progression during or after their last prior therapy for MM
2. Creatinine clearance ≥ 50 mL/min (calculated using the Cockcroft-Gault equation)
3. Platelets:
   - $\geq 75 \times 10^9$/L for subjects in whom < 50% of bone marrow nucleated cells are plasma cells
   - $\geq 30 \times 10^9$/L for subjects in whom ≥ 50% of bone marrow nucleated cells are plasma cells.

Additional Key Inclusion Criteria for the Treatment With MOR03087, Dexamethasone and Pomalidomide

1. Documented diagnosis of MM; specifically, relapsed and refractory MM defined as:
   - Received at least 2 previous therapies including LEN and a proteasome inhibitor
   - All subjects must have documented progression during or within 60 days after their last prior therapy for MM
2. Creatinine clearance ≥ 45 mL/min (calculated using the Cockcroft-Gault equation)
3. Platelets:
   - $\geq 75 \times 10^9$/L for subjects in whom < 50% of bone marrow nucleated cells are plasma cells
   - $\geq 30 \times 10^9$/L for subjects in whom ≥ 50% of bone marrow nucleated cells are plasma cells

3.3 Method of Treatment Assignment and Randomization

The study is not randomized. Subjects are allocated to open cohorts only. The allocation is performed centrally by the project management. In case more than 1 cohort is open in parallel subjects who meet the inclusion-/exclusion criteria for more than 1 cohort are allocated to 1 of the open cohorts based on a specific cohort assignment plan. The project management department is the owner of the cohort assignment plan and the latest version is Version 6, 30-JUN-2016.

3.4 Treatment Masking (Blinding)

This is an open-label study. No personnel involved in the study will remain blinded.

4. ANALYSIS AND REPORTING

4.1 DMC Analysis

An independent DMC will review the safety data at several timepoints during the study. Details of the safety data output provided for the DMC by Premier Research Biostatistics are described in a separate Statistical Interim Safety Analysis Plan, Final Version 4.0, dated 26-MAY-2015.

4.2 Final Analysis

The analyses identified in the protocol and in this SAP will be performed after all subjects enrolled have reached the Cycle 3 Day 1 visit or end of study assessments (whatever comes first) and all relevant study data have been processed, all relevant data has been frozen and this SAP has been approved. A cut-off date will be determined for the analysis (which will be after all subjects enrolled have reached Cycle 3 Day 1 or end of study assessments) and all data available up to the cut-off date will be included into the analysis. The final analysis is also referred to as "primary completion analysis".

4.3 Follow-up Analyses

After the final analysis, additional supplemental analyses of long-term efficacy and safety follow-up will be performed. For this analysis, it is planned to re-run all analyses described in this SAP.

Key statistics and study results will be made available to MorphoSys AG following database lock and prior to completion of the final CSR.

Any, post-hoc, exploratory analyses completed to support planned study analyses, which were not identified in this SAP, will be documented and reported in appendices to the CSR. Any results from these unplanned analyses (post-hoc) will also be clearly identified in the text of the CSR.

5. SAMPLE SIZE DETERMINATION

A 3 + 3 design is used for the dose-escalation part of the study with confirmation cohorts of 6 subjects. At least 9 subjects will be analyzed in the recommended dose groups of each part: 6 subjects from the confirmation cohort and at least 3 subjects from the dose-escalation cohort who receive the same dose and regimen and combination treatment (if applicable). [redacted]

6. ANALYSIS POPULATIONS

The following analysis populations are planned for this study:

Total Population (All Subjects)

The Total Population will consist of all subjects including screening failures.

Safety Population

The Safety Population will consist of all enrolled subjects who received any of the IMP at least once.

DLT Evaluable Population

The DLT Evaluable Population will consist of all enrolled subjects who have received at least 1 cycle of MOR03087 (at least 4 doses for q1w or 2 doses for the q2w dosing schedule) (monotherapy or combination therapy) and if applicable per cohort, at least 16 doses of LEN or POM without dose modifications and who have minimum safety evaluations, including the first

cycle and AEs reported from Day 1 after the start of the first infusion until Day 1 of the second cycle (before start of infusion).

- Subjects who withdraw before having received the minimum number of infusions/doses and safety evaluations due to DLT will be included in the DLT evaluable population.
- Subjects who discontinue study treatment or require a dose modification for LEN or POM for reasons unrelated to a DLT within the first cycle will be excluded from the DLT evaluable population.

Efficacy Evaluable Population

The Efficacy Evaluable Population will consist of all subjects who take at least 1 dose of IMP and who have at least one investigator response assessment (including potential unscheduled response assessment/ visits) after baseline. Only a post-baseline lab value without an Investigator response assessment does not qualify for inclusion.

Pharmacokinetic Population

The Pharmacokinetic Population will consist of all subjects who have sufficient pharmacokinetic data to characterize the time course of MOR03087 or LEN or POM in serum or plasma for the first IMP administration at a minimum.

7. GENERAL ISSUES FOR STATISTICAL ANALYSIS

7.1 General Statistical Methodology

A table for disposition of all subjects (see section 8.1) will be produced for all subjects who provide informed consent, including screening failures. The Safety Population will be used for safety analysis and to analyze immunogenicity and the pharmacodynamic endpoints. The DLT Evaluable Population will be used to determine the maximum tolerated dose. Summaries for the analysis of tumor response will be provided for the Efficacy Evaluable Population and the Safety Population. Pharmacokinetic data evaluation will be not part of this SAP but described in a separate Pharmacokinetic Analysis Plan.

Each safety listing will contain a flag indicating which subjects are DLT-evaluable and which subjects are not DLT-evaluable after the subject number. All listings will be sorted by cohort (if data from more than 1 cohort is presented).

In the tables all available data of subjects including all cycles will be presented unless otherwise specified. For the AE tables presenting DLT, TEAEs by grading and SAEs, additional tables will be produced including data of the first cycle only.

Tabulations of summary statistics, graphical presentations, and statistical analyses will be performed using SAS software, Version 9.4 or later.

Continuous, quantitative variable summaries will include the number of subjects (N) (with non-missing values), mean, standard deviation, median, minimum, maximum, and first and third quartiles. First and third quartile will not be shown in by-cohort-tables (tables of type 1, see section 7.2).

Some of the descriptive summaries (as specified in the subsequent sections) will additionally include the 95%-confidence interval for the mean (absolute) change from baseline. The

confidence interval will be calculated based on the quantiles of the t-distribution assuming normal distribution of the data. Moreover, some of the descriptive summaries (as specified in subsequent sections) will include the 95%-confidence interval for the median (absolute or percentage) change from baseline. The 95%-confidence interval for the median will be calculated without any assumption on the distribution of the data (nonparametric confidence interval). [redacted]

Categorical, qualitative variable summaries will include the frequency and percentage of subjects who are in a particular category. Unless otherwise stated the calculation of proportions will be based on the number of subjects of the analysis set of interest. Therefore counts of missing observations will be included in the denominator and presented as a separate category.

[redacted]

The last pre administration observation will be used as the baseline value for calculating post administration changes from baseline. Thus baseline will be Cycle 1 Day 1 in case there is a value available (not missing) and screening otherwise.

All data obtained on the electronic case report for (eCRF) and entered into the database will be provided in separate data listings showing individual subject values. The planning and reporting of statistical analyses will be carried out as described in the Premier Research Biostatistics standard operating procedures.

Any subject who withdraws from the study will be analyzed with the data available. Imputation of missing values will not be performed.

7.2 Structure of Tables

Three different types of tables will be produced:

1) tables for the total study data by cohort
2) tables for the total study data by part
   - bi-weekly (Part A)
   - weekly without dexamethasone (Part B)
   - weekly with dexamethasone (Part C)
   - combination with POM (Part D)
   - combination with LEN (Part E)

3) tables for recommended dose data by part

   - weekly with dexamethasone (Part C)
   - combination with POM (Part D)
   - combination with LEN (Part E)

The safety and baseline summary tables will additionally contain a summary of the total number of subjects of the corresponding analysis (sub-) group.

In the tables for recommended dose data, all data from the recommended (or MTD) dose levels will be summarized together, i.e. data from the confirmation cohort will be combined with the data from the cohort of the dose escalation scheme that received the same dose and regimen and combination treatment (if applicable).

Summaries of type 2) and 3) will be referred to as combined presentations or combined data in subsequent sections, in contrast to summaries by dose level.

The 95% confidence intervals will only be presented for these combined presentations and will not be presented by dose level due to the small number of subjects by dose level.

7.3 Derived and Computed Variables

The following derived and computed variables have been initially identified as important for the statistical analysis. Additional variables may be required. The SAP will not be amended for additional variables that are not related to the primary target or key secondary target variables. Any additional derived or computed variables will be identified and documented in the SAS programs that create the analysis files. If the SAP is not amended, further derivations related to primary and secondary target variables will be described in the CSR.

7.3.1 Baseline Variables

Table 1 shows the variables, which will be calculated for the analysis of subject disposition and baseline characteristics and to define subgroups based on baseline characteristics.

