Janssen Research & Development
Biostatistics and Programming

Statistical Analysis Plan/Data Presentation Specifications for Clinical Study Report

A Randomized, Open-label, Multicenter, Multiphase Study of JNJ-63723283, an Anti-PD-1 Monoclonal Antibody, Administered in Combination with Daratumumab, Compared with Daratumumab Alone in Subjects with Relapsed or Refractory Multiple Myeloma

Protocol 54767414MMY2036; Phase 2/3
JNJ-63723283; JNJ-54767414 (DARZALEX®, daratumumab)

Date: 25 September 2018

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Compliance: The study described in this report was performed according to the principles of Good Clinical Practice (GCP).

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LIST OF IN-TEXT TABLES AND FIGURES

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AMENDMENT HISTORY

The statistical analysis plan (SAP) has been revised and description of the changes and the section affected are provided below.

Amendment -1 (07Sep2018)

Summary of change:
1. Included biomarker analysis

Applicable Section	Description of Change
1.9 Biomarker	Since biomarker analysis would be included in the final CSR, this new section for biomarker analysis was added in this SAP.

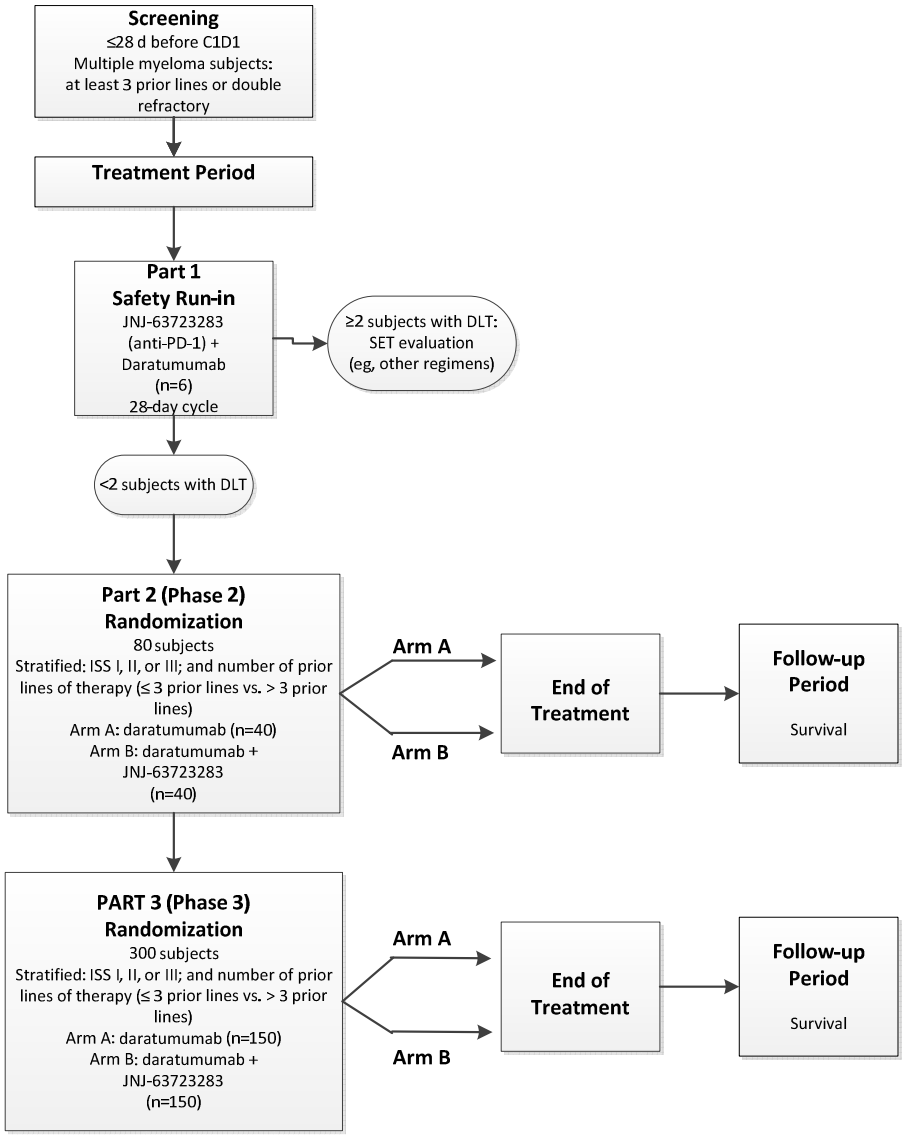
1. ANALYSIS DETAILS

This document contains definitions of analysis sets, derived variables and planned data presentation specifications which will be used in clinical study report of study 54767414MMY2036. The analysis will be performed after final data base lock when protocol 54767414MMY2036, Amendment 2 is approved and implemented at all sites.

1.1. Overview of Study Design

This is a randomized, open-label, multicenter, multiphase study assessing the efficacy and safety of JNJ-63723283 (an anti-PD-1 monoclonal antibody) in combination with daratumumab compared with daratumumab alone in subjects with multiple myeloma who have received at least 3 prior lines of therapy including a PI and an IMiD or whose disease is double refractory to both a PI and an IMiD. A diagram of the study design is provided in Figure 1.

Figure 1: Study Scheme



As of 25 May 2018, the Sponsor terminated further enrollment into this study and subjects in Screening were deemed Screen Failures and were not further randomized into the study. Subjects continuing on study will receive daratumumab monotherapy starting 25 May 2018. Part 3 is no longer applicable for this study.

1.2. Analysis Sets

- **Safety analysis set:** includes all subjects who have received at least 1 dose of study agent (JNJ-63723283 or daratumumab, partial or complete) in either Safety Run-in Part 1 or Part 2 of the study. This analysis set will be used for below analyses.
- **Pharmacokinetics (PK)-evaluable analysis set:** includes all subjects who have received at least 1 dose of daratumumab or JNJ-63723283 and have at least 1 post-infusion sample in Safety Run-in Part 1 of the study.
- **Immunogenicity analysis set:** include all subjects who have received at least 1 dose of JNJ-63723283 or daratumumab and have appropriate serum samples for detection of antibodies to JNJ-63723283 or daratumumab (i.e., subjects with at least 1 sample obtained after their first dose of JNJ-63723283 or daratumumab) in Safety Run-in Part 1 of the study.

1.3. Treatment Groups

The treatment groups are Safety Run-in (JNJ-63723283+daratumumab); and Arm A (daratumumab alone) and Arm B (JNJ-63723283+ daratumumab) for Part 2.

1.4. End of Follow-up and Duration of Follow-up

The end of follow-up is the date of death for subjects who died. For those who are still alive, the end of follow-up is defined as the maximum date of the following study evaluations: labs (hematology, chemistry, serology, coagulation, thyroid function), adverse events, vital signs, ECOG performance status, study drug administration, 12-lead ECG, pre-infusion medications, post-infusion medications, concomitant medications, subsequent anti-cancer treatment, tumor assessment, clinical events/disease response per investigator and date of last known to be alive.

Duration of follow-up (in months) equals the end of follow-up minus the first dosing date plus 1 for Part 1 and equals the end of follow-up minus the randomization date plus 1 for Part 2, divided by 365.25/12.

Study duration of follow-up will be summarized by treatment group and overall for safety Analysis Set.

1.5. Subject information

The distribution of subjects by region and country will be presented for safety analysis set by treatment group and overall.

- **Demographics and baseline characteristics:** Demographics and baseline characteristics will be summarized for safety analysis set by treatment group and overall. A listing of subject demographic and baseline characteristics will be provided as well. Table 1 and Table 2

respectively present a list of the demographic variables and baseline disease characteristics that will be summarized by treatment group and overall.

Table 1: Demographic Variables

Continuous Variables:	**Summary Type**
Age (years)	Descriptive statistics (N, mean, standard deviation [STD], median and range [minimum and maximum]).
Weight (kg)	
Height (cm)	
Categorical Variables	
Age (<65 years, ≥65 years and <75 years, ≥75 years)	N, frequency distribution with the number and percentage of subjects in each category.
Weight (≤65kg, >65kg and ≤85kg, >85kg)	
Sex (male, female)	
Race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White, Multiple [a], not reported)	
Ethnicity (Hispanic or Latino, not Hispanic or Latino, not reported)	
Baseline ECOG (0, 1, 2)	

[a] If multiple race categories are indicated, the Race is recorded as 'Multiple'

Table 2: Baseline Disease Characteristics

Continuous Variables:	**Summary Type**
Time since MM diagnosis (years)	Descriptive statistics (N, mean, standard deviation [STD], median and range [minimum and maximum]).
Categorical Variables	
Type of multiple myeloma (IgG, IgA, IgM, IgD, IgE, light chain only [kappa and lambda], biclonal, negative immunofixation, not detected)	N, frequency distribution with the number and percentage of subjects in each category.
Type of measurable disease (serum measurable only [IgG, IgA and Other], both serum and urine measurable, urine measurable only, serum FLC measurable)	
ISS staging at screening by central laboratory assessment (I, II, III)	
Number of lytic bone lesions (None, 1-3, 4-10, more than 10)	
Presence of diffuse myeloma-related osteopenia (Yes, No)	
Number of extramedullary plasmacytomas (0, ≥1)	
Bone marrow % plasma cells (<10, 10 – 30, >30)	
Status of cytogenetic abnormality (standard-risk, high-risk [Del17p, T(4;14), T(14;16)]),	
ECG overall conclusion (normal, abnormal [clinically significant, not clinically significant, not evaluable)	

- **Subject Disposition:** The number of subjects in the following disposition categories will be summarized throughout the study for safety population by treatment group and overall: subjects who discontinued study treatment, reasons for discontinuation of study treatment, subjects who terminated study prematurely, and reasons for termination of study. Listings of subjects will be provided for the following categories: subjects who discontinued study treatment, and subjects who terminated study prematurely.

