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A Study to Compare CNTO 328 (Anti-IL-6 Monoclonal Antibody) and VELCADE-Melphalan-Prednisone (VMP) With VMP Alone in Previously Untreated Multiple Myeloma Patients

This study has been completed.

Sponsor:
Janssen Research & Development, LLC

Information provided by (Responsible Party):
Janssen Research & Development, LLC

ClinicalTrials.gov Identifier:
NCT00911859

First received: May 29, 2009
Last updated: November 17, 2014
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History of Changes

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Results First Received: September 11, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Multiple Myeloma
Interventions:	Drug: Siltuximab11 mg/kg Drug: Siltuximab 8.3 mg/kg or 11 mg/kg Drug: Velcade (bortezomib)

	Drug: Melphalan Drug: Prednisone

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
The study was conducted at 40 centers in 12 countries: Australia; France; India; Israel; Italy; Poland; Romania; Russian Federation; Singapore; South Korea; Spain; and the United States.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
In Part 2, 105 participants received treatment (VMP: 53 and VMP+Siltuximab: 52). In the VMP+Siltuximab arm, 21 participants who achieved partial response or better entered the maintenance period and received only Siltuximab for 18 months, or until disease progression, unacceptable toxicity, or withdrawal from treatment, whichever occurred first.

Reporting Groups

	Description
Part 1: VMP + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Participant Flow for 3 periods

Period 1: Treatment Period

	Part 1: VMP + Siltuximab	Part 2: VMP	Part 2: VMP + Siltuximab
STARTED	12	54	52
Received Treatment	12	53	52
COMPLETED	4	33	27
NOT COMPLETED	8	21	25
Adverse Event	3	3	7
Death	1	3	5
Lack of Efficacy	1	7	5
Physician Decision	3	3	3
Withdrawal by Subject	0	4	5
Did not receive study treatment	0	1	0

Period 2: Maintainance Period

	Part 1: VMP + Siltuximab	Part 2: VMP	Part 2: VMP + Siltuximab
STARTED	0	0	21 [1]
COMPLETED	0	0	0
NOT COMPLETED	0	0	21
Lack of Efficacy	0	0	9
Physician Decision	0	0	9
Withdrawal by Subject	0	0	3

[1] Participants who received siltuximab only during the 18-month maintenance period

Period 3: Follow-up Period

	Part 1: VMP + Siltuximab	Part 2: VMP	Part 2: VMP + Siltuximab
STARTED	12 [1]	53 [1]	52 [1]
COMPLETED	1	7	11
NOT COMPLETED	11	46	41
Death	5	8	10
Lost to Follow-up	1	1	0
Withdrawal by Subject	0	4	4
Study terminated by sponsor	5	33	27

[1] Participants followed until death or 3.5 years after the last participant was assigned to treatment

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Part 1: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Total	Total of all reporting groups

Baseline Measures

	Part 1: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Part 2: VMP (Velcade+Melphalan+Prednisone)	Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Total
Number of Participants [units: participants]	**12**	**54**	**52**	**118**
Age [units: years] Mean (Standard Deviation)	**73.6 (6.3)**	**70.3 (7.27)**	**71.6 (4.76)**	**71.2 (6.21)**
Gender [units: participants]				
Female	**7**	**30**	**29**	**66**
Male	**5**	**24**	**23**	**52**
Region of Enrollment [units: participants]				
AUSTRALIA	**0**	**2**	**2**	**4**
FRANCE	**0**	**5**	**2**	**7**

INDIA	**0**	**3**	**1**	**4**
ISRAEL	**0**	**7**	**5**	**12**
ITALY	**0**	**2**	**2**	**4**
POLAND	**0**	**5**	**11**	**16**
ROMANIA	**0**	**2**	**0**	**2**
RUSSIAN FEDERATION	**0**	**10**	**10**	**20**
SINGAPORE	**0**	**3**	**2**	**5**
SOUTH KOREA	**0**	**7**	**8**	**15**
SPAIN	**12**	**5**	**7**	**24**
UNITED STATES	**0**	**3**	**2**	**5**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Who Achieved Complete Response (CR) - European Group for Blood and Marrow Transplantation (EBMT) Criteria [Time Frame: Up to disease progression, approximately 3 years]

Measure Type	Primary
Measure Title	Percentage of Participants Who Achieved Complete Response (CR) - European Group for Blood and Marrow Transplantation (EBMT) Criteria
Measure Description	CR was assessed using EMBT criteria: disappearance of the original monoclonal paraprotein from the blood and urine on at least 2 determinations for a minimum of 6 weeks by immunofixation studies, <5% plasma cells in the bone marrow on at least 1 determination, if skeletal survey is available: no increase in the size or number of lytic bone lesions (development of a compression fracture does not exclude response), disappearance of soft tissue plasmacytomas for at least 6 weeks.