Table 1: Derived Subject Disposition and Baseline Variables

Data	Variable	Derivation
Disposition	time on study [months]	Time on study will be calculated as time from Cycle 1 Day 1 until date of last visit or date of study completion whichever is later [= (date of last visit/study completion – Cycle 1 Day 1 + 1)/[redacted]]
	Time since first diagnosis of multiple myeloma [months]	Time since first diagnosis will be calculated as time from date of first diagnosis until Cycle 1 Day 1. If date of diagnosis is incomplete, time since first diagnosis [months] will be calculated based on the latest possible date for date of diagnosis.
Previous Drug Treatment of MM	Refractory to previous drug treatment [Yes/no/missing]	Progression of disease while on a specific therapy, or within 60 days of completion of a given therapy. (S. Lonial, Hematology 2010) [4] In case of incomplete dates mid of month (15th)/ mid of year (30JUN) will be used for date of end of previous therapy and/or date of progression. Each previous drug treatment of 1 therapy line should have the same date of progression. In

		case date of progression is missing for a treatment or different dates are entered, the latest date of progression will be used for all treatments of this therapy line. In case date of progression or date of end of previous therapy is completely missing or progression status is not determined at all for previous therapies (e.g. subjects enrolled at the beginning of the study), variable will be missing This variable will be determined for each previous drug treatment.
	Refractory to most recent previous drug treatment line [Yes/no/missing]	The most recent drug treatment will be selected based on most recent end date. Refractory will be determined as described above. This variable will be determined per subject.
	Double-Refractory to previous drug treatments containing a proteasome inhibitor and IMiD [Yes/no/missing]	Refractory to a proteasome inhibitor and refractory to an IMiD. Refractory will be determined as described above.
Cytogenetics of MM Cells (Bone Marrow)	high risk evaluation [Yes/no/missing]	Reference: Chng et al., Leukemia, 2014 [5] high risk is met [Yes] if a subject has (1) chromosomal aberration t(4;14) or Del17p13and (2) International Staging System (ISS) criteria II/III In case chromosomal aberations and/or ISS are not determined or one chromosomal aberation is missing and the other one is absent, variable will be missing.

7.3.2 Immunogenicity

Subject has positive anti-MOR03087 antibodies (yes/no/missing) by visit:

- yes, if a titer is available (in this case the sample is confirmed positive)
- no, if result is reported as negative
- missing, if anti-MOR03087 measurement is not available

Subject has developed positive anti-MOR03087 antibodies during study

(yes/no/transient/not evaluable/missing):

- yes, if the subject has at least 1 confirmed positive post-baseline sample containing anti-MOR03087 antibodies including the last sample analyzed; baseline sample has to be tested negative
- no, if baseline as well as all post-baseline results are negative
- transient, if the subject has at least 1 confirmed positive post-baseline sample containing anti-MOR03087 antibodies but a negative result for the last sample analyzed; baseline sample has to be tested negative
- not evaluable, if the baseline sample of the respective subject was tested positive
- missing, if no post-baseline anti-MOR03087 measurement is available

Time to development of anti-MOR03087 antibodies [months]: Time to development of anti-MOR03087 antibodies will be defined as time from Cycle 1, Day 1 until Date of first blood sample containing anti-MOR03087 antibodies. Subjects who do not develop any antibodies by end of study will be considered as censored at the date of last blood sample taken for MOR03087 antibody analysis.

7.3.3 Efficacy Endpoints Based on Investigator Assessment

The Investigator will assess efficacy at specific study visits according to the response criteria for MM as defined in section 18.3 of the study protocol version valid at the time of the assessment. All of the criteria are based on the International Myeloma Working Group (IMWG) Uniform Response Criteria [6], except for MR, which is based on the (adopted) European Group for Blood and Marrow Transplantation (EBMT) criteria [7].

The response evaluation of the Investigator is based on the serum and urine M-protein levels, and, where applicable, the serum FLC level, and FLC ratio.

The categories of overall tumor response assessment of the Investigator will be as follows:

- sCR – Stringent Complete Response
- CR - Complete Response
- VGPR - Very Good Partial Response
- PR - Partial Response
- MR - Minimal Response
- SD - Stable Disease
- PD - Progressive disease
- Missing (if response assessment is not done)

In case of progressive disease, the date of progression will be given by the Investigator.

All responses need 2 consecutive assessments, ideally being confirmed at Day 1 of the next cycle. Thus all endpoints defined to evaluate responses per-subject across time points (see section 7.3.3.2 and 7.3.3.3) will include confirmed responses only.

For all endpoints where dates are used in the derivations (e.g. date of first response, date of first

progression), the following dates will be taken into consideration to determine the time point each response assessment refers to:

- Date of assessment or date of visit, whichever is earlier if the assessment is non-PD (this approach is chosen as the assessment is sometimes done retrospectively and not at the date of the visit)
- date of progression given by the Investigator in the field "Date of Progression" in the response assessment form if the assessment is PD

In case any non-study anti-MM treatments are given before end of study (see also section 8.3, it is regarded as protocol non-compliance. Tumor assessments after start of non-study anti-MM treatment will not be taken into account for any of the derived efficacy variables described below. In case the start date of non-study anti-MM treatment is incomplete, an imputed start date will be used in all derivations. The imputed start date will always be the first possible start date, but after the end-of-study (EOS) visit. For example, in case day is missing, but month and year are complete, the first day of the month will be taken if after EOS, otherwise date of EOS + 1.

7.3.3.1 Responses by subject and visit

The following variables will be derived by visit based on the overall tumor assessment of the Investigator:

Any response (PR or better) (yes/no) by visit:

- yes, if tumor response assessment is sCR, CR, VGPR, or PR
- no, if tumor response assessment is MR, SD, PD or Missing

Any clinical benefit (MR or better) (yes/no) by visit:

- yes, if tumor response assessment is sCR, CR, VGPR, PR or MR
- no, if tumor response assessment is SD, PD or Missing

Any disease control (SD or better) (yes/no) by visit:

- yes, if tumor response assessment is sCR, CR, VGPR, PR, MR or SD
- no, if tumor response assessment is PD or Missing

7.3.3.2 Responses derived per-subject across time points:

The subsequent variables will be derived per-subject across time points, based on the overall tumor assessment of the Investigator.

Best Overall Response (BOR): The best overall response will be defined as the best response across all time points. The best possible overall response is sCR, followed by CR, VGPR, PR, MR, SD, and PD.

To be assigned a status of sCR, CR, VGPR, PR, MR, SD, the first assessment must be confirmed by the next consecutive non-missing assessment (missing values will not be taken into account). Both assessments must show a status of sCR, CR, VGPR, PR, MR or SD, and the assigned confirmed status will be the weaker status of both assessments.

A single progression of disease (PD) assessment which did not cause a discontinuation of

treatment and which has been disproven by the next consecutive non-missing tumor assessment will not be considered in the evaluation of best overall response. If no post-baseline confirmed response assessment or PD is available, then the best overall response will be "Not Evaluable" (NE).

Secondary efficacy endpoint variables:

Any response (yes/no) in study:

- yes, if best overall response is sCR, CR, VGPR or PR
- no, if best overall response is MR, SD, PD or NE

The **Overall response rate (ORR),** defined as the proportion of subjects who meet the criteria of confirmed sCR, CR, PR or VGPR at any time during study, will be calculated from this variable.

Additional efficacy variables:

Any clinical benefit (yes/no) in study:

- yes, if best overall response is sCR, CR, VGPR, PR or MR
- no, if best overall response is SD, PD or NE

The **Clinical benefit rate (CBR),** defined as the proportion of subjects who meet the criteria of confirmed CR, PR, VGPR or MR at any time during study, will be calculated from this variable.

Any disease control (yes/no) in study:

- yes, if best overall response is sCR, CR, VGPR, PR, MR or SD
- no, if best overall response is PD or NE

The **Disease control rate (DCR)** defined as the proportion of subjects who meet the criteria of confirmed sCR, CR, VGPR, PR, MR or SD at any time during study, will be calculated from this variable.

7.3.3.3 Time-related efficacy endpoints

With respect to the time-related efficacy endpoints defined subsequently, a single PD assessment which did not cause a discontinuation of treatment and which has been disproven by the next consecutive non-missing tumor assessment will not be considered when determining the date of first progression and the censoring variables.

Thus, the date of progression used for the derivations will be the date of progression related to the first PD assessment that fulfills at least 1 of the following criteria:

- the next consecutive non-missing tumor assessment is also PD
- the PD assessment is the last tumor assessment in the study

The start date for sCR, CR, VGPR, PR, MR and SD is defined as the date of the first time point at which the response was noted, provided that the response was confirmed at a later time point (as described in section 7.3.3.2). However, a response followed by ≥ 2 non-confirming consecutive non-missing planned response assessments will not be considered for the determination of the first date at which the response was noted.

The date of death due to progression is the stop date of AEs with a fatal outcome and a preferred AE term “Disease progression” or “Multiple myeloma”.

All time-related efficacy endpoints defined below will be reported in months.

Secondary efficacy endpoint variables:

Duration of response (DoR): The duration of response will be calculated in the subgroup of subjects showing confirmed sCR, CR, VGPR or PR. Duration of response will be defined as the time from date of first response (sCR, CR, VGPR or PR) until date of progression or death due to progression (as defined above) whichever is documented first. For censoring rules see Table 2.