- **Medical history:** Medical history collected at baseline or screening visit will be summarized by system-organ class and preferred term for each treatment group and overall.
- **Prior and concomitant medication:** Summaries of concomitant medications will be presented by therapeutic class, pharmacologic class and preferred term by treatment group and overall for safety population. A summary of prior therapies (systemic therapy, radiotherapy, or cancer-related surgery/ procedure) will be provided by treatment group. Specifically, the number of prior lines of therapy will be calculated according to IWMG consensus guidelines (Durie 2006; Kumar 2016; Rajkumar 2011) [1,2,3] and summarized by the following categories: ≤ 3 and > 3 through frequency and descriptive statistics. Subjects with prior cancer-related surgery/procedure and with prior radiotherapy will be listed for safety population.
- **Pre-infusion and post-infusion medication:** Pre-infusion and post-infusion medication will be summarized by therapeutic class, pharmacologic class and preferred term by treatment group and overall for safety population. A listing will be provided for pre-infusion medication and post-infusion medication, respectively.
- **Exposure:** Summary of treatment exposure will be provided for safety population. The total number of treatment cycles received for each subject will be summarized by frequency and descriptive statistics (N, mean [SD], median, range [minimum, maximum]) by treatment group. Descriptive statistics for duration of study treatment, defined as (date of last dose of study treatment – date of first dose of study treatment) +1, will be presented by treatment group. Subject-month of exposure are calculated as days of duration/365.25*12. Total number of daratumumab and JNJ-63723283 infusions will be calculated. respectively. Exposure will be listed for safety population.

  The number and percentage of subjects with treatment cycle delay will be calculated by treatment group. The frequencies of actions planned prior to infusion start (infusion delayed, infusion skipped or study drug permanently discontinued) and taken during infusion (infusion interrupted, infusion rate decrease, infusion aborted) will be summarized, together with reasons reported (adverse events or other) accordingly.

  Descriptive statistics will be presented for the following parameters: dose and relative dose intensity of daratumumab, dose and relative dose intensity of JNJ-63723283.

- **Protocol deviation:** A listing of subjects with major protocol deviations including treatment group, subject ID, type of deviation, and reasons for deviation will be provided.

1.6. Efficacy

A listing of subjects' best response, and disease progressions based on investigator's assessment, and overall survival will be provided for the safety analysis set, including treatment group, subject ID, and baseline measurable disease type. For subjects who had progression disease (PD), the PD reasons based on investigator's assessment will be listed.

1.7. Safety

- **Adverse events:**
  - An overview of treatment-emergent adverse events (TEAEs) will be summarized for safety population by treatment group and overall.
  - Incidence of TEAEs will be summarized by MedDRA SOC, and preferred term.
  - List of subjects with any TEAEs, serious TEAEs, toxicity grade 3 or 4 TEAEs, treatment-emergent Infusion Related Reactions (IRRs), and immune-mediated TEAEs will be provided for safety population.
  - List of subjects with any TEAEs leading to all treatment discontinuation, TEAEs leading to any treatment discontinuation, TEAEs with outcome death, TEAEs leading to cycle delay or dose modifications, and TEAEs leading to infusion interrupted, infusion rate decreased or infusion aborted will be provided for safety population.
  - Subjects who died during the study, and had new malignancies will also be listed, respectively.

- **Laboratory values:** Laboratory values will be listed at each time points for safety analysis set.
  - The hematology parameters include: hemoglobin, lymphocytes, neutrophils, platelet, and white blood cell (WBC).
  - The chemistry parameters include: alanine aminotransferase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), amylase, calcium, creatinine, creatinine clearance, potassium, sodium, total bilirubin, and total lipase,
  - The thyroid function parameters include: free thyroxine, free triiodothyronine, thyroid stimulating hormone, and total triiodothyronine.

- **Electrocardiograms (ECG):** ECG values will be reported at each time points for safety analysis set in listings.

- **Vital signs:** Vital signs will be listed at each time points for safety analysis set. The variables include: weight, blood pressure (systolic and diastolic).

1.8. Pharmacokinetics/Immunogenicity

- **Pharmacokinetics:** PK analyses will be performed on the PK-evaluable population. The pharmacokinetic parameters are defined as
  - Minimum observed concentration (C_{min}) - the concentration observed immediately before infusion.
  - Maximum observed concentration (C_{max}) – the concentration observed after the end of infusion

  For both JNJ-63723283 and daratumumab, the PK evaluations include C_{min} and C_{max}. All serum concentrations below the lowest quantifiable concentration or missing data will be labeled as such in the concentration data presentation. Concentrations below the lowest quantifiable concentration will be treated as zero in the summary statistics.

The C_{min} and C_{max} will be summarized at each sampling time point by descriptive statistics (N, mean, STD, median, range, coefficient variation and geometric mean) for JNJ-63723283 and daratumumab, respectively, by treatment group. Line plot of mean (±STD) daratumumab and JNJ-63723283 serum peak and trough concentrations over time will be provided.

- **Immunogenicity:** Immunogenicity analyses will be performed on the immunogenicity analysis set. The incidence of anti-daratumumab and anti-JNJ-63723283 antibodies will be summarized for all subjects who receive a dose of daratumumab or JNJ-63723283 and have appropriate samples for detection of antibodies to daratumumab or JNJ-63723283 by treatment group. In addition, subjects who are positive for antibodies to daratumumab or JNJ-63723283 will also be listed.

1.9. Biomarker

Descriptive statistics for values and changes from baseline at each scheduled visit for absolute counts (cells/µl) and percentage of total NK cells, CD8+ T cells, and B cells in peripheral blood will be provided by treatment group. Similar analysis for total and CD38+ myeloid derived suppressor cells (MDSCs), and total and CD38+ regulatory T cells (Tregs) will be performed. Plots for these biomarkers over time will be provided. In additional, percent of activated CD8+ T cells will be summarized and plotted.

2. LIST OF PLANNED OUTPUT

Output Identifier	*Output Title*	*Analysis Set*	*Use for What Effort (TLR, IA, INTXT, DMC)*	*Reference Mock*	*Column Layout*
Subject and Treatment Information (SI)					
Subject Disposition and Study Completion/Withdrawal Information					
TSIDS01	Subjects Disposition	Safety	INTXT	TSIDS-ST02	1
LSIDS01	Listing of Subjects Disposition	Safety		LSIDS-ST01	
TSIFU01	Summary of Study Duration of Follow-up	Safety	INTXT	TSIFU01	1
Demographics and Baseline Characteristics					
TSIPOP01	Subject Populations for Evaluation	Safety	INTXT	TSIDEM-ST03	1
TSIENR01	Subject Enrollment by Region and Country	Safety		TSIDEM-ST04	1
TSIDEM01	Summary of Demographics and Baseline Characteristics	Safety	INTXT	TSIDEM-ST01	1
TSIDEM02	Summary of Baseline Disease Characteristics;	Safety	INTXT	TSIDEM02	1
LSIDEM01	Listing of Demographics and Baseline Characteristics	Safety		LSIDEM-ST01	
TSIMH01	Summary of Medical History by MedDRA System Organ Class and Preferred Term	Safety		TSIMH01	1
Prior and Concomitant Therapies					
TSIPM01	Summary of Prior Systemic Therapy	Safety	INTXT	TSIPM01	1
TSICM01	Summary of Concomitant Medications	Safety		TSICM-ST01	1
TSICM02	Summary of Pre-infusion Medications	Safety		TSICM-ST01	1
TSICM03	Summary of Post-infusion Medications	Safety		TSICM-ST01	1
LSICM01	Listing of Pre-infusion Medications	Safety		LSICM01	
LSICM02	Listing of Post-infusion Medications	Safety		LSICM02	
LSIPM01	Listing of Subjects with Prior Cancer-related Surgery/Procedure	Safety		LSIPM01	
LSIPM02	Listing of Subjects with Prior Radiotherapy	Safety		LSIPM02	
Protocol Deviations					
LSIDEV01	Listing of Subjects with Major Protocol Deviations	Safety		LSIDEV-ST01	
Extent of Exposure					
TSIEXP01	Summary of Treatment Cycles, Duration of Study Treatment and Dose Intensity	Safety	INTXT	TSIEX-ST01	2

Output Identifier	*Output Title*	*Analysis Set*	*Use for What Effort (TLR, IA, INTXT, DMC)*	*Reference Mock*	*Column Layout*
TSIEXP02	Summary of Treatment Cycle Delays, Incidences of and Reasons for Study Treatment Dose Modifications	Safety		TSIEXP02	2
TSIEXP03	Summary of Action Taken During the Infusion	Safety		TSIEXP03	2
LSIEX01	Listing of Treatment Exposure	Safety		LSIEX-ST01	
Efficacy Results (EF)					
LEFRSP01	Listing of Efficacy Variables Based on Investigator Assessment	Safety		LEFRSP01	
Safety Results (SF)					
Adverse Events					
TSFAE01	Overview of Treatment-emergent Adverse Events	Safety	INTXT	TSFAE-ST01	1
TSFAE02	Treatment-emergent Adverse Events by System Organ Class and Preferred Term	Safety	INTXT	TSFAE-ST02	1
LSFAE01	Listing of Treatment-emergent Adverse Events	Safety		LSFAE01	
LSFAE02	Listing of Treatment-emergent Serious Adverse Events	Safety		LSFAE01	
LSFAE03	Listing of Treatment-emergent Grade 3 or 4 Adverse Events	Safety		LSFAE01	
LSFAE04	Listing of Subjects who Discontinued All Study Treatment Because of 1 or More Treatment-emergent Adverse Events;	Safety		LSFAE01	
LSFAE05	Listing of Subjects Who Discontinued Any of Study Drugs Because of 1 or More Treatment-emergent Adverse Events	Safety		LSFAE01	
LSFAE06	Listing of Treatment-emergent Infusion Related Reactions	Safety		LSFAE01	
LSFAE07	Listing of Immune-mediated Treatment-emergent Adverse Event	Safety		LSFAE01	
LSFAE08	Listing of Treatment-emergent Adverse Events Leading to Cycle Delay or Dose Modifications	Safety		LSFAE01	
LSFAE09	Listing of Treatment-emergent Adverse Events Leading to Infusion Interrupted, Infusion Rate Decreased or Infusion Aborted	Safety		LSFAE01	