Time Frame	Up to disease progression, approximately 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Response-evaluable population: Participants who had a confirmed diagnosis of multiple myeloma and measurable disease according to the EBMT criteria were evaluated for disease response. Also, participants must have received at least 1 administration of study medication and have at least 1 post-baseline disease assessment.

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	**Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab**
Number of Participants Analyzed [units: participants]	**49**	**49**
Percentage of Participants Who Achieved Complete Response (CR) - European Group for Blood and Marrow Transplantation (EBMT) Criteria [units: Percentage of participants]	**22.4**	**26.5**

No statistical analysis provided for Percentage of Participants Who Achieved Complete Response (CR) - European Group for Blood and Marrow Transplantation (EBMT) Criteria

2. Secondary: Percentage of Participants Who Achieved Overall Response ie, Complete Response (CR) or Partial Response (PR) - European Group for Blood and Marrow Transplantation (EBMT) Criteria [Time Frame: Up to disease progression, approximately 3 years]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved Overall Response ie, Complete Response (CR) or Partial Response (PR) - European Group for Blood and Marrow Transplantation (EBMT) Criteria
Measure Description	CR or PR was assessed using EBMT criteria. CR: disappearance of the original monoclonal paraprotein from the blood and urine on at least 2 determinations for a minimum of 6 weeks by immunofixation studies, <5% plasma cells in the bone marrow on at least 1 determination, if skeletal survey is available: no increase in the size or number of lytic bone lesions (development of a compression fracture does not exclude response), disappearance of soft tissue plasmacytomas for at least 6 weeks; PR: >=50% reduction in the level of serum monoclonal paraprotein for at least 2 determinations 6 weeks apart, if present, reduction in 24-hour urinary light chain excretion by either >=90% or to <200 mg for at least 2 determinations 6 weeks apart, >=50% reduction in the size of soft tissue plasmacytomas (by clinical or radiographic examination) for at least 6 weeks, if skeletal survey is available: no increase in size or number of lytic bone lesions
Time Frame	Up to disease progression, approximately 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Response-evaluable population: Participants who had a confirmed diagnosis of multiple myeloma and measurable disease according to the EBMT criteria were evaluated for disease response. Also, participants must have received at least 1 administration of study medication and have at least 1 post-baseline disease assessment.

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab
Number of Participants Analyzed [units: participants]	**49**	**49**
Percentage of Participants Who Achieved Overall Response ie, Complete Response (CR) or Partial Response (PR) - European Group for Blood and Marrow Transplantation (EBMT) Criteria [units: Percentage of participants]	**79.6**	**87.8**

No statistical analysis provided for Percentage of Participants Who Achieved Overall Response ie, Complete Response (CR) or Partial Response (PR) - European Group for Blood and Marrow Transplantation (EBMT) Criteria

3. Secondary: Percentage of Participants Who Achieved Stringent Complete Response (sCR) - International Myeloma Working Group (IMWG) Criteria [Time Frame: Up to disease progression, approximately 3 years]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved Stringent Complete Response (sCR) - International Myeloma Working Group (IMWG) Criteria

Measure Description	sCR was assesses by IMWG Criteria: Negative immunofixation on the serum and urine, disappearance of any soft tissue plasmacytomas, <=5% plasma cells in bone marrow, normal free light chain ratio, absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence. sCR is a CR that has been confirmed by immunofixation + free light chain assay + either bone marrow immunohistochemistry or immunofluorescence
Time Frame	Up to disease progression, approximately 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Response-evaluable population: Participants who had a confirmed diagnosis of multiple myeloma and measurable disease according to the EBMT criteria were evaluated for disease response. Also, participants must have received at least 1 administration of study medication and have at least 1 post-baseline disease assessment.

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	**Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab**
Number of Participants Analyzed [units: participants]	**49**	**49**

Percentage of Participants Who Achieved Stringent Complete Response (sCR) - International Myeloma Working Group (IMWG) Criteria [units: Percentage of participants]	**6.1**	**4.1**

No statistical analysis provided for Percentage of Participants Who Achieved Stringent Complete Response (sCR) - International Myeloma Working Group (IMWG) Criteria

4. Secondary: Progression-Free Survival (PFS) [Time Frame: From the date of randomization until disease progression or death, whichever occurred first, as assessed up to the last efficacy assessment for disease progression (approximately 3 years)]

Measure Type	Secondary
Measure Title	Progression-Free Survival (PFS)
Measure Description	PFS was defined as the time between randomization and either disease progression or death, whichever occurred first.
Time Frame	From the date of randomization until disease progression or death, whichever occurred first, as assessed up to the last efficacy assessment for disease progression (approximately 3 years)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: all randomized participants.