Time to progression (TTP): Time to progression will be defined as the time from Cycle 1, Day 1 until date of progression or death due to progression (as defined above) whichever is documented first. For censoring rules see Table 2.

Table 2: Censoring Rules for DoCB, DoR and TTP

Situation	Date of Progression or Censoring	Outcome
Disease Progression	Date of progression	Progressed
No baseline tumor assessment	Date of first treatment	Censored
No disease progression	Date of last tumor assessment	Censored
Subject received non-study MM treatment before disease progression	Date of last tumor assessment prior to non-study treatment	Censored
Death from other causes than disease progression, without documented disease progression before	Date of last tumor assessment	Censored
Death caused by disease progression between adequate assessments	Date of death	Progressed
Death caused by disease progression or progression after > 65 days (2x 29-day cycle +7 days) after last tumor response assessment (representing the time interval of 2 or more consecutive missed tumor response assessments)	Date of last tumor assessment	Censored

Progression-free survival (PFS): Progression-free survival will be defined as the time from

Cycle 1, Day 1 until date of progression (as defined above) or date of death, whatever occurs earlier, or date of censoring (as defined below). For censoring rules see Table 3.

Table 3: Censoring Rules for PFS

Situation	**Date of Progression or Censoring**	**Outcome**
Disease progression	Date of progression	Progressed
No post-baseline tumor assessment	Date of first treatment	Censored
No disease progression	Date of last tumor assessment	Censored
Subject received non-study MM treatment before disease progression	Date of last tumor assessment prior to non-study treatment	Censored
Death before any date of PD assessment	Date of death	Progressed
Death between adequate assessments	Date of death	Progressed
Death or progression after > 65 days (2x 29-day cycle +7 days) after last tumor response assessment (representing the time interval of 2 or more consecutive missed tumor assessments)	Date of last tumor assessment	Censored

Additional time to event variables:

Duration of clinical benefit (DoCB): The duration of clinical benefit will be calculated in the subgroup of subjects showing confirmed sCR, CR, VGPR, PR or MR. Duration of clinical benefit will be defined as the time from date of first clinical benefit (sCR, CR, VGPR, PR or MR) until date of progression or death due to progression (as defined above), whichever is documented first. For censoring rules see Table 2.

Additionally, the DoR of sCR/CR and sCR/CR/VGPR according to the above defined rules will be reported separately.

Time to next treatment (TTNT): TTNT will be defined as the time from Cycle 1, Day 1 until start date of new anti-MM treatment as documented at the end of trial visit under "Subsequent anti-MM Treatment" or date of death. Subjects with no documented start date for a subsequent anti-MM treatment and no documented date of death will be considered censored using the date of the last visit.

Event-free survival (EFS): EFS will be defined as the time from Cycle 1, Day 1 until date of progression, date of death, or date of discontinuation of treatment for any reason (e.g. toxicity, subject preference, or initiation of a new treatment without documented progression), whichever occurs earlier. Subjects still on treatment, without disease progression, will be censored at the date of the last available tumor assessment.

Additional time to event variables for the subgroup of responders:

Time to first response: Time to first response will be defined as the time from Cycle 1, Day 1 until start date of first response (sCR, CR, VGPR or PR).

Time to best response: Time to best response will be defined as the time from Cycle 1, Day 1 until best response (sCR, CR, VGPR or PR).

Time to first clinical benefit: Time to first clinical benefit will be defined as the time from Cycle 1, Day 1 until first clinical benefit (sCR, CR, VGPR, PR or MR).

7.3.4 Quantitative Efficacy Variables based on Serum or Urine M-Protein, and/or Serum FLCs

Serum and urine M-protein and serum FLCs were analyzed by a local laboratory at the beginning of the study and by central laboratory for subjects enrolled after Nov 2014 (starting from cohort 7c/ cohort 8 partially) using the response criteria for MM as defined in the current version of the protocol. The following parameters will be measured by visit:

- Serum M-protein level [g/L]
    - Measurements are given g/L, g/dL, mg/L or mg/dL. All values will be converted to [g/L].
- Urine M-protein result [g/24h]
    - Measurements are given g/24h or mg/24h. All values will be converted to [g/24h].
- Lambda FLCs [mg/L]
    - Values smaller than the limit of quantification will be analyzed with the value for the limit of quantification.
- Kappa FLCs [mg/L]
    - Values smaller than the limit of quantification will be analyzed with the value for the limit of quantification.
- Kappa/lambda FLC ratio
    - Kappa/lambda FLC ratio will be recalculated by biostatistics.

For all of these parameters, absolute and percentage changes from baseline will be calculated by visit.
Moreover, the following variables will be derived per subject across timepoints:

Relative change (%) in serum M-protein level from baseline to post-baseline nadir:

This variable will be calculated for all subjects that have measurable serum M-protein levels at baseline and at least 1 post-baseline serum M-protein measurement. The post-baseline nadir will

be the smallest serum M-protein level recorded after baseline. The relative change (%) will be derived as follows:
100* (serum M-protein level at post-baseline nadir – baseline serum M-protein level) / (baseline serum M-protein level).

Relative change (%) in urine M-protein result from baseline to post-baseline nadir:

This variable will be calculated for all subjects that have measurable urine M-protein results at baseline and at least 1 post-baseline urine M-protein measurement. The post-baseline nadir will be the lowest urine M-protein result recorded after baseline. The relative change (%) will be derived as follows:
100* (urine M-protein result at post-baseline nadir – baseline urine M-protein result) / (baseline urine M-protein result).

In case any new anti-MM treatments are given before end of study (see also section8.3), this will be regarded as protocol non-compliance. M-protein values measured after start of new anti-MM treatment will be flagged in listings. Moreover, these will be excluded from tables and will not be taken into account when deriving relative changes from baseline to post-baseline nadir.

7.3.5 Quality of Life

Quality of life (QoL) will be assessed using the Quality of Life Questionnaire for Cancer Subjects (QLQ-C30) (version 3) [8] and the Quality of Life Questionnaire for Myeloma Subjects (QLQ-MY20) [9], [10] developed by the European Organisation for Research and Treatment of Cancer (EORTC).

The QLQ-C30 instrument is a reliable and validated 30-item questionnaire composed of 5 functional scales (physical, role, emotional, social, and cognitive), 3 symptom scales (fatigue, nausea and vomiting, and pain) and a global health status/quality of life scale, and 6 single symptoms (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). The QLQ-MY20 instrument is a 20-item disease-specific modular questionnaire regarding subject-reported symptoms or problems. It is usually completed in addition to the QLQ-C30 questionnaire.

The QLQ-C30 will be scored as described in the EORTC QLQ-C30 Scoring Manual from the EORTC Data Center (2001) [11]. The QLQ-MY 20 will be scored according to the same principles as described in the addendum: scoring instructions for newly validated modules.

A score will be calculated for all scales (categories) shown in Table 4.

Table 4 Scales for Scoring the QLQ-C30 (version 3.0) and QLQ-MY 20

		Number of items	Item Range*	Item numbers (Version 3.0)
QLQ-C30 (Item Numbers 1-30)	**Global health status / QoL**			
	Global health status/QoL	2	6	29, 30
	Functional scales			
	Physical functioning	5	3	1 to 5
	Role functioning	2	3	6, 7
	Emotional functioning	4	3	21 to 24
	Cognitive functioning	2	3	20, 25
	Social functioning	2	3	26, 27

		Number of items	Item Range*	Item numbers (Version 3.0)
	Symptom scales / items			
	Fatigue	3	3	10, 12, 18
	Nausea and vomiting	2	3	14, 15
	Pain	2	3	9, 19
	Dyspnea	1	3	8
	Insomnia	1	3	11
	Appetite loss	1	3	13
	Constipation	1	3	16
	Diarrhea	1	3	17
	Financial difficulties	1	3	28
QLQ-MY 20 (Item Numbers 31-50)	**Functional scales / items**			
	Future perspective	3	3	48 – 50
	Body image	1	3	47
	Symptom scales			
	Disease symptoms	6	3	31 –36
	Side effects of treatment	10	3	37 – 46**

*Item range is the difference between the possible maximum and the minimum response to individual items; functional and symptom scales take values from 1 =Not at all to 4= Very Much, resulting in range = 3. Questions regarding global health status take values from 1 to 7, resulting in range =6.

** Question 42 is considered scored "not at all" if question 41 is scored "not at all".

For all scales (categories), the Raw Score (RS) is the mean of the component items.

In case of missing items within an answered questionnaire, the RS for the scale will only be calculated if at least half of the items from the scale have been answered. In this case the mean will be calculated only including those questions which have been answered.

The RS will be transformed into a standardized score using a linear transformation so that scores range from 0 to 100; a higher standardized score represents a higher ("better") level of functioning for functional scales, or a higher ("worse") level of symptoms for symptom scales. The following formula will be used for transformation:

- Functional scales: Score = [1- (RS-1)/range]*100
- Symptom scales: Score = (RS-1)/range *100

A global score based upon the sum of all items of the QLQ-C30 and/or the QLQ-MY20 will not be calculated according to the recommendations of the EORTC data center. The Global health status / QoL scale (based on questions 29 and 30) will be used as an overall summary measure for the QLQ-C30.