Output Identifier	*Output Title*	*Analysis Set*	*Use for What Effort (TLR, IA, INTXT, DMC)*	*Reference Mock*	*Column Layout*
LSFAE10	Listing of Subjects Who Had New Malignancies	Safety		LSFAE10	
LSFDTH01	Listing of Subjects Who Died During the Study	Safety		LSFDTH-ST01	
Clinical Laboratory Evaluation					
TSFLAB01	Shift Table of Baseline versus Worst Toxicity Grade during Treatment in Hematological Test	Safety		TSFLAB-ST07	2
TSFLAB02	Shift Table of Baseline versus Worst Toxicity Grade during Treatment in Biochemistry Test;	Safety		TSFLAB-ST07	2
LSFLAB01	Listing of Other Laboratory Values	Safety		LSFLAB-ST01	
Electrocardiograms					
LSFECG01	Listing of ECG Results	Safety		LSFECG-ST01	
Vital Signs					
LSFVS01	Listing of Vital Signs Values	Safety		LSFLAB-ST01	
Pharmacokinetics/Immunogenicity (PK/IR)					
TPKCONC01	Summary of Daratumumab Concentration (ug/mL)	PK-evaluable	INTXT	TPK-ST07	3
TPKCONC02	Summary of JNJ-63723283 Concentration (ug/mL)	PK-evaluable	INTXT	TPK-ST07	3
GPKCONC01	Mean (SD) Daratumumab Serum Peak and Trough Concentrations (ug/mL)	PK-evaluable		GPK-ST05	
GPKCONC02	Mean (SD) JNJ-63723283 Serum Peak and Trough Concentrations (ug/mL)	PK-evaluable		GPK-ST05	
TPKIR01	Summary of Anti-daratumumab Antibodies Status	Immunogenicity	INTXT	TPKIR-ST01	4
TPKIR02	Summary of Anti-JNJ-63723283 Antibodies Status	Immunogenicity	INTXT	TPKIR-ST01	4
LPKCONC01	List of Subjects Positive for Anti-daratumumab Antibodies Status	Immunogenicity		LPKIR-ST01	
LPKCONC02	List of Subjects Positive for Anti-JNJ-63723283 Antibodies Status	Immunogenicity		LPKIR-ST01	
Biomarkers					
Natural Killer (NK) Cells					
TBMKNK01	Summary of Percent of Total Natural Killer Cells in Blood Over Time	Safety		TBMK01	

Output Identifier	*Output Title*	*Analysis Set*	*Use for What Effort (TLR, IA, INTXT, DMC)*	*Reference Mock*	*Column Layout*
TBMKNK02	Summary of Total Natural Killer Cells (Absolute Count) in Blood Over Time	Safety		TBMK01	
GBMKNK01	Plot of Percent of Total Natural Killer cells in Blood over time	Safety		GBMK01	
GBMKNK02	Plot of Total Natural Killer Cells (Absolute Count) in Blood Over Time	Safety		GBMK01	
T Cells					
TBMKTC01	Summary of Percent of CD8+ T Cells in Blood Over Time	Safety		TBMK01	
TBMKTC02	Summary of CD8+ T Cells (Absolute Count) in Blood Over Time	Safety		TBMK01	
GBMKTC01	Plot of Percent of CD8+ T Cells in Blood Over Time	Safety		GBMK01	
GBMKTC02	Plot of CD8+ T Cells (Absolute Count) in Blood Over Time	Safety		GBMK01	
TBMKTC03	Summary of Percent of Activated CD8+T Cells in Blood Over Time	Safety		TBMK01	
GBMKTC03	Plot of Percent of Activated CD8+ T cells in Blood Over Time	Safety		GBMK01	
B Cells					
TBMKBC01	Summary of Percent of B Cells in Blood Over Time	Safety		TBMK01	
TBMKBC02	Summary of B Cells (Absolute Count) in Blood Over Time	Safety		TBMK01	
GBMKBC02	Plot of B Cells (Absolute Count) in Blood Over Time	Safety		GBMK01	
GBMKBC01	Plot of Percent of B Cells in Blood Over Time	Safety		GBMK01	
CD38+ MDSCs					
TBMKMDSC 01	Summary of Percent of Total monocytic MDSCs in Blood Over Time	Safety		TBMK01	
TBMKMDSC 02	Summary of Percent of CD38+ monocytic MDSCs in Blood Over Time	Safety		TBMK01	
GBMKMDSC 01	Plot of Percent of Total monocytic MDSCs in Blood over time	Safety		GBMK01	
GBMKMDSC 02	Plot of Percent of CD38+ monocytic MDSCs in Blood Over Time	Safety		GBMK01	

Output Identifier	*Output Title*	*Analysis Set*	*Use for What Effort (TLR, IA, INTXT, DMC)*	*Reference Mock*	*Column Layout*
TBMKMDSC03	Summary of Total Monocytic MDSCs (Absolute Count) in Blood Over Time	Safety		TBMK01	
GBMKMDSC03	Plot of Total monocytic MDSCs (Absolute Count) in Blood Over Time	Safety		GBMK01	
CD38+ Tregs					
TBMKTR01	Summary of Percent of Total Tregs in Blood Over Time	Safety		TBMK01	
TBMKTR02	Summary of Percent of CD38+ Tregs in Blood Over Time	Safety		TBMK01	
TBMKTR03	Summary of Total Tregs (Absolute Count) in Blood Over Time	Safety		TBMK01	
TBMKTR04	Summary of CD38+ Tregs (Absolute Count) in Blood Over Time	Safety		TBMK01	
GBMKTR01	Plot of Percent of Total Tregs in Blood Over Time	Safety		GBMK01	
GBMKTR02	Plot of Percent CD38+ Tregs in Blood Over Time	Safety		GBMK01	
GBMKTR03	Plot of Total Tregs (Absolute Count) in Blood Over time	Safety		GBMK01	
GBMKTR04	Plot of CD38+ Tregs (Absolute Count) in Blood Over Time	Safety		GBMK01	

3. COLUMN LAYOUTS FOR TABLES

All tables listed in Section 2 are to be presented with the following columns layout, unless specified otherwise.

Layout 1: To be used in demographics, baseline disease characteristics, prior systemic therapies, medical history, TEAE overview, safety.

Safety Run-in	Phase 2 Arm A	Total

Layout 2: To be used in exposure tables.

Safety Run-in	Phase 2 Arm A

Layout 3: To be used in PK tables

Safety Run-in	
Pre-dose	Post-dose

Layout 4: To be used in immunogenicity tables

Safety Run-in

Programming notes:

1. Footnotes that correspond to the naming of the treatment groups are specified as below:
   Key: Arm A = daratumumab alone;

4. MOCK LAYOUTS

TSIDS-ST02: Subjects Disposition; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	###	###	###	###	###
Subjects who discontinued treatment	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Reason for discontinuation					
Adverse Event	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Death	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Non-compliance with study drug	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Physician decision	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Pregnancy	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Progressive disease	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Study terminated by sponsor	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Subject refused further study treatment	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Other	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	## (xx.x%)
Subjects who discontinued study	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Reason for discontinuation					
Death	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Lost to follow-up	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Physician desicion	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Pregnancy	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Screen failure	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Study terminated by sponsor	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Withdrawal by subject	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Other	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)

Note: Percentages calculated with the number of subjects in each group as denominator.

Display Specifications	
Output Identifier	TSIDS01
Programming Notes: 1. Reasons for discontinuation should be presented in descending frequency in the overall total column. 2. Remove the specific reason for discontinuation if there is no subject belongs to that.	

LSIDS-ST01: Listing of Subjects Disposition; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Disposition Event	Study Day[a] of Last Study Agent Administered	Total Dose for Dara/JNJ283 (mg/kg or mg)[b]	Discontinuation Date (Study Day[a])	Primary Reason for Discontinuation

[a] Study day is relative to the date of first dose of study agent.
[b] Total dose is defined as a cumulative sum of all study agent administered. Dara=daratumumab; JNJ283=JNJ-63723283.

Display Specifications	
Output Identifier	LSIDS01

Programming Notes:
1. Sort listing based on treatment group (Safety run-in, Arm A, Arm B), site ID, and subject ID.
2. Study day of last study agent administered is the study day that the subject received their last non-zero dose of study agent.
3. If the reason for discontinuation is Adverse event or Other, specify the AE preferred term or other reason in parentheses.

TSIFU01: Summary of Study Duration of Follow-up; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	##	##	##
Duration of follow-up (months)			
N	##	##	##
Mean (SD)	##.# (##.##)	##.# (##.##)	##.# (##.##)
Median[a]	##	##	##
Range	(##; ##)	(##; ##)	(##; ##)

[a] Based on Kaplan-Meier product limit estimate.
Note: Duration of follow-up is relative to the date of first dose.

Programming Notes:
1. Mark '+" for the range values if come from the subjects who died, and the following footnote is needed: "+ Denotes subjects who died".

TSIDEM-ST04: Subject Enrollment by Region and Country; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	###	###	###	###	###
Region/Country	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Region 1	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Country 1	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Country 2	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Country 3	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)

Note: Percentages are calculated with the number of subjects in each group as denominator.