7.3.6 Exposure

Table 5 shows the variables that will be calculated to measure exposure to study drugs (MOR03087, DEX, LEN, POM). Exposure to MOR03087 will be calculated for all subjects, exposure to LEN and POM will be only calculated for subjects in the respective combination therapy cohorts. Dexamethasone exposure will be derived for subjects in the dose-escalation part

receiving weekly MOR03087 treatment plus dexamethasone, and in subjects in both combination therapy cohorts. In cohorts where dexamethasone may be added later, dexamethasone intake will be summarized within the concomitant medication table.

Table 5 Derived Variables for Exposure

Exposure to Any Study Drug		
Variables calculated on a per-subject basis	Duration of treatment [months]	(date of last dosing day of any IMP – date of first dosing day of any IMP + 1)/[redacted]
Exposure to MOR03087		
Variables calculated for each study drug administration	Percentage of actual volume administered vs. planned volume [%]	Actual volume administered [mL]/planned volume [mL]*100% Note: The planned volume is either 100 mL or 250 mL. In case no actual volume administered is given, the value will be set • to the planned volume in case dosing modified is answered with "No" • to 0 in case dosing modified is answered with "Yes" and the type of modification is "Infusion not given" • to 0 in case infusion page is not filled out, but visit took place, and infusion planned according to treatment schedule and visit date is before last date of dosing • to missing in case dosing modified is answered with "Yes" and type of modification is other than "Infusion not given". In case actual volume is 0 and planned volume is unknown, the percentage will still be calculated as 0%.
	Actual dose administered [mg/kg]	(Actual volume administered [mL]/planned volume [mL])*Assigned dose [mg/kg] Note: This calculation assumes that the study drug solution is prepared correctly and contains the correct amount of study drug.
	Actual dose administered [mg]	(Actual volume administered [mL]/planned volume [mL])*Assigned dose [mg/kg]* Weight[kg] Note: Weight will be taken from the same visit from the Vital Signs form. In case no weight is available for this visit the most recent previous available weight will be

		taken.
	Duration of infusion [min]	Duration, calculated as stop time of infusion – start time of infusion
	Duration of infusion [categorized]	Duration will be categorized into: <40min; <1h, <2h; <3h; ≥3h
Variables calculated on a per-subject basis including data of all cycles	Number of cycles initiated	Number of cycles initiated per subject according to the following definition: A cycle will be qualified as "initiated" if at least 1 dose (non null) of study drug was administered in this cycle.
	Number of cycles completed	Number of cycles completed = number of cycles initiated, in case a subject drops out at the end of a cycle (i.e. at Day 22 or later, with last infusion at Day 22 administered in case of weekly treatment), but before start of next cycle. Number of cycles completed = number of cycles initiated – 1, in case a subject drops out within the last cycle.
	Number of cycles with all infusions completed	Number of cycles with all infusions completed (i.e. study drug administration page is filled for all intended infusions of the cycle and it is not ticked "Infusion not given".)
	Number of infusions administered	Number of all infusions where a study drug administration page is filled and it is not ticked "Infusion not given".
	Percentage of infusions administered	Number of infusions administered/ Number of planned infusions from Cycle 1, Day 1 up to and including the last visit for which the question "Was treatment modified" was answered (in any form).
	Number of infusions administered with any modification	Number of all infusions with any treatment modification except "Infusion not given".
	Average percentage of actual volume administered vs. planned volume [%]	Mean of the variable "Percentage of actual volume administered vs. planned volume [%]" over all infusions
	Total actual dose	Sum of the variable "Actual dose

	administered [mg/kg]	administered [mg/kg]" over all infusions
	Total actual dose administered [mg]	Sum of the variable "Actual dose administered [mg]" over all infusions
	Average actual dose administered [mg/kg]	Mean of the variable "Actual dose administered [mg/kg]" over all infusions
	Number of infusions not given	Number of all infusions with "Actual volume administered [mL]" of zero. Missing data will be replaced as described above.
	Percentage of infusions not given [%]	Number of infusions not given / Number of planned infusions from Cycle 1, Day 1 up to and including the last visit for which the question "Was treatment modified" was answered (in any form)
	Shortest infusion duration category per subject	Select from all available infusion duration categories per subject the shortest one in the order of <40min; >=40 min to <1h; >= 1h to <2h; >= 2h to <3h, and ≥3h
Exposure to Lenalidomide		
Variables calculated on a per-subject basis including data of all cycles	Number of days treated	Sum of durations of intake [=Start date – Stop date + 1] over all entries (in the eCRF LEN administration log) with non-zero dose
	Total actual dose taken [mg]	Sum of (durations of intake * dose [mg]) over all entries (in the eCRF LEN administration log)
	Average daily dose taken during days treated [mg/day]	Total actual dose taken [mg]/ Number of days treated
	Average daily dose taken during study [mg/day]	Total actual dose taken [mg]/ Duration of treatment [weeks] *7
	Percentage of actual dose vs. planned dose [%]	Total actual dose taken [mg]/ Planned dose [mg] Where planned dose = sum of (starting dose of each cycle * 21 days), calculated over all cycles initiated. Starting dose of each cycle is taken from eCRF LEN administration page for Day 1 of each cycle

	Number of days with missed doses	Sum of durations of intake of 0 dose [=Start date – Stop date + 1] over all entries (in the eCRF LEN administration log) with reason other than "Subject is in Rest Period between Day22 and Day28"
	Any dose reduction	Any reduced dose applications (compared to starting dose in first cycle)
	Any permanent discontinuation of LEN but continuation of MOR03087	Discontinuation of LEN but continuation of MOR03087 during at least 2 MOR03087 infusions until last MOR03087 dosing day
Exposure to Pomalidomide		
Variables calculated on a per-subject basis including data of all cycles	Number of days treated	Sum of durations of intake [=Start date – Stop date + 1] over all entries (in the eCRF POM administration log) with non-zero dose
	Total actual dose taken [mg]	Sum of (durations of intake * dose [mg]) over all entries (in the eCRF POM administration log)
	Average daily dose taken during days treated [mg/day]	Total actual dose taken [mg]/ Number of days treated
	Average daily dose taken during study [mg/day]	Total actual dose taken [mg]/ Duration of treatment [weeks] *7
	Percentage of actual dose vs. planned dose [%]	Total actual dose taken [mg]/ Planned dose [mg] Where planned dose = sum of (starting dose of each cycle * 21 days), calculated over all cycles initiated. Starting dose of each cycle is taken from eCRF POM administration page for Day 1 of each cycle
	Number of days with missed doses	Sum of durations of intake of zero dose [=Start date – Stop date + 1] over all entries (in the eCRF POM administration log) with reason other than "Subject is in Rest Period between Day22 and Day28"
	Any dose reduction	Any reduced dose (compared to starting dose in first cycle)
	Any permanent	Discontinuation of POM but continuation of

	discontinuation of POM but continuation of MOR03087	MOR03087 during at least 2 MOR03087 infusions until last MOR03087 dosing day
Exposure to Dexamethasone		
Variables calculated on a per-subject basis including data of all cycles	Number of applications	Number of DEX intakes where a study drug administration page is filled and the question "Was dexamethasone taken?" is answered with "Yes".
	Total actual dose taken [mg]	Sum over all doses administered
	Average actual dose taken during days treated [mg]	Total actual dose taken [mg]/ number of intakes
	Number of infusion days without administration of DEX	Number of all MOR03087 infusions where a study drug administration page is filled out and it is not ticked "Infusion not given" but DEX is not taken
	Any dose reduction	Any reduced dose (compared to starting dose in first cycle)
	Any permanent discontinuation of DEX but continuation of MOR03087	Discontinuation of DEX but continuation of MOR03087 during at least 2 MOR03087 infusions until last MOR03087 dosing day

7.4 Subgroups Used for Efficacy Analysis

For efficacy analyses the following subgroups will be defined:

- Age: < 65 years / ≥ 65 years
- Age: ≤ 75 years / > 75 years
- Prior therapy lines: ≤ median / > median (Note: median will be determined in total safety population)
- High risk cytogenetics: Yes / No
- Sex: Male / Female
- ISS: I or II / III
- Percentage of plasma cells in bone marrow at screening: < 60 / ≥ 60
- Subjects refractory to
    - Proteasome inhibitors (PIs) and Immunomodulatory Drugs (IMiDs)
    - any IMiDs only (not refractory to any PIs, but allowed to be refractory to any other previous drug)
    - any PIs only (not refractory to any IMiDs, but allowed to be refractory to any other previous drug)

- last prior treatment line Yes / No
- any prior treatment line Yes / No

8. STUDY SUBJECTS AND DEMOGRAPHICS

8.1 Disposition of Subjects and Withdrawals

All subjects who provide informed consent will be included in the database and will thus be accounted for in this study. Descriptive summaries of population data will be presented for the total population and the safety population and will include

- The frequency and percent of subjects in each study population
- The disposition of subjects including
    - number of subjects screened, who failed screening and who are eligible
    - number of subjects treated
    - number of subjects who completed 1st treatment cycle (subjects with number of cycles completed >=1, see definition in section 7.3.6)
    - number of subjects who completed of 2nd treatment cycle (subjects with number of cycles completed >=2, see definition in section 7.3.6)
    - number of subjects with at least one Cycle 3+ treatment
    - number of subjects who terminated the study
    - number of subjects still ongoing
- Study discontinuations for all subjects treated by reason (as specified in eCRF) (safety population only)
- time on study [months] and duration of treatment [months] (see definition in section 7.3.6)

Moreover, a listing of screening failures with corresponding reasons will be provided.

8.2 Protocol Non-compliances

Evaluability of subjects according to the definition of the DLT evaluable population is checked on an ongoing basis by the clinical study team of Premier Research. If a subject is non-evaluable, a new subject will be enrolled and will need to meet the definition for the DLT evaluable population before DMC review, to have the required number of DLT evaluable population subjects. The information that indicates why subjects are not evaluable together, with the reason for the exclusion from the DLT evaluable population, will be provided by the clinical study team to biostatistics before each DMC review.

For the final analyses, the DLT evaluable population will be defined according to the decisions for inclusion/exclusion at the time of the DMC meeting.

Exclusions from the other analysis populations will be checked programmatically according to the definition of the analysis population, but will be reviewed case-by-case before data release for final analysis.

Individual subjects with their reasons for exclusion from any analysis population will be listed.

The clinical non-compliance tracker will be displayed separately in the appendix of the clinical study report.

8.3 Demographics and Other Baseline Characteristics

Descriptive summaries of the demographic and other baseline characteristics will be completed for the safety population.

Descriptive summaries of demographic and other baseline conditions will include:

- Demographics (age [both as a continuous variable and as number of subjects aged < 65 and aged ≥ 65, aged ≤ 75 and aged > 75 as well as 18-64, 65-84 and >= 85 years], gender, race, height, weight at screening, body mass index [BMI])
- Medical history
- Disease staging based on Durie-Salmon (including subclassifications A and B) and on ISS Criteria
- Previous non-drug and drug treatment of multiple myeloma
- Time since first diagnosis of multiple myeloma [months]
- Cytogenetics of MM cells (bone marrow)
- DNA analysis of FcγRIIIa polymorphism (mucosal cheek swab)
- Concomitant medication

Medical History: Note that medical history will be coded with Medical Dictionary for Regulatory Activities (MedDRA Version 20.1, and updated to the newest version 23.0 for the follow-up analyses). Incidences of findings in medical history will be summarized by system organ class (SOC) and preferred term.

Disease Staging Based on Durie-Salmon (including subclassification A or B), *and on ISS Criteria:* Disease staging will be summarized descriptively by main classification (I/II/III) and by subclassification as applicable separately for both staging criteria.

Previous Non-Drug/Drug Treatment: Previous non-drug treatment will also be coded with MedDRA. The following groups will be defined for previous non-drug treatment: stem cell transplantation, radiotherapy, other. Incidences of previous non-drug treatments will be summarized by group.

Previous drug treatment will be coded using the WHO Drug Dictionary (March 2011, and updated to the newest version March 2020 for the follow-up analyses). Based on preferred term and coding levels of the WHO Drug Dictionary, previous drug treatments will be allocated to the following groups and subgroups:

- Group “Cytotoxic agents” with subgroups “Alkylating agents”, “Antimetabolites”, “Alkaloids”, “Anthracycline agents”, “Platinum compounds” and “Other cytotoxic compounds”
- Group “Other agents” with subgroups “Antibodies”, “Protein kinase inhibitors”, “Proteasome inhibitors”, “HDAC inhibitors”, “Interferons, “Immunomodulatory drugs”,

"Glucocorticoids", "Other antineoplastic agents", "Other"

Incidences of previous drug treatments will be summarized by group, subgroup and agent.

Moreover the number of previous lines of therapy (as entered into the eCRF) will be summarized descriptively (summary statistics and frequency table). The frequency table will contain cumulative subcategories, i.e. number of subjects with >= x prior therapy lines, for all possible numbers x.

Best response under treatment and type of progression associated with each previous drug treatment will be included in listings.

Moreover, it will be determined for each previous drug treatment if the subject was refractory to the treatment (see section 7.3.1).

Incidences of previous drug treatments to which subjects were refractory will be summarized by group, subgroup and agent.

In addition, the rate of subjects who were refractory to the most recent drug treatment line and the rate of subjects who were double-refractory will be presented.

Time Since First Diagnosis of Multiple Myeloma [Months]: Time since first diagnosis will be measured from date of first diagnosis until Cycle 1 Day 1.

Cytogenetics of MM Cells (Bone Marrow): The frequency of translocations t(4;14) and t(14;16) and deletions Del13 and Del17p13 and other documented cytogenetic abnormalities (measured at screening or known from historical data) will be summarized descriptively in a frequency table (categories: yes/no/missing/not tested). Moreover, the table will contain frequencies for high risk evaluation (see section 7.3.1).

DNA Analysis of FcγRIIIa Polymorphism (Mucosal Cheek Swab): The frequency of each genotype (158FF, 158VF, 158VV, other, missing) will be summarized descriptively in a frequency table.

Concomitant Medication: All medications will be coded using the WHO Drug Dictionary (March 2011, and updated to the newest version March 2020 for the follow-up analyses). Incidences of concurrent medications will be summarized by Anatomical Therapeutic Chemical (ATC) level 2 and ATC level 4.

Concomitant medication is defined as a medication other than study drug that was administered during the treatment or follow-up period from day of first treatment up to the end of study.

Therefore entries of medications which were discontinued before start of treatment will be excluded from concomitant medication tables but will be included and flagged in the listings as previous medications.

If the start/stop dates of medication are partially or completely missing a medication will be assumed to be concomitant if it cannot be definitely shown that the medication was not administered during the treatment or follow-up period. Missing dates will not be replaced.

Thus, the following approach will be taken for exclusion from concomitant medication because of discontinuation before start of treatment:

- If stop day is missing but month is complete, medication will only be excluded from concomitant medication if stop month is before month of treatment start.
- If stop day and month are missing but year is complete, medication will only be excluded from concomitant medication if stop year is before year of treatment start.
- If stop date is completely missing and/or medication is specified as "ongoing", medication will not be excluded

Anti-MM Treatments During Study: If a subject receives any anti-MM treatment other than the IMP(s) during study, it is regarded as protocol non-compliance. Introduction of new anti-MM treatment should result in exclusion of the subject from further study participation.

Subsequent Anti-MM Treatments: The first subsequent anti-MM treatment planned and the corresponding start date will be captured in the eCRF, for subjects included based on protocol amendment 6 or afterwards.

Subsequent anti-MM treatment will be presented in listings. Moreover, it will be taken into account for the derivation of efficacy endpoints (see section 7.3.3).

9. IMMUNOGENICITY, EFFICACY AND PHARMACODYNAMIC ANALYSES

This study will examine the immunogenicity, efficacy and pharmcodynamics of MOR03087. Formal planned analyses are described below. It may be necessary for additional exploratory analyses to be completed in this study after results from the planned analysis are completed, to assess continued study of MOR03087. Full details of additional analyses will be given in the CSR.

9.1 Immunogenicity Analysis

One of the primary endpoints is to evaluate the immunogenicity of MOR03087 in the Safety Population. Anti-MOR03087 antibodies will be determined by a central laboratory. The analysis will be based on both absolute numbers (number and percentage of subjects who develop anti-MOR03087 antibodies) and semiquantitative assessments (anti-MOR03087 antibody titer determination of confirmed positive samples).

The number and percentage of subjects who developed confirmed anti-MOR03087 antibodies during the study will be summarized descriptively. Rates will be calculated with respect to all subjects in the analysis group.

Exact 95%-confidence intervals will be provided for the rate of subjects who developed anti MOR03087 antibodies in combined presentations (see section 7.2).

Time to development of anti-MOR03087 antibodies [months] will be summarised descriptively using Kaplan-Meier estimates for the median, 25% quantile, and 75% quantile. 95%-confidence intervals for median, 25% quantile and 75% quantile will be provided in combined presentations.

Moreover the percentage of subjects having developed antibodies after 2, 4 and 6 months together with the corresponding 95%-confidence intervals will be estimated from the Kaplan-Meier curve for combined data.

Kaplan-Meier plots for time to development of anti-MOR03087 antibodies [months] will be provided for combined data.

Exact 95% confidence intervals and Kaplan-Meier analyses will not be produced if only very few subjects develop anti MOR03087 antibodies.

Also, if only a few subjects develop anti MOR03087 antibodies, quantitative assessments will only be presented in listings. Otherwise, summary tables may be added.

9.2 Efficacy Analysis

All efficacy analyses will be provided for the Safety Population and will be repeated for the Efficacy Evaluable Population.