Programming Notes:

1. Region and Country are presented in alphabetical order

TSIDEM-ST03: Subject Populations for Evaluation; Safety Analysis Set (Study 54767414MMY2036)

Safety analysis set [a]	###	###	###	###	###
Pharmacokinetic-evaluable analysis set [b]	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Immunogenicity analysis set [c]	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)

[a] Safety analysis set includes all subjects who have received at least 1 dose of study agent (JNJ-63723283 or daratumumab, partial or complete) in either safety run-in or Part 2 of the study.
[b] Pharmacokinetic-evaluable analysis set includes all subjects who have received at least 1 dose of daratumumab or JNJ-63723283 and have at least 1 postinfusion sample in either safety run-in or Part 2 of the study.
[c] Immunogenicity analysis set include all subjects who have received at least 1 dose of JNJ-63723283 or daratumumab and have appropriate serum samples for detection of antibodies to JNJ-63723283 or daratumumab (i.e., subjects with at least 1 sample obtained after their first dose of JNJ-63723283 or daratumumab) in either safety run-in or Part 2 of the study
Note: Percentages are calculated with the number of subjects in each group as denominator.

Display Specifications	
Output Identifier	TSIPOP01

TSIDEM-ST01: Summary of Demographics and Baseline Characteristics; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	###	###	###	###	###
Age, (years)					
N	###	###	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)
Category, n(%)					
< 65	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
65-<75	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
≥ 75	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Sex, n(%)					
N	###	###	###	###	###
Female	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Male	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Race, n(%)					
N	###	###	###	###	###
American Indian or Alaska Native	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Asian	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Black or African American	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Native Hawaiian or Other Pacific Islander	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
White	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Multiple[a]	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Not reported	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Ethnicity, n(%)					
N	###	###	###	###	###
Hispanic or Latino	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Not Hispanic or Latino	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Not reported	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Weight, kg					
N	###	###	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)
Category, n(%)					
≤ 65	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
>65-85	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
>85	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Height, cm					
N	###	###	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)	(xx;xx)

TSIDEM-ST01: Summary of Demographics and Baseline Characteristics; Safety Analysis Set (Study 54767414MMY2036)

Baseline ECOG score, n(%)					
N	###	###	###	###	###
0	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
1	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
2	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)

Key: ECOG=Eastern Cooperative Oncology Group.
[a] If multiple race categories are indicated, the subject's race is include in 'Multiple'.
Note: Percentages are calculated with the number of subjects in each group with available data as denominator.

Programming Notes:

1. For sex, race, and ethnicity, categories are presented in alphabetical order.
2. For race, each subject must appear in only one category.
3. For ordered categories (eg, age (years): <65, >=60), all category levels will be displayed regardless of whether there are zero counts within a level; for categories with no inherent order (eg, race), only category levels with counts >0 will be displayed.

TSIDEM02: Summary of Baseline Disease Characteristics; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	##	##	##
Type of myeloma by immunofixation or serum FLC assay, n (%)			
N	##	##	##
IgG	### (xx.x%)	### (xx.x%)	### (xx.x%)
IgA	### (xx.x%)	### (xx.x%)	### (xx.x%)
IgM	### (xx.x%)	### (xx.x%)	### (xx.x%)
IgD	### (xx.x%)	### (xx.x%)	### (xx.x%)
IgE	### (xx.x%)	### (xx.x%)	### (xx.x%)
Light chain	### (xx.x%)	### (xx.x%)	### (xx.x%)
Kappa	### (xx.x%)	### (xx.x%)	### (xx.x%)
Lambda	### (xx.x%)	### (xx.x%)	### (xx.x%)
Biclonal	### (xx.x%)	### (xx.x%)	### (xx.x%)
Negative Immunofixation	### (xx.x%)	### (xx.x%)	### (xx.x%)
Not detected	### (xx.x%)	### (xx.x%)	### (xx.x%)
Type of measurable disease [a], n(%)			
N	##	##	##
Serum only			
IgG	### (xx.x%)	### (xx.x%)	### (xx.x%)
IgA	### (xx.x%)	### (xx.x%)	### (xx.x%)
Other [b]	### (xx.x%)	### (xx.x%)	### (xx.x%)
Serum and urine	### (xx.x%)	### (xx.x%)	### (xx.x%)
Urine only	### (xx.x%)	### (xx.x%)	### (xx.x%)
Serum FLC only	### (xx.x%)	### (xx.x%)	### (xx.x%)
NE	### (xx.x%)	### (xx.x%)	### (xx.x%)
ISS staging [c], n(%)			
N	##	##	##
I	### (xx.x%)	### (xx.x%)	### (xx.x%)
II	### (xx.x%)	### (xx.x%)	### (xx.x%)
III	### (xx.x%)	### (xx.x%)	### (xx.x%)
Number of lines of prior therapy [d]			
N	##	##	##
Mean (SD)	##.# (##.##)	##.# (##.##)	##.# (##.##)
Median	##	##	##
Range	(##; ##)	(##; ##)	(##; ##)
Category, n (%)			
≤ 3	#(XX.X%)	#(XX.X%)	#(XX.X%)
> 3	#(XX.X%)	#(XX.X%)	#(XX.X%)
Time from MM diagnosis to first dosing date(years)			
N	##	##	##
Mean (SD)	##.##(##.###)	##.##(##.###)	##.##(##.###)
Median	##.##	##.##	##.##
Range	(##.#; ##.#)	(##.#; ##.#)	(##.#; ##.#)

TSIDEM02: Summary of Baseline Disease Characteristics; Safety Analysis Set (Study 54767414MMY2036)

Number of lytic bone lesions, n (%)			
N	##	##	##
None	### (xx.x%)	### (xx.x%)	### (xx.x%)
1-3	### (xx.x%)	### (xx.x%)	### (xx.x%)
4-10	### (xx.x%)	### (xx.x%)	### (xx.x%)
More than 10	### (xx.x%)	### (xx.x%)	### (xx.x%)
Presence of diffuse myeloma-related osteopenia, n (%)			
N	##	##	##
Yes	### (xx.x%)	### (xx.x%)	### (xx.x%)
No	### (xx.x%)	### (xx.x%)	### (xx.x%)
Number of extramedullary plasmacytomas, n (%)			
N	##	##	##
0	### (xx.x%)	### (xx.x%)	### (xx.x%)
≥ 1	### (xx.x%)	### (xx.x%)	### (xx.x%)
Presence of evaluable bone marrow assessment, n (%)			
N	##	##	##
Yes	### (xx.x%)	### (xx.x%)	### (xx.x%)
No	### (xx.x%)	### (xx.x%)	### (xx.x%)
% Plasma cells, bone marrow biopsy/aspirate, n (%)			
N	##	##	##
<10	### (xx.x%)	### (xx.x%)	### (xx.x%)
10-30	### (xx.x%)	### (xx.x%)	### (xx.x%)
>30	### (xx.x%)	### (xx.x%)	### (xx.x%)
Cytogenetic risk [e], n (%)			
N	##	##	##
Standard Risk	### (xx.x%)	### (xx.x%)	### (xx.x%)
High Risk [f]	### (xx.x%)	### (xx.x%)	### (xx.x%)
Del(17p)	### (xx.x%)	### (xx.x%)	### (xx.x%)
T(4;14)	### (xx.x%)	### (xx.x%)	### (xx.x%)
T(14;16)	### (xx.x%)	### (xx.x%)	### (xx.x%)

TSIDEM02: Summary of Baseline Disease Characteristics; Safety Analysis Set (Study 54767414MMY2036)

Baseline ECG			
N	##	##	##
Normal	### (xx.x%)	### (xx.x%)	### (xx.x%)
Abnormal, not clinically significant	### (xx.x%)	### (xx.x%)	### (xx.x%)
Abnormal, clinically significant	### (xx.x%)	### (xx.x%)	### (xx.x%)

Key: ECG = electrocardiogram; FLC = serum free light chain; ISS = International Staging System; MM = multiple myeloma; NE=not evaluable.

[a] Includes subjects without measurable disease in serum and urine.

[b] Includes subjects with IgD, IgM, IgE and biclonal.

[c] ISS staging is derived based on the combination of serum β2-microglobulin and albumin.

[d] Based on data recorded on prior systemic therapy eCRF page.

[e] Cytogenetic risk is based on FISH or karyotype testing.

[f] Subject may have more than one high-risk abnormality [del17p, t(4;14) or t(14;16)].

Note: Percentages calculated with the number of subjects in each group with available data as denominator.

Display Specifications	
Output Identifier	TSIDEM02
Programming Notes: 1. No need to show "Not detected" or "NE" categories if no such subjects exist	

LSIDEM-ST01: Listing of Demographics and Baseline Characteristics; Safety Analysis set (Study 54767414MMY2036)

						Baseline		
Treatment Group	Site ID	Subject ID	Informed Consent Date	Age (years)/ Sex/Race	Ethnicity	Weight (kg)	Height (cm)	ECOG Performance Score
[redacted]	[redacted]	[redacted]	[redacted]	*30/M* [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Key: ECOG=Eastern Cooperative Oncology Group.

Display Specifications	
Output Identifier	LSIDEM01
Programming Notes: 1. Sort listing based on treatment group (Safety run-in, Arm A, Arm B), site ID, and subject ID.	

TSIMH01: Summary of Medical History by MedDRA System Organ Class and Preferred term; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	##	##	##
Total number of subjects with 1 or more medical history	#(X.X%)	#(X.X%)	#(X.X%)
MedDRA system organ class / Preferred term	#(X.X%)	#(X.X%)	#(X.X%)
System organ class	#(X.X%)	#(X.X%)	#(X.X%)
Preferred term	#(X.X%)	#(X.X%)	#(X.X%)

Note: Percentages calculated with the number of subjects in each treatment group as denominator. Medical history is coded using MedDRA version 20.X.