Rates will be calculated for each response category (sCR, CR, VGPR, PR, MR, SD, PD, missing) by visit (for C3D1, C6D1, and C12D1). Moreover, the ORR (PR or better), the CBR (MR or better) and the DCR (SD or better) will be calculated by visit (see section 7.3.3.1). The corresponding number of subjects in each of these response categories and all rates will be summarized in a frequency table by visit.

For best overall response, frequencies will be calculated for each response category (sCR, CR, VGPR, PR, MR, SD, PD, NE). Moreover, the ORR (PR or better), CBR (MR or better) and the DCR (SD or better) will be calculated, based on BOR per subject (see section 7.3.3.2). The corresponding number of subjects in each of these response categories and all rates will be summarized in a frequency table. The exact Clopper-Pearson 95%-confidence intervals for ORR, CBR and DCR will also be shown in combined presentations.

The denominator for calculating the rates (rates by visit and best response rates) will be the total number of subjects within the corresponding analysis group. In the summary of rates by visit, all withdrawals and protocol non-compliances after start of new anti-MM therapy will be analyzed as missing for all visits after withdrawal, and the counts of missing observations will be included into the denominator.

Both TTP and PFS will be analyzed using Kaplan-Meier methods. Kaplan-Meier tables for PFS and TTP will contain number of subjects, number of subjects with an event (non-censored subjects), percentage of subjects with an event, median time [months], 25% and 75% quantile. The 95%-confidence intervals for median, 25% quantile and 75% quantile will be provided in combined presentations.

Moreover, the percentage of subjects having an event after 2, 4 and 6 months together with the corresponding 95%-confidence intervals will be retrieved from the Kaplan-Meier curve in combined presentations.

For PFS, the reason for censoring as stated in Table 3 will be tabulated together with reasons for discontinuation (based on study completion page) for patients who discontinued the study without a PFS event. This information will be included in the listings as well together with detailed information concerning AE term(s) leading to withdrawal.

In these Kaplan-Meier analyses, the confidence intervals for the median will be calculated according to Brookmeyer and Crowley (1982) [12] and confidence intervals for the quartiles according to Klein and Moeschberger (1997) [13] who generalized the methods developed by Brookmeyer and Crowley. Confidence intervals for the survival function estimates at above

defined time points will be derived using the log-log transformation according to Kalbfleisch and Prentice (1980) [14] ([redacted]). The estimate of the standard error will be computed using Greenwood's formula.

Time to next treatment and EFS will also be analyzed using Kaplan-Meier methods. The same type of presentations as for TTP and PFS will be prepared.

In addition, time to first response, time to best response and time to first clinical benefit will be analyzed using Kaplan-Meier methods restricted to the subgroups of responders without having any censored subjects. The same type of presentations as for TTP and PFS will be prepared.

Duration of response and further duration variables defined in section 7.3.3.3 will also be analyzed using Kaplan-Meier estimates for median, 25% and 75% quantile, but this analysis will be restricted to the subgroup of subjects with response or in general, the subgroup of subjects where the duration can be calculated

Kaplan-Meier plots for all time-to-event variables will be provided for combined data.

9.2.1 Subgroup Analysis

For BOR, ORR, CBR, DCR and PFS, subgroup analyses will be performed within the subgroups defined in section 7.4. The data will be presented in the same format as described above, within those subgroups of the safety population. The subgroup analysis will only be performed for combined presentations.

9.3 Pharmacodynamic Analysis

All pharmacodynamic analyses, except of serum and urine M-protein, and serum FLCs, will be performed for the safety population only.

MorphoSys AG will perform further post hoc exploratory analysis to investigate correlations between different biomarkers and response variables, which are not further described in this SAP.

In general, pharmacodynamic analyses by visit will only include all cycles until Cycle 6, Cycle 12 and EOS.

9.3.1 Pharmacodynamic Parameters Measured in Blood or Urine

Actual values and absolute and percent changes from baseline will be summarised descriptively by visit for the pharmacodynamic parameters specified below. Moreover, 95%-confidence intervals will be provided for mean and median changes in summaries of absolute changes from baseline and for median changes in summaries of percentage changes from baseline in all combined presentations.

Measurements of B, T, and NK cell populations and CD16 expression on NK cells: Descriptive summaries (as specified above) will be provided for the following parameters:

- Measurements of B, T, and NK cells [%]
  Measurements of B, T, and NK cells [/µl]

  Measurements of B, T, NK cells are given in % and/or as absolute count [/µl] by the investigator, whereas the absolute count is often missing. Therefore absolute count [/µl] will be also be derived using the lymphocytes absolute values [G/l = n*1000/µl = /nl] from the laboratory hematology data (lymphocytes absolute * [measurement in % /100]

* 1000, rounded without decimals). Two tables each will be presented, one table based on % values (original values only) and a further table based on absolute counts [/µl] (derived and original values, both rounded wihout decimals).

- CD16 expression on NK cells [Antibodies bound per cell]

  The analysis will be based on the unit "antibodies bound per cell". Measurements cannot be included in the analysis if measurements in the unit "antibodies bound per cell" are missing.

Result of Flow Cytometry of Peripheral MM Cells: Descriptive summaries will be provided for the following parameters:

- Measurements of CD138 cells [Count per 10^6 cells]
- Percentage of malignant CD38 cells [%]
- Measurement of CD38 expression on malignant cells in [MFI] (MFI = Median Fluorescence Intensity)
- Measurement of CD38 expression on malignant cells in [Antibodies bound per cell]

In the summaries of actual values for CD38 variables, only subjects who have counts of CD138+ cells equal and above 100 counts per 10^6 cells at the corresponding visit will be included since for subjects who have counts of CD138+ cells below 100 counts per 10^6 cells no values for CD38 variables will be available. In the summary of absolute and percentage changes from baseline for CD38 variables, only subjects who have counts of CD138+ cells above 100 counts per 10^6 cells at both baseline and post-baseline visits will be included.

Serum and Urine M-Protein, Serum FLCs: Serum and urine M-protein and serum FLCs were analyzed by a local laboratory at the beginning of the study and by central laboratory enrolled after November 2014 (starting from cohort 7c/ cohort 8 partially, see section 7.3.4 for parameters measured and derived). Descriptive summaries by visit (including summaries of absolute and percentage changes) will be provided for the following parameters by visit:

- Serum M-protein level [g/L]
- Urine M-protein result [g/24h]
- Lambda FLCs [mg/L]
- Kappa FLCs [mg/L]
- Kappa/lambda FLC ratio

Moreover, descriptive summaries across time points will be prepared for

- relative change (%) in serum M-protein result from baseline to post-baseline nadir
- relative change (%) in urine M-protein result from baseline to post-baseline nadir.

Anti-TT data (Anti-Tetanus Toxoid IgG data): Anti-TT data will only be presented in listings.

9.3.2 Pharmacodynamic Parameters Measured in Bone Marrow

A bone marrow examination will be performed at screening (results from bone marrow examination done within 4 weeks prior to screening are also acceptable, if the subject has been hematologically stable since then). Post-baseline bone marrow data will only be assessed for

subjects who provided an additional informed consent at follow-up visit, or at the Cycle 2 Day 1 visit for subjects enrolled after Nov 2014 (starting from cohort 7c/ cohort 8 partially). Descriptive summaries will be provided for baseline and post-baseline values of the parameters specified below. Summaries for absolute and percentage changes are not planned to be provided, because of the expected low number of subjects who have bone marrow data after start of treatment. However, these may be added if a sufficient number of subjects with post-baseline bone marrow data will be available.

Bone Marrow Histology: Descriptive summaries of actual values will be provided for the following parameters:

- % of plasma cells
- Myeloid to erythroid ratio
    - The myeloid to erythroid ratio will be given in the format "xx:xx". For descriptive summary tables the quotient will be calculated.

All other parameters (Cellularity, histology of plasma cells, histology of erythroid cells, histology of myeloid cells and histology of megacaryocytes) will only be included in listings since these are captured as free text.

Immunophenotyping of MM cells (bone marrow): Descriptive summaries of actual values will be provided for the following parameters:

- Measurements of CD138 cells [% of all bone marrow cells]
- Measurements of CD38 cells
    - Percentage of malignant CD38 cells [%]
    - Measurement of CD38 expression on malignant cells in [HIT2 MFI]
    - Measurement of CD38 expression on malignant cells in [QuantiBrite™ MFI]
    - Measurement of CD38 expression on malignant cells in [HIT2 Antibodies bound per cell]
    - Measurement of CD38 expression on malignant cells in [QuantiBrite™ Antibodies bound per cell]

9.4 Pharmacokinetic Analysis

The pharmacokinetic analysis will be described in a separate pharmcokinetic analysis plan.

9.5 Other Parameters

In general, other analyses by visit will only include all cycles until Cycle 6, Cycle 12 and EOS.

9.5.1 Cytokines

Cytokines will be measured at Day 1, Cycle 1 before study drug administration and 2 hours after end of study drug administration. Actual values and absolute and percent changes from pre-administration to post-administration will be summarised descriptively. Moreover, 95% confidence intervals will be provided for mean and median changes in summaries of

absolute changes from baseline and for median changes in summaries of percentage changes from baseline in combined presentations.