TSIPM01: Summary of Prior Systemic Therapies; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	##	##	##
Total number of subjects with any prior therapies for multiple myeloma, n (%)	#(XX.X%)	#(XX.X%)	#(XX.X%)
Prior systemic therapy	#(XX.X%)	#(XX.X%)	# (XX.X%)
Prior autologous stem cell transplant (ASCT)	#(XX.X%)	#(XX.X%)	#(XX.X%)
Prior radiotherapy	#(XX.X%)	#(XX.X%)	# (XX.X%)
Prior cancer-related surgery	#(XX.X%)	#(XX.X%)	#(XX.X%)
Prior PI, n (%)			
Bortezomib	#(XX.X%)	#(XX.X%)	#(XX.X%)
Carfilzomib	#(XX.X%)	#(XX.X%)	#(XX.X%)
Ixazomib	#(XX.X%)	#(XX.X%)	#(XX.X%)
Prior IMiD, n (%)			
Lenalidomide	#(XX.X%)	#(XX.X%)	#(XX.X%)
Pomalidomide	#(XX.X%)	#(XX.X%)	#(XX.X%)
Thalidomide	#(XX.X%)	#(XX.X%)	#(XX.X%)
Prior PI+IMiD, n (%)			
Prior corticosteroids, n (%)			
Dexamethasone	#(XX.X%)	#(XX.X%)	#(XX.X%)
Prednisone	#(XX.X%)	#(XX.X%)	#(XX.X%)
Prior alkylating agents, n (%)	#(XX.X%)	#(XX.X%)	#(XX.X%)
Prior anthracyclines, n (%)	#(XX.X%)	#(XX.X%)	# (XX.X%)

Note: Percentages calculated with the number of subjects in each group as denominator

TSICM-ST01: Summary of Concomitant Medications; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	###	###	###	###	###
Subjects with one or more concomitant medications	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
ATC Level 2	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
ATC Level 3	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Standardized medication name	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)

Note: Percentages calculated with the number of subjects in each group as denominator.

Display Specifications	
Output Identifier	TSICM01
Programming Notes: 1. Order by decreasing incidence of ATC level and decreasing incidence of standardized medication name based on the overall total column.	

Display Specifications	
Output Identifier	TSICM02
Programming note: 1. Change the ‘concomitant’ to ‘pre-infusion’ in the title and table. 2. Order by decreasing incidence of ATC level and decreasing incidence of standardized medication name based on the overall total column.	

Display Specifications	
Output Identifier	TSICM03
Programming note: 1. Change the ‘concomitant’ to ‘post-infusion’ in the title and table. 2. Order by decreasing incidence of ATC level and decreasing incidence of standardized medication name based on the overall total column.	

LSICM01: Listing of Pre-infusion Medications; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Visit	Start Date/Time (Study Day)	Medication Coded Term [Verbatim Term]	Dose (unit)	Route
Safety run-in	XXX	XXXXXXXX	CYCLE 1 DAY 1	2017-11-01T09:00 (1)	CLEMASTINE FUMARATE [TAVEGYL]	2 (mg)	INTRAVENOUS
			CYCLE 1 DAY 8	2017-11-08T09:00 (8)	CLEMASTINE FUMARATE [TAVEGYL]	2 (mg)	INTRAVENOUS
		XXXXXXXX	CYCLE 1 DAY 1	2017-11-01T09:00 (1)	CLEMASTINE FUMARATE [TAVEGYL]	2 (mg)	INTRAVENOUS

Programming note: please sort data by Treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, start Date/Time

LSICM02: Listing of Post-infusion Medications; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Visit	Start Date (Study Day)	End Date (Study Day)	Medication Coded Term [Verbatim Term]	Dose (unit)	Route	Frequency
Safety run-in	XXX	XXXXXXXX	CYCLE 1 DAY 1	2017-11-01 (1)	2017-11-02 (2)	METHYLPREDNISOLONE [MEDROL]	20 (mg)	ORAL	Twice Daily
			CYCLE 1 DAY 8	2017-11-08 (8)	2017-11-08 (9)	METHYLPREDNISOLONE [MEDROL]	20 (mg)	ORAL	Twice Daily
		XXXXXXXX	CYCLE 1 DAY 1	2017-11-01 (1)	2017-11-02 (2)	METHYLPREDNISOLONE [MEDROL]	20 (mg)	ORAL	Twice Daily
		XXXXXXXX	CYCLE 1 DAY 1	2017-11-01 (1)	2017-11-02 (2)	METHYLPREDNISOLONE [MEDROL]	20 (mg)	ORAL	Twice Daily

Programming note: please sort data by Treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Start date.

LSIPM01: List of Subjects with Prior Cancer-Related Surgery/Procedure; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Description of Surgery or Procedure	Start Date	End Date	Indication

Programming Notes:
1. Listing is sorted by treatment (Safety run-in, Arm A and Arm B), site ID, subject ID, start date of procedure.

LSIPM02: List of Prior Radiotherapy; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Start Date	End Date	Location	Indication	Total Dose (Gy)

Programming Notes:
1. Listing is sorted by treatment (Safety run-in, Arm A and Arm B), site ID, subject ID, start date of procedure.
2. If indication/location is “Other” and there is a specific description of the indication/location, then the specific description should be displayed

LSIDEV-ST01: Listing of Subjects with Major Protocol Deviations; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Type of Protocol Deviation	Protocol Deviation Verbatim Term

Programming Notes:
1. The sort order is Treatment Group (Safety run-in, Arm A and Arm B), Site ID, Subject ID, and Study Day of Deviation.

TSIEX-ST01: Summary of Treatment Cycles, Duration of Study Treatment and Dose Intensity; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	###	###	###
Duration of treatment (months)			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)
Number of treatment cycles			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)
≥ 1 cycle	## (XX.X%)	## (XX.X%)	## (XX.X%)
≥ 2 cycles	## (XX.X%)	## (XX.X%)	## (XX.X%)
≥ 3 cycles	## (XX.X%)	## (XX.X%)	## (XX.X%)
≥ 4 cycles	## (XX.X%)	## (XX.X%)	## (XX.X%)
≥ 5 cycles	## (XX.X%)	## (XX.X%)	## (XX.X%)
Total number of daratumumab infusions			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)
Total dose of daratumumab (mg/kg)			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)
Dose intensity for daratumumab (mg/kg/cycle) [a]			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)
Relative dose intensity for daratumumab (%)			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)
Total number of JNJ-63723283 infusions			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)
Total dose of JNJ-63723283 (mg)			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)

TSIEX-ST01: Summary of Treatment Cycles, Duration of Study Treatment and Dose Intensity; Safety Analysis Set (Study 54767414MMY2036)

Dose intensity for JNJ-63723283 (mg/cycle) [b]			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)
Relative dose intensity for JNJ-63723283 (%)			
N	###	###	###
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Range	(xx;xx)	(xx;xx)	(xx;xx)

[a] Dose intensity (mg/kg/cycle) is calculated as the sum of total doses (mg/kg) received in all cycles divided by the number of treatment cycles on daratumumab.
[b] Dose intensity (mg/cycle) is calculated as the sum of total doses (mg) received in all cycles divided by the number of treatment cycles on JNJ-63723283.
Note: The relative dose intensity (%) is the ratio of total actually received dose and total planned dose.

TSIEXP02: Summary of Treatment Cycle Delays, Incidences of and Reasons for Study Treatment Dose Modifications; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	##	##
Subjects with cycle delays	## (XX.X%)	## (XX.X%)
Reason for cycle delays		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)
Subjects with dose delays		
Daratumumab	## (XX.X%)	## (XX.X%)
Reason for delays		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)
JNJ-63723283	## (XX.X%)	## (XX.X%)
Reason for delays		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)
Subjects with dose skipped		
Daratumumab	## (XX.X%)	## (XX.X%)
Reason for skipping		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)

TSIEXP02: Summary of Treatment Cycle Delays, Incidences of and Reasons for Study Treatment Dose Modifications; Safety Analysis Set (Study 54767414MMY2036)

JNJ-63723283	## (XX.X%)	## (XX.X%)
Reason for skipping		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)

Note: Percentages calculated with the number of subjects in each group as denominator.

TSIEXP03: Summary of Action Taken During the Infusion; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	##	##
Subjects with infusion interrupted		
Daratumumab	## (XX.X%)	## (XX.X%)
Reason for infusion interrupted		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)
JNJ-63723283	## (XX.X%)	## (XX.X%)
Reason for infusion interrupted		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)
Subjects with infusion rate decreased		
Daratumumab	## (XX.X%)	## (XX.X%)
Reason for infusion rate decreased		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)
JNJ-63723283	## (XX.X%)	## (XX.X%)
Reason for infusion rate decreased		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)
Subjects with infusion aborted		
Daratumumab	## (XX.X%)	## (XX.X%)
Reason for infusion aborted		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)
JNJ-63723283	## (XX.X%)	## (XX.X%)
Reason for infusion aborted		
Adverse event	## (XX.X%)	## (XX.X%)
Other	## (XX.X%)	## (XX.X%)

Note: Percentages calculated with the number of subjects in each group as denominator.

LSIEX-ST01: Listing of Treatment Exposure; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Study Drug	Visit	Infusion Date (Study Day)	Total Dose (mg)	Start/End Time	Action Planned Prior to Infusion Start	Reason for Action Planned Prior to Infusion Start	Action Taken During Infusioin	Reason for Action Taken During Infusion	If 'INFUSION INTERRUPTED', Interruption Start/End Time

Programming Notes:
The sort order is Treatment Group (Safety run-in, Arm A, Arm B), Site ID, Subject ID, Study Drug and Infusion Date

LEFRSP01: Listing of Efficacy Variable Based on Investigator Assessment; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Measurable Disease Type	Best Resp.	Date of Best Resp. (Study Day)	Date of PD (Study Day)	Reason for PD	Reason for PD Censoring	Date of Last Disease Assessment (Study Day)	PFS (Month)	Date of Death/ Last Date Known to be Alive (Study Day)	OS (Month)
Arm A	XX	XX	Serum	CR	2018-06-04 (XX)			XX	2018-06-14 (xx)	2.4+	2018-06-14 (xx)	2.4+

Key: sCR=stringent complete response; CR=complete response; VGPR=very good partial response; PR=partial response; MR=minimal response; SD=stable disease; PD=progression disease; NE=not evaluable.
Key: OS=Overall Survival; PFS=Progression-free Survival; Resp.=Response.
+: Censoring.

Programming notes:
Sort the listing by Treatment group (Arm A, Arm B), Site ID, and Subject ID.

TSFAE-ST01: Overview of Treatment-emergent Adverse Events; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	###	###	###	###
Any TEAE	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related[a]	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related to daratumumab	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related to JNJ-63723283	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Maximum toxicity grade				
Grade 1	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Grade 2	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Grade 3	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Grade 4	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Grade 5	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Any serious TEAE	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related [a]	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related to daratumumab	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related to JNJ-63723283	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
TEAE leading to discontinuation of study treatment [b]	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
TEAE leading to discontinuation of daratumumab	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related to daratumumab	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
TEAE leading to discontinuation of JNJ-63723283	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related to JNJ-63723283	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
TEAE with outcome of death	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related to daratumumab	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
At least one related to JNJ-63723283	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)

Key: TEAE = treatment-emergent adverse event.
[a] TEAEs related to at least 1 of the 2 study treatments: daratumumab and JNJ-63723283.
[b] Includes those subjects indicated as having discontinued treatment due to an adverse event on the end of treatment CRF page.
Note: Adverse events are coded using MedDRA version XX.X. Percentages are calculated with the number of subjects in each group as denominator.

Display Specifications	
Output Identifier	TSFAE01

Programming Notes:

1. TEAE with outcome of death are based on an AE outcome equal to Fatal or toxicity grade of 5 from AE page.
2. An AE is considered to result in discontinuation of study agent if the "action taken regarding study agent" is "drug withdrawn" on the AE eCRF page. If an attribute of the AE is missing, it will not be imputed.
3. An AE is considered to result in discontinuation of study treatment if the reason for termination on the End of Treament disposition page is AE.

TSFAE-ST02: Treatment-emergent Adverse Events by System Organ Class and Preferred Term; Safety Analysis Set (Study 54767414MMY2036)

Analysis set: Safety	###	###	###	###
Total number of subjects with TEAE	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
MedDRA system organ class/preferred term				
System organ class	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Preferred term	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
System organ class	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)
Preferred term	### (xx.x%)	### (xx.x%)	### (xx.x%)	### (xx.x%)

Key: TEAE = treatment-emergent adverse event,
Note: Subjects are counted only once for any given event, regardless of the number of times they actually experienced the event. Adverse events are coded using MedDRA Version *XX.X*. Percentages are calculated with the number of subjects in each group as denominator.

Display Specifications	
Output Identifier	TSFAE02
Programming Notes: 1. For any uncoded system organ class, present system organ class in table as "Uncoded"; for any uncoded preferred terms, present 'Uncoded' and add verbatim in parenthese next to the preferred term.	

LSFAE01: Listing of Treatment-emergent Adverse Events; Safety Analysis set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Onset Date (Study Day)	End Date (Study Day)	Preferred Term	SAE?	Toxicity Grade	Relationship to[a]		Action Taken with[b]		Outcome	IRR Associated with[c]		Immune Mediated? (Y/N)	A DLT ? (Y/N)
								Dara	JNJ-283	Dara	JNJ-283		Dara	JNJ-283		
xxx	xxx	xxx	2014-06-21 (1)	2014-06-21 (1)	Cough	No	1	VL	NR	DI	DNC	RECOVERED/ RESOLVED	Y	N	N	N
			2014-06-29 (9)	2014-06-30 (10)	Blood blister	Yes	3	NR	VL	DI	DW	RECOVERED/ RESOLVED	N	N	N	Y

Key: Dara=daratumumab. JNJ-283=JNJ-63723283. SAE = Serious adverse event. IRR=infusion related reaction. DLT=dose-limiting toxicity.
[a]: NR = Not Related. DO = Doubtful, Poss. = Possible, Prob. = Probable, VL = Very Likely.
[b]: DI = Drug Interrupted, DNC = Dose Not Changed, DR = Dose Reduced, DW = Drug Withdrawn, NA = Not Applicable, UN = Unknown.
[c]: Y=Yes. N=No. NA=Not Applicable. UN=Unknown.
Note: Adverse events are coded using MedDRA version XX.X.

Display Specifications	
Output Identifier	LSFAE01
Programming notes: 1. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

Display Specifications	
Output Identifier	LSFAE02
Programming notes: 1. Update 'Treatment-emergent Adverse Events' in the title to 'Treatment-emergent Serious Adverse Events'. 2. Remove the 'SAE?' column 3. Delete the 'SAE=Serious adverse event' in the footnote. 4. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

Display Specifications	
Output Identifier	LSFAE03
Programming notes: 1. Update 'Treatment-emergent Adverse Events' in the title to 'Treatment-emergent Grade 3 or 4 Adverse Events'. 2. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

Display Specifications	
Output Identifier	LSFAE04
Programming notes: 1. Update 'Treatment-emergent Adverse Events' in the title to 'Subjects who Discontinued All Study Treatment Because of 1 or More Treatment-emergent Adverse Events'. 2. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

Display Specifications	
Output Identifier	LSFAE05
Programming notes: 1. Update 'Treatment-emergent Adverse Events' in the title to 'Subjects who Discontinued Any Study Drugs Because of 1 or More Treatment-emergent Adverse Events'. 2. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

Display Specifications	
Output Identifier	LSFAE06
Programming notes: 1. Update 'Treatment-emergent Adverse Events' in the title to 'Infusion Related Reactions'. 2. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

Display Specifications	
Output Identifier	LSFAE07
Programming notes: 1. Update 'Treatment-emergent Adverse Events' in the title to 'Immune Mediated Adverse Events'. 2. Remove the 'Immune Mediated? (Y/N)' column. 3. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

Display Specifications	
Output Identifier	LSFAE08
Programming notes: 1. Update 'Treatment-emergent Adverse Events' in the title to 'Treatment-emergent Adverse Events Leading to Cycle Delay or Dose Modifications'. 2. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

Display Specifications	
Output Identifier	LSFAE09
Programming notes: 1. Update 'Treatment-emergent Adverse Events 'Treatment-emergent Adverse Events Leading to Infusion Interrupted, Infusion Rate Decreased or Infusion Aborted'. 2. Sort the list by treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID, Onset Date	

LSFAE10: Listing of Subjects Who Had New Malignancies; Safety Analysis set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Line Number	Diagnosis	Diagnosis Date (Study Day)	Existing malignancy (Y/N) / Initiation Diagnosis Date if 'Y' (Study Day)	Confirmed by pathology (Y/N) / Diagnosis Method if 'Y'	Stage of Disease/Staging System	Total No./Dose (mg/kg) of Dara Infusions	Total No./Dose (mg)of JNJ-283 Infusions	Treatment for The New Malignancy	Outcome
xxx	xxx	xx	1	ACUTE MONOBLASTIC LEUKEMIA		Y/2005-05-01 (-100)	Y/Biopsy	III/ISS	15/300	10/2400	Curative Surgery	RECOVERED/RESOLVED

Key: Dara= daratumumab. JNJ-283=JNJ-63723283.

LSFDTH-ST01: Listing of Subjects Who Died During the Study; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Total No. of Dara Infusions/Total Dose (mg/kg) /Study Day of Last Infusion	Total No. of JNJ-283 Infusions/Total Dose (mg)/Study Day of Last Infusion	Date of Death (Study Day)	Primary Cause of Death (If 'AE', Preferred Term)	Relationship to[a]	
							Dara	JNJ-283
[b]Infliximab 5 mg/kg	*XX*	*SSSS-PPPP*	*20/320/270*	*8/1920/270*	*2017-07-21 (xx)*	*AE(Upper respiratory tract infection)*	*NR*	*NR*

Key: Dara=daratumumab. JNJ-283=JNJ-63723283
[a]: NR = Not Related. DO = Doubtful, Poss. = Possible, Prob. = Probable, VL = Very Likely.
Note: Adverse events are coded using MedDRA version XX.X.

Display Specifications	
Output Identifier	LSFDTH01
Programming Notes: 1. Sort listing based on treatment group (Safety run-in, Arm A, Arm B), site ID, subject ID.	

TSFLAB-ST07: Shift Table of Baseline versus Worst Toxicity Grade during Treatment in Hematological Test; Safety Analysis Set (Study 54767414MMY2036)

		Treatment Group and Evaluation at baseline				
	N	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Analysis set: Safety	###					
WBC low (Leukopenia)						
Post-baseline	###					
Grade 0		##	##	##	##	##
Grade 1		##	##	##	##	##
Grade 2		##	##	##	##	##
Grade 3		##	##	##	##	##
Grade 4		##	##	##	##	##

Etc.

Note: N is the number of subjects with non-missing values for the specific lab test at baseline and at least one postbaseline visit during treatment. The laboratory toxicity grades are derived based on the NCI CTCAE (National Cancer Institute Common Terminology Criteria for Adverse Events) Version 4.03.