9.5.2 Bone / Skeletal Survey

Bone/skeletal survey by x-ray, computer tomography or magnetic resonance imaging will only be performed at screening and EOS where medically indicated as a regular assessment of standard care. Thus, the data of bone/skeletal surveys will only be listed.

9.5.3 Quality of Life

Standardized scores for quality of life for all categories (scales) will be calculated as described in section 7.3.5. The standardized scores and the absolute changes from baseline will be summarized descriptively by visit. Moreover, 95%-confidence intervals will be provided for mean and median changes in summaries of absolute change from baseline for combined data.

10. SAFETY AND TOLERABILITY ANALYSES

The analysis of safety assessments in this study will include summaries of the following categories of safety data collected for each subject:

- Adverse Events (AEs), i.e. pre-treatment AEs, treatment emergent AEs (TEAEs), and Serious AEs (SAEs)
- AEs leading to discontinuation
- Any deaths
- Dose-limiting toxicities
- Infusion reactions
- Clinical laboratory investigations (hematology, serum chemistry, coagulation, endocrinology, urinalysis)
- Vital signs (blood pressure, heart rate, respiratory rate, body temperature)
- Electrocardiogram (ECG) results
- Physical examination results
- Exposure to study drug
- Discontinued subjects

10.1 Dose Limiting Toxicities and Maximum Tolerated Dose

One of the primary endpoints will be to determine the MTD or recommended dose and dosing regimen for MOR03087 with or without DEX and in combination with 2 standard IMiD therapies, Lenalidomide and Pomalidomide. This primary endpoint will be determined in the DLT Evaluable Population and will be based on a 4-week safety assessment period (one 28-day cycle).

Following completion of Parts A-C (dose escalation of MOR03087 alone and in combination with DEX using 2 dosing schedules), the MTD and/or recommended dose will be confirmed in a minimum of 6 subjects. Following completion of Parts D and E (dose escalation of MOR03087

in combination with POM + DEX and in combination with LEN + DEX), the MTD and/or recommended dose in each treatment arm will be confirmed in a minimum of 6 subjects.

The recommended doses for the confirmation cohorts will be determined after review of all available safety data from the corresponding dose escalation portion of the study and based on the recommendation of the DMC. The recommended dose may be the MTD or a dose below the MTD.

The MTD is defined as the dose level below the dose level at which 2 out of 3 subjects or 2 out of 6 subjects experience a DLT, as described in the dose-escalation plan (see section 3.1).

All DLTs will be entered as AEs on the Adverse Event Page and identified by the investigator as DLTs by ticking the corresponding field (dose limiting toxicity yes/no). Moreover, there is an additional field on the AE page (hidden for site entry) which contains the information regarding whether the AE is a DLT according to the decision of the sponsor assessment or DMC as documented in the meeting minutes. The additional DLT field will not need to be filled out in case of unambiguous cases.

Thus, the analysis of DLTs will be described within the subsequent sections covering the analysis of AEs. For DLT analyses, DLTs will be filtered based on the following approach. If the field "DLT as per sponsor assessment or DMC decision" is filled out, this field will be used to determine if AE is a DLT, otherwise the field "Is this Adverse Event a Dose-Limiting Toxicity?", which is filled out by the Investigator, will be used.

The DLT summaries will only be presented for the first cycle, as the DLT period covers Day 1 of Cycle 1 (starting with first study drug administration) until Day 29 (before start of the second cycle). DLTs occurring in subjects from the confirmation cohorts will be included.

10.2 Adverse Events

All TEAEs and SAEs will be coded using MedDRA (MedDRA Version 20.1, and updated to the newest version 23.0 for the follow-up analyses).

The body systems 'Blood and lymphatic system disorders' and 'Investigations' will be combined for the purpose of analysis. Moreover, all preferred terms from those two body systems that are subsequently listed in the same row will be combined:

- Red blood cell count decreased / Haemoglobin decreased / Haematocrit decreased / Mean cell volume decreased / Anaemia
- Fibrin D dimer increased / International normalised ratio increased / Prothrombin time shortened / Coagulopathy
- Eosinophil count increased / Eosinophilia
- Blood fibrinogen increased / Hyperfibrinogenaemia
- White blood cell count increased / Leukocytosis
- White blood cell count decreased / Leukopenia
- Lymphocyte count decreased / Natural killer cell count decreased / CD4 lymphocytes decreased / B-lymphocyte count decreased / Lymphopenia
- Monocyte count decreased / Monocytopenia
- Neutrophil count decreased / Neutropenia
- Neutrophil count increased / Neutrophilia
- Plasma cells increased / Plasmacytosis
- Platelet count decreased / Thrombocytopenia

TEAEs are defined as AEs occurring or worsening after the start (date and time) of the first study treatment (any IMP) and up to 28 days after the last study treatment including all treatment cycles (treatment emergent period). However, AEs occurring or worsening later than 28 days after the last treatment with study drug are defined as treatment emergent if these are considered to be related to the study drug.

If the start date and time of an AE are partially or completely missing, the AE will be assumed to be treatment-emergent if it cannot be definitely shown that the AE did not occur or worsen during the treatment-emergent period (worst case approach). Missing dates and times will not be replaced.

Thus, the following approach will be taken:

- If the start time of an AE is missing but the start date is complete, an AE will only be excluded from TEAEs if the start day is before the day of first treatment or the start day is after the end day of the treatment-emergent period.
- If the start time and day are missing but the start month is complete, an AE will only be excluded from TEAEs if the start month is before the month of first treatment or the start

month is after the end month of the treatment-emergent period or if stop date/time is before start of first treatment.

- If the start day and months are missing but the start year is complete, an AE will only be excluded from TEAEs if the start year is before the year of first treatment or if the start year is after the end year of the treatment-emergent period or if the stop date/time is before the start of first treatment.
- If the start date is completely missing, an AE will not be excluded from TEAEs unless the stop date/time is before the start of first treatment.

Time from first treatment to onset of AE [days] will be calculated for complete dates only and will be included in listings.

The TEAE grading will be determined by the investigators according to the NCI-CTC toxicity criteria. If a subject experiences a specific type of adverse event more than once, only the maximum grading will be considered in tables of TEAEs by grading when calculating the incidences (number and percentage of subjects with AE of specific type and grade).

One of the primary endpoints will be to determine the incidence and severity of AEs.

A TEAE summary table will be presented showing the incidence and frequency of all

- Treatment-emergent AEs (TEAEs)
- TEAEs by grading (according to NCI-CTCAE toxicity criteria)
- TEAEs with Grade ≥ 3
- TEAEs with Grade 1 and 2
- TEAEs with Grade 3 and 4
- TEAEs related to MOR03087 / Pomalidomide / Lenalidomide / Dexamethasone
- Serious adverse events (SAEs)
- Serious adverse events (SAEs) related to MOR03087 / Pomalidomide / Lenalidomide / Dexamethasone
- MOR03087-related TEAEs by grading (according to NCI-CTCAE toxicity criteria)
- Pomalidomide-related TEAEs by grading (according to NCI-CTCAE toxicity criteria)
- Lenalidomide-related TEAEs by grading (according to NCI-CTCAE toxicity criteria)
- Dexamethasone-related TEAEs by grading (according to NCI-CTCAE toxicity criteria)
- DLTs
- Infusion reactions
- TEAEs leading to any action on MOR03087 / Pomalidomide / Lenalidomide / Dexamethasone
- TEAEs leading to withdrawal of MOR03087 / Pomalidomide / Lenalidomide / Dexamethasone

- TEAEs that caused the subject to withdraw from the study
- Symptomatic overdoses reported as TEAE

The incidence refers to the number and percentage of subjects with at least 1 TEAE of the specified type and the frequency to the number and percentage of AEs.

Exact 95%-confidence intervals for the incidence rates will be included in the summary tables for the combined data.

The analyses by grading will be based on the NCI-CTCAE grade (version 4.0). If the NCI-CTCAE grade is not available, this will be analyzed as "Missing".

A further summary table of the same structure will be presented which includes only AEs with a start date in the first cycle (relevant for the determination of the MTD and recommended dose). In case of incomplete start dates, an AE will be allocated to the first cycle, if it cannot be excluded that the AE started within the first cycle based on the month or year of the incomplete start date.

Summaries of incidence rates (number and percentage of subjects) and frequencies (number and percentage of AEs) of individual TEAEs by MedDRA SOC and Preferred Term will be prepared. Such summaries will be displayed for all AEs in fhe following categories:

- TEAEs
- TEAEs related to MOR03087
- TEAEs related to DEX
- TEAEs related to LEN
- TEAEs related to POM
- TEAEs by maximum grading according NCI-CTCAE
- DLTs
- Infusion reactions
- TEAEs leading to withdrawal of any study drug
- TEAEs that caused the subject to withdraw from the study
- TEAEs of Grade ≥ 3
- TEAEs with Grade 1 and 2
- TEAEs with Grade 3 and 4
- SAEs
- SAEs related to any treatment
- SAEs leading to death
- SAEs leading to death related to any treatment
- Non-serious TEAEs

In these summaries each subject will be counted only once within each preferred term to calculate the incidences.