Display Specifications	
Output Identifier	TSFLAB01
Programming Notes: 1. Parameters: Platelets low (Thrombocytopenia), Neutrophils low (Neutropenia), Hemoglobin low (Anemia), and Lymphocytes low (Lymphocytopenia)	

Display Specifications	
Output Identifier	TSFLAB02
Programming Notes: 1. Update 'Hematology' in the title to 'Chemistry' 2. List for parameters: ALT high, AST high, Creatinine high, Sodium high (Hypernatremia), Sodium low (Hyponatremia), Potassium high (Hyperkalemia), Potassium low (Hypokalemia), Bilirubin high (hyperbilirubinemia), Alkaline phosphatase high, Corrected calcium high (Hypercalcemia), Corrected calcium low (Hypocalcemia), amylase high (hyperamylasemia), total lipase high (hyperlipasemia)	

LSFLAB-ST01: Listing of Hematology Laboratory Values; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Parameter (Unit)	Visit	Assessment Date (Study Day)	Result	Normal Range
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	*xx*	*xx-xx*

Display Specifications	
Output Identifier	LSFLAB01
Programming Notes: 1. Update 'Hematology' in the title to 'Other' 2. List for parameters: **Thyroid Stimulating Hormone; Free triiodothyronine (T3); Total triiodothyronine (T3); Free thyroxine (T4)** 3. Unscheduled results or multiple results taken at the same visit will be reported here. 4. The standard sort order is Treatment Group, Site ID, Subject ID, Parameter, and Assessment Date.	

Display Specifications	
Output Identifier	LSFVS01
Programming Notes: 1. Update 'Hematology' in the title to 'Vital Signs' 2. List for parameters: **Diastolic blood pressure (mmHg), Systolic blood pressure (mmHg) and weight (kg)** 3. Unscheduled results or multiple results taken at the same visit will be reported here. 4. The standard sort order is Treatment Group, Site ID, Subject ID, Parameter, and Assessment Date. 5. Remove the 'Normal Range' column.	

LSFECG-ST01: Listing of ECG Results; Safety Analysis Set (Study 54767414MMY2036)

Treatment Group	Site ID	Subject ID	Visit	Assessment Date (Study Day)	Oerall Interpretation	If 'Abnormal', Clinically Significant? (Y/N)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Display Specifications	
Output Identifier	LSFECG01

Programming Notes:

1. Unscheduled results or multiple results taken at the same visit will be reported here.
2. The standard sort order is Treatment Group, Site ID, Subject ID, Parameter, and Assessment Date.

TPK-ST07: Summary of Daratumumab Concentrations (ug/mL); Pharmacokinetic-evaluable Analysis Set (Study 54767414MMY2036)

Analysis set: pharmacokinetic-evaluable analysis set	##	##	##	##
Cycle 1 Day 1				
N	###	###	###	###
Mean (SD)	x.xx (x.xxx)	x.xx (x.xxx)	x.xx (x.xxx)	x.xx (x.xxx)
Median	xxx.x	xxx.x	xxx.x	xxx.x
Range	(xxx.x, xxx.x)	(xxx.x, xxx.x)	(xxx.x, xxx.x)	(xxx.x, xxx.x)
CV (%)	xxx	xxx	xxx	xxx
Geometric mean	x.xx	x.xx	x.xx	x.xx
Cycle 2 Day 1				
N	###	###	###	###
Mean (SD)	x.xx (x.xxx)	x.xx (x.xxx)	x.xx (x.xxx)	x.xx (x.xxx)
Median	xxx.x	xxx.x	xxx.x	xxx.x
Range	(xxx.x, xxx.x)	(xxx.x, xxx.x)	(xxx.x, xxx.x)	(xxx.x, xxx.x)
CV (%)	xxx	xxx	xxx	xxx
Geometric mean	x.xx	x.xx	x.xx	x.xx
Cycle 3 Day 1				
N	###	###	###	###
Mean (SD)	x.xx (x.xxx)	x.xx (x.xxx)	x.xx (x.xxx)	x.xx (x.xxx)
Median	xxx.x	xxx.x	xxx.x	xxx.x
Range	(xxx.x, xxx.x)	(xxx.x, xxx.x)	(xxx.x, xxx.x)	(xxx.x, xxx.x)
CV (%)	xxx	xxx	xxx	xxx
Geometric mean	x.xx	x.xx	x.xx	x.xx
…				

Key: SD = standard deviation, CV = coefficient of variation.
Note: Table includes subjects who received at least 1 administration of daratumumab and have at least 1 pharmacokinetic sample concentration value after the first infusion.
Note: Predose samples with a time of collection prior to the start of infusion for Cycle 1 Day 1, and up to 6 hours prior to the start of infusion for other predose samples will be included from summary statistics. Postdose samples with a time of collection before the end of infusion or more than 15 min after the end of infusion will be excluded from summary statistics.

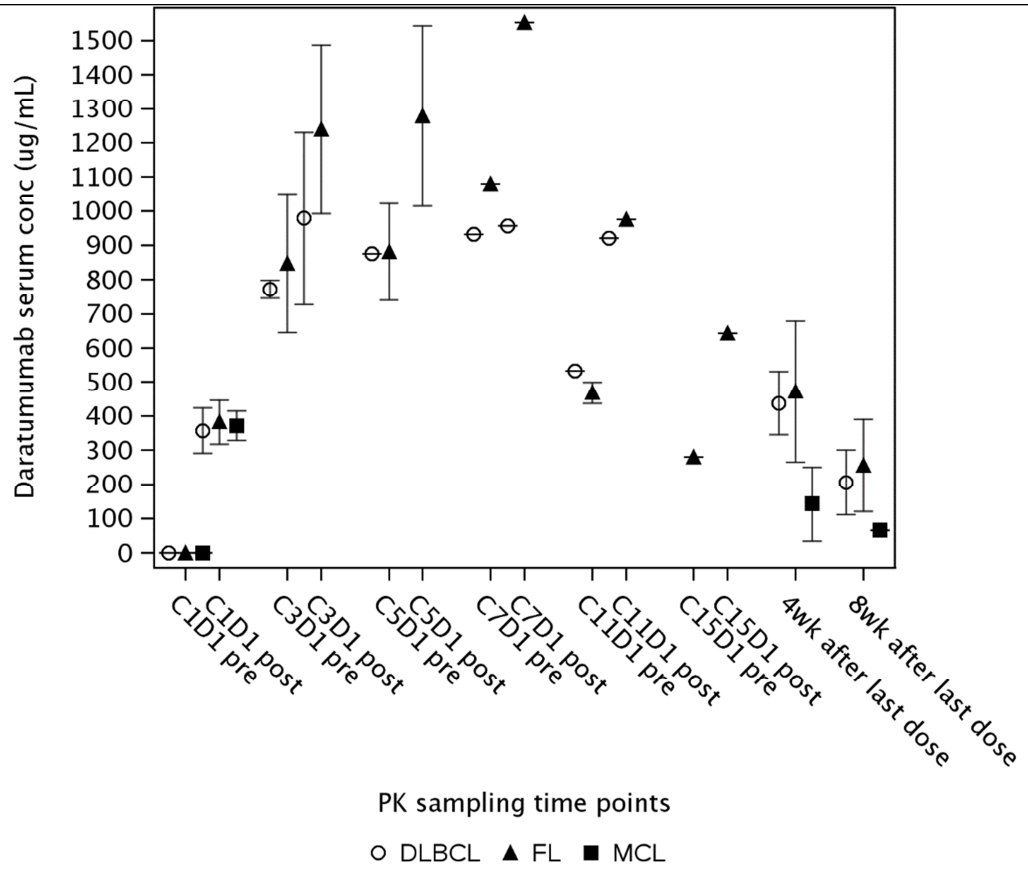
Display Specifications	
Output Identifier	TPKCONC01
Programming notes: 1. Present all available visits. 2. For visits of '4 weeks after last dose' and '8 weeks after last dose', data are displayed in the postinfusion column.	

Display Specifications	
Output Identifier	TPKCONC02

Programming notes:

1. Change ‘Daratumumab’ in the title to ‘JNJ-63723283’.
2. Present all available visits.
3. For visits of ‘4 weeks after last dose’ and ‘8 weeks after last dose’, data are displayed in the postinfusion column.

GPK-ST05: Mean and Standard Deviation of Daratumumab Serum Peak and Trough Concentrations (ug/mL); Pharmacokinetic-evaluable Analysis Set (Study 54767414MMY2036)



Note: At each time point, concentration values are plotted on linear scale, and the error bars are mean +/- standard deviation.
Note: Predose samples with a time of collection before the start of infusion for Cycle 1 Day 1, and up to 6 hours prior to the start of infusion for other predose samples will be included from summary statistics. Postdose samples with a time of collection before the end of infusion or more than 15 min after the end of infusion will be excluded from summary statistics.

Display Specifications	
Output Identifier	GPKCONC01
Programming Notes: 1. Present all available visits in x-axis. 2.	

Display Specifications	
Output Identifier	GPKCONC02
Programming Notes: 1. Change 'Daratumumab' in the title to 'JNJ-63723283' 2. Present all available visits in x-axis.	

TPKIR-ST01: Summary of Anti-daratumumab Antibodies Status; Immunogenicity Analysis Set (Study 54767414MMY2036)

Analysis set: immunogenicity	###	###	###
Subjects with appropriate samples[a]	###	###	###
Subjects with baseline positive samples[b,c]	### (xx.x%)	### (xx.x%)	### (xx.x%)
Subjects positive for anti-daratumumab antibodies[b,d]	### (xx.x%)	### (xx.x%)	### (xx.x%)
Peak titer			
1:20	###	###	###
Subjects positive for neutralizing antibodies	### (xx.x%)	### (xx.x%)	### (xx.x%)
Subjects negative for anti-daratumumab antibodies[b,e]	### (xx.x%)	### (xx.x%)	### (xx.x%)

[a] Subjects with appropriate samples had 1 or more samples obtained after their first daratumumab administration.
[b] Denominator is subjects with appropriate samples.
[c] Subjects with baseline samples positive had samples positive for anti-daratumumab antibodies at baseline, regardless of status after first daratumumab administration.
[d] Subjects positive for anti-daratumumab antibodies includes all subjects who were positive (treatment-boosted or treatment-induced) at any time after their first daratumumab administration. Subjects with baseline positive samples and without increased titer after treatment are not considered treatment-boosted.
[e] Excludes subjects who were positive at any time.

Display Specifications	
Output Identifier	TPKIR01
Programming notes: 1. Please remove row of "Peak titer" if there is no subject positive for antibodies to daratumumab. 2. Please remove 'd' if there are no subject positive for antibody to daratumumab, and change the label 'e' to 'd'.	

Display Specifications	
Output Identifier	TPKIR02
Programming notes: 1. Change 'Daratumumab' to 'JNJ-63723283' in the whole table. 2. Please remove row of "Peak titer" if there is no subject positive for antibodies to JNJ-63723283. 3. Please remove 'd' if there are no subject positive for antibody to JNJ-63723283, and change the label 'e' to 'd'.	

LPKIR-ST01: List of Subjects Positive for Anti-daratumumab Antibodies Status; Immune Response-evaluable Analysis Set (Study 54767414MMY2036)

Treatment Group	Subject ID	Visit/Time Point	Infusion Given?	Infusion Related Reaction	Serious	Toxicity Grade	Daratumumab Conc. (µg/mL)	Antibody to Daratumumab Titer
Safety run-in	######	CYCLE 1 DAY 1/PREDOSE	Yes	Yes	No	1	LLOQ	NEGTIVE
		CYCLE 2 DAY 1/PREDOSE	No	NA			443.7	1:20

Key: NA= not applicable.

Display Specifications	
Output Identifier	LPKCONC01

Programming Notes:

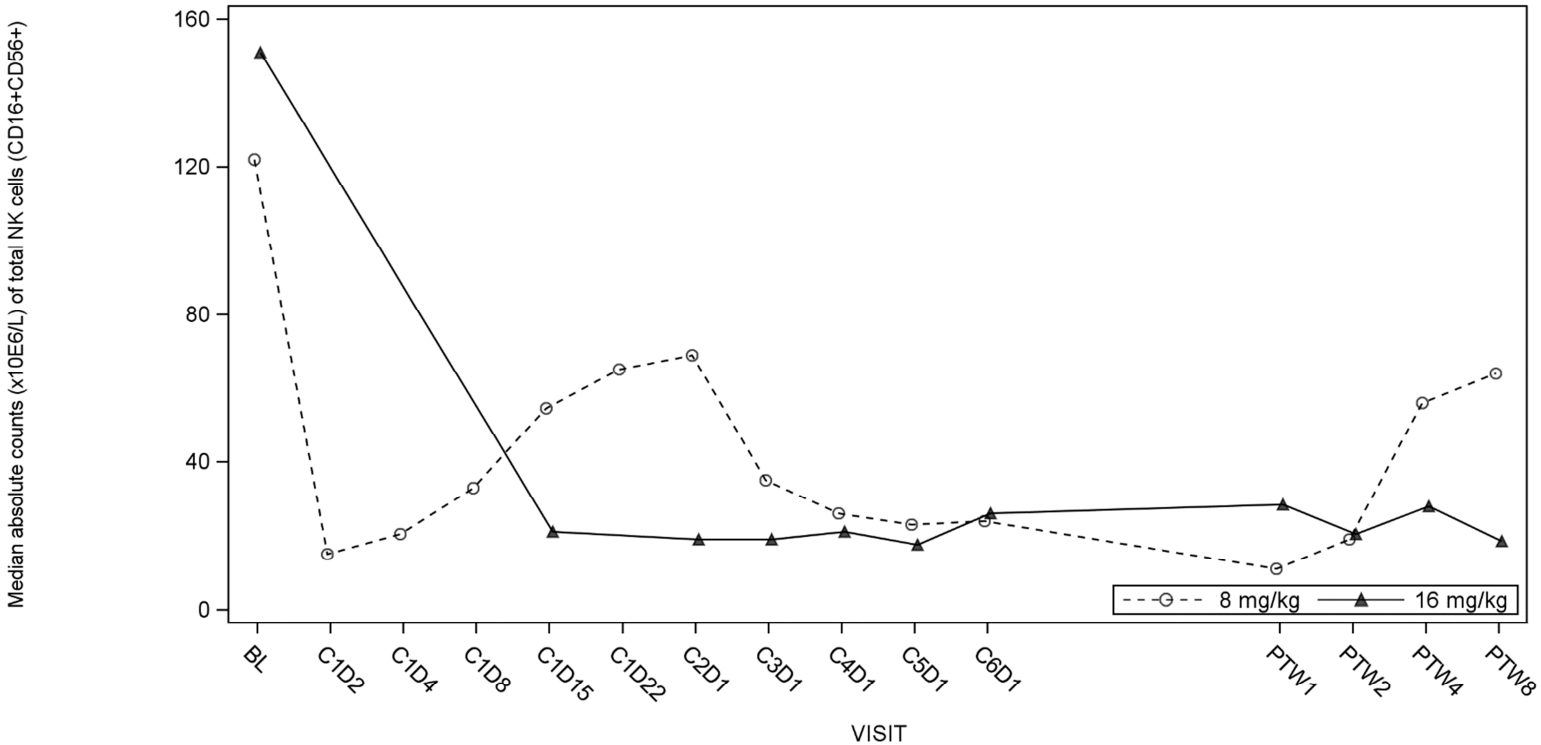
1. Listing sort: Treatment Group, Subject ID, and Visit.
2. This listing should include all visits where PK sampling was performed for subjects positive for ADA. The titer column will either present the actual titer value (which means they were positive), will be 'NEGATIVE' if there is no titer value (which means they were negative at that visit), or will be "NA" if there was no titer sample at that visit.

Display Specifications	
Output Identifier	LPKCONC02

Programming Notes:

1. Change the 'daratumumab' to 'JNJ-63723283' in the listing.
2. Listing sort: Treatment Group, Subject ID, and Visit.
3. This listing should include all visits where PK sampling was performed for subjects positive for ADA. The titer column will either present the actual titer value (which means they were positive), will be 'NEGATIVE' if there is no titer value (which means they were negative at that visit), or will be "NA" if there was no titer sample at that visit.

GBMK01: Plot of Percent of Total Natural Killer Cells in Blood Over Time; Safety Analysis Set (Study 54767414MMY2036)



Number of Subjects															
8 mg/kg	17	17	14	16	16	13	15	10	9	4	4	3	5	9	7
16 mg/kg	103				100		95	80	59	44	40	28	42	37	6

Programming note:

1. *Display the treatment groups as 'Safety Run-in' or 'Arm A',*
2. *Display the scheduled visits for this study.*
3. *Update the y-lab as appropriate.*

TBMK01: Summary of Percent of Total Natural Killer Cells in Blood Over Time; Safety Analysis Set (Study 54767414MMY2036)

								Change from Baseline					
	N	Mean	SD	Med	Min	Max	Base Mean	N	Mean	SD	Med	Min	Max
Percent of total natural killer cells (%)													
Safety Run-in													
Baseline	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x	xxx.xx						
Cycle 1 Day 8	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x	xxx.xx	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x
Cycle 1 Day 15	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x	xxx.xx	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x
…	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x	xxx.xx	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x
Arm A													
Baseline	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x	xxx.xx						
Cycle 1 Day 8	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x	xxx.xx	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x
Cycle 1 Day 15	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x	xxx.xx	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x
…	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x	xxx.xx	xxx	xxx.xx	xxx.xxx	xxx.xx	xx.x	xxx.x

Programming note:

1. *Display the scheduled visits for this study.*
2. *Update the biomarker name in the title as appropriate.*
3. *Update the biomarker name in the first row of the table and unit as appropriate.*

5. NARRATIVE CRITERION

- Deaths within 30 days of last dose of study treatment
- Discontinuations of study treatment due to treatment-emergent AEs
- Treatment-emergent serious AEs
- Adverse events of clinical interest
  - Infusion-related reaction, Grade 3 or higher
  - Treatment-emergent Immune-related AE, Grade 3 or higher
  - Treatment-emergent infections/infestations, SAE or Grade 3 or higher
  - Treatment-emergent hemorrhage events, SAE or Grade 3 or higher
  - Treatment-emergent tumor lysis syndrome, SAE or Grade 3 or higher
  - New Malignancies
  - Treatment-emergent anaphylaxis or suspected anaphylaxis
- Treatment-emergent for subject who require the DIRA test result to confirm CR/sCR or treatment-emergent for subject who has earlier date of CR/sCR due to DIRA
- Treatment-emergent intravascular hemolysis
- Treatment-emergent interference with cross-matching and red blood cell antibody screening

6. PROGRAMMING CODE FOR STATISTICAL PROCEDURES (IF REQUIRED)

7. LIST OF POST HOC OUTPUT (IF REQUIRED)

IDENTIFIER	OUTPUT TITLE	ANALYSIS SET	TO DO	REFERENCE LAYOUT

8. ADDITIONAL ANALYSIS/DEVIATION RULES

Please see DPS_ part 2.

REFERENCES

1. Durie BG, Harousseau JL, Miguel JS, et al. International uniform response criteria for multiple myeloma. Leukemia. 2006;20(9):1467-1473.

2. Kumar S, Paiva B, Anderson KC et al. International Myeloma Working Group consensus criteria for response and minimal residual disease assessment in multiple myeloma. Lancet Oncol. 2016;17(8):e328-46

3. Rajkumar SV, Harousseau JL, Durie B, et al. Consensus recommendations for the uniform reporting of clinical trials: report of the International Myeloma Workshop Consensus Panel 1. Blood. 2011;117(18):4691-4695