The summaries of all TEAEs (summary table + TEAEs by grading) will be repeated including only TEAEs from the first cycle. The DLT summary will only be presented for the first cycle.

The time to the first TEAE will be summarized by summary statistics (n (number of subjects with event), mean, standard deviation, median, Q1, Q3, min, max) for the following TEAEs:

- Each AESI (infusion reactions >= grade 3, cytokine release >= grade 3, allergic reaction to MOR03087 >= grade 3, second primary malignancies (all grades) and DLTs (all grades)
- All PTs >= grade 3 in SOC Infections, and per PT in SOC infections with >= grade 3
- Hematological AEs per PT >= grade 3 (i.e. all PTs >= grade 3 in SOC Blood and lymphatic system disorder including the ones combined with SOC Investigations as described above, and per PT in SOC Blood and lympathatic system disorder including the ones combined with SOC Investigations as described above with >= grade 3)
- Diarrhoea >= grade 3

Only patients experiencing a TEAE as mentioned above will be included in the summary table. The same table will be repeated for TEAEs related to MOR03087.

Exposure-adjusted incidence rate (EAIR) will be expressed as the number of patients experiencing an AE per patient-year (PY) of exposure to treatment and is derived as the number of patients with the event divided by the sum of all patient time at risk. Time at risk is the number of years from first treatment date to first event for patients experiencing a given event, or time on treatment in years (up to 28 days after the last study treatment) for patients who did not experience the event.

EAIR will be summarized by SOC and PT for the following:

- All TEAEs
- TEAEs related to MOR03087
- TEAEs related to any study drug
- TEAEs by grading according to NCI-CTCAE
- TEAEs leading to withdrawal of any study drug
- TEAEs that caused the subject to withdraw from the study
- SAEs

In the AE listings, AEs that started prior to the administration of any study drug will be flagged as pre-treatment AEs. Any AEs that start 28 days after the last study treatment, including all treatment cycles, will be flagged as post-treatment AEs.

A special AE summary listing displaying details of the event(s) captured on the eCRF in a compact format will be provided for

- DLTs
- Infusion reactions
- AEs leading to discontinuation on MOR03087
- AEs leading to discontinuation on Pomalidomide / Lenalidomide
- SAEs

Serious adverse event reconciliation will be performed by Data Management, Clinical Research, and Premier Research Drug Safety and Pharmacovigilance via data listings, as detailed in the SAE reconciliation plan.

The sponsor will describe other AEs of special interest (i.e. infusion reactions, cytokine release, allergic reaction to MOR03087, second primary malignancies and DLTs), in addition to those reported as SAEs.

10.3 Clinical Laboratory Evaluations

Safety laboratory data (hematology, serum chemistry, endocrinology, coagulation, urinalysis) will be analyzed by the respective local laboratories of each involved site.

The analysis of safety laboratory parameters will be presented separated into blood parameters (hematology, serum chemistry, endocrinology, coagulation) and urine parameters (urinalysis). All data will be listed.

The blood parameters will be transformed to SI values based on SI units to make laboratory parameters comparable between different local laboratories. The relevant reference ranges supplied by each laboratory will also be transformed to SI reference ranges for each laboratory.

Descriptive summaries of actual (absolute) values and changes from baseline values will be presented for all blood parameters.

Creatinine clearance will be calculated according to the Cockcroft-Gault formula and will be included in descriptive summaries of actual (absolute) values and changes from baseline.

Each abnormal value will be flagged to show whether it is a value below or above the reference range. For the assessment of laboratory variables, 5 categories will be used that take into account

the investigator's assessment of clinical relevance: 'clinically relevant, above', 'non-clinically relevant, above', 'within', 'non-clinically relevant, below', 'clinically relevant, below'.

The assessment of laboratory variables will be tabulated by time point for each clinical laboratory analyte (frequency tables).

If NCI-CTCAE grades are available for a clinical laboratory analyte, these will be derived according to NCI-CTCAE version 4.0 and used to present additional frequency based on NCI-CTCAE grades.

For hematology parameters, shifts in assessments from baseline to worst-post baseline will be presented based on classifications relative to the laboratory reference ranges (low/normal/high) for hematology parameters where NCI-CTCAE grades are not defined. If a subject experiences both "Low" and "High" assessments in the course of the trial, the worst post-baseline will be defined as "Low and High".

If NCI-CTCAE grades are available for a hematology parameter, frequency, shift and summary tables based on grades will be created as follows:

- Incidence of subjects with worst post-baseline grade. Each subject will be counted only for the worst grade
- Shift tables to compare baseline to the worst post-baseline value using CTCAE grades
- Summary of time to onset toworst post-baseline grade (defined as the time from treatment start to first occurrence of worst post-baseline grade): this table will present summary statistics over all grades, but only patients with a worst post-baseline grade will be included.

A separate listing will be prepared to list the time course of a laboratory parameter for a subject with any abnormal, clinically significant laboratory value (for all laboratory values irrespectively of whether NCI-CTCAE grades are available).

The investigator's assessment of categorical urinalysis variables ('normal', 'abnormal, not clinically significant', 'abnormal clinically significant') will be tabulated by time point for each urine parameter (frequency tables).

Additionally, for each of these urine parameters, shifts in assessments from baseline to Cycle 2 Day 1 and to EOS will be presented for combined data.

For all shift tables, baseline percentage will be based on the number of patients in the analysis set (N). Percentage for worst post-baseline value will be based on Baseline n for the baseline category the percentage refers to.

Laboratory values that are outside the reference range will also be flagged in the data listings, along with corresponding reference ranges.

Results of unscheduled laboratory evaluations, laboratory data of the emergency laboratory, results of urine microscopy (if available), results of the pregnancy test and screening serology results will only be included in listings.

In general, laboratory summaries except for the tables analyzing the hematology parameters (worst post-baseline assessments/grades) as described above will only include time points of Cycle 1+2 and EOS visit. For the tables analysing the hematological parameters, all available time points will be included when deriving worst assessment/worst grade.

10.4 Vital Signs and Body Weight

Descriptive summaries of actual values and changes from baseline will be calculated for vital signs (systolic blood pressure [SBP], diastolic blood pressure [DBP], body temperature, heart rate [HR], and respiratory rate [RR]) and body weight and BMI. These summaries will be presented for all time points.

Each abnormal value will be flagged to show whether it is a value below or above the normal limit. The normal limits are detailed in the appendix of the study protocol (section 18.2 of the study protocol).

In general, vital signs summaries will only include time points of Cycle 1+2 and EOS visit.

10.5 Electrocardiograms

The summary ECG assessment (categories: <normal; abnormal clinically significant; abnormal not clinically significant>) will be tabulated by visit.

Each abnormal PR, QRS, and RR interval value will be flagged to show whether it is a value below or above the normal limit. The normal limits are detailed in the appendix of the study protocol (section 18.2 of the study protocol).

Descriptive summaries of actual values and changes from baseline will be presented by visit for ECG measures of RR interval, PR interval, QRS interval, QT interval, QTc interval (both correction methods), and HR (Heart rate).

The Bazett's Correction (QTc_b) and Fridericia's Correction (QTc_f) for the QTc interval will be derived as follows:

Bazett's Correction (QTc_b) $$QTc_b = \frac{QT_{msec}}{\sqrt{RR}}$$

Fridericia's Correction (QTc_f) $$QTc_f = \frac{QT_{msec}}{\sqrt[3]{RR}}$$

where: RR = Relative Rate = 60 / HR

HR = Heart Rate obtained from the ECG.

Also, the number and percent of subjects with QTc values (Bazett's correction) above the normal limit (441-480 ms, 481-500 ms, or > 500 ms) and the number and percent of subjects who experienced a change > 30 ms or a change > 60 ms from baseline will be presented by visit.

Moreover, shifts in QTc category (Bazett's correction) from baseline to all post-baseline visits will be presented for combined data, based on the following categories (normal, 441-480 ms, 481-500 ms, or > 500 ms).

QTcF interval will only be presented in listings (along with the QTcB interval).

In general, ECG summaries will only include time points of Cycle 1+2 and EOS visit.

10.6 Physical Examination

The physical examination assessments (normal, abnormal not clinically significant, abnormal clinically significant) will be summarized by body system and visit.

Separate listings will be prepared to list the time course for the assessments of a specific body system for a subject with any abnormal, clinically significant result.

In general, physical examination summaries will only include time points of Cycle 1+2 and EOS visit.

10.7 Measurement of Exposure

Variables that will be calculated to measure exposure to study drugs (MOR03087, POM, LEN, DEX) are described in section 7.3.6. All variables calculated on a per-subject basis for all cycles will be summarized descriptively.

Summaries for POM, LEN and DEX will be presented for the respective combination cohorts only.

10.8 Karnofsky Performance Status

The Karnofsky performance status [%] will usually be given in steps of 10% each, e.g. possible values are 100%, 90%, 80%, …, 10%, 0% (if in between values are given, values will be rounded in accordance with typical mathematical principles). The Karnofsky performance status [%] will be summarized categorically in a frequency table by visit. A further table showing summary statistics will be presented.

11. REPORTING CONVENTIONS

12. REFERENCES

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