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with

	VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab
Number of Participants Analyzed **[units: participants]**	**54**	**52**
Progression-Free Survival (PFS) **[units: Days]** **Median (95% Confidence Interval)**	**518** **(460 to 582)**	**519** **(443 to 673)**

No statistical analysis provided for Progression-Free Survival (PFS)

5. Secondary: 1-year Progression-Free Survival (PFS) Rate [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	1-year Progression-Free Survival (PFS) Rate
Measure Description	The 1-year PFS rate was defined as the percentage of participants surviving 1 year after randomization without disease progression or death.
Time Frame	1 year
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: all randomized participants

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	**Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab**
Number of Participants Analyzed [units: participants]	**54**	**52**
1-year Progression-Free Survival (PFS) Rate [units: Percentage of participants]	**77.5**	**72.1**

No statistical analysis provided for 1-year Progression-Free Survival (PFS) Rate

6. Secondary: Duration of Response (DOR) [Time Frame: From the date participants achieved CR or PR to either date for disease progression (including relapse from CR) or the censoring date for progressive disease, as assessed Up to 30 days after last dose of study medication]

Measure Type	Secondary

Measure Title	Duration of Response (DOR)
Measure Description	DOR was defined as length from the earliest date a participant achieved a complete response (CR) or partial response (PR) to either date for disease progression (including relapse from CR) or the censoring date for progressive disease. Responders without disease progression were censored at the last efficacy assessment for disease progression.
Time Frame	From the date participants achieved CR or PR to either date for disease progression (including relapse from CR) or the censoring date for progressive disease, as assessed Up to 30 days after last dose of study medication
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Included participants in the randomized population who achieved CR or PR.

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	**Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab**
Number of Participants Analyzed [units: participants]	**39**	**43**

Duration of Response (DOR) [units: Days] Median (95% Confidence Interval)	**497 (457 to 637)**	**583 (449 to N/A) [1]**

[1] Insufficient number of participants with events; therefore, upper limit of 95% CI not reached.

No statistical analysis provided for Duration of Response (DOR)

7. Secondary: 1-year Survival Rate [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	1-year Survival Rate
Measure Description	Percentage of participants who are alive at the end of year 1 after randomization
Time Frame	1 year
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: all randomized participants

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus

	injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab
Number of Participants Analyzed [units: participants]	**54**	**52**
1-year Survival Rate [units: Percentage of participants]	**87.8**	**87.5**

No statistical analysis provided for 1-year Survival Rate

8. Secondary: Overall Survival [Time Frame: From the date of randomization till the date of death, as assessed up to the end of study (approximately 3 years)]

Measure Type	Secondary
Measure Title	Overall Survival
Measure Description	Overall survival is defined as the time interval in days between the date of randomization and the participant's death from any cause.
Time Frame	From the date of randomization till the date of death, as assessed up to the end of study (approximately 3 years)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Intent-to-treat (ITT) population: all randomized participants.

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab
Number of Participants Analyzed **[units: participants]**	**54**	**52**
Overall Survival **[units: Days]** **Median (95% Confidence Interval)**	**NA** **[1]**	**NA** **(783 to N/A)** **[2]**

[1] Insufficient number of participants with events; therefore, median and 95% CI not reached.
[2] Insufficient number of participants with events; therefore, median and upper limit of 95% CI not reached.

No statistical analysis provided for Overall Survival

9. Secondary: Change From Baseline to Cycle 9 in Global Health Status/Quality of Life Subscale of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C30) [Time Frame: Baseline (Day 1 predose) and Cycle 9 (Week 54)]

Measure Type	Secondary
Measure Title	Change From Baseline to Cycle 9 in Global Health Status/Quality of Life Subscale of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C30)
Measure Description	Global health status/quality of life is a subscale of the EORTC QOL C30, which comprises two questions related to overall health/quality of life during the past week. The raw score to each question ranged from 1 (very poor) to 7 (excellent). The raw mean score of health status/quality of life subscale is calculated for each participant and a linear transformation applied to standardize the raw score, so that scores range from 0 to 100; a higher score represents a higher ("better") health and quality of life.
Time Frame	Baseline (Day 1 predose) and Cycle 9 (Week 54)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: all randomized participants with evaluable data during baseline and Cycle 9

Reporting Groups

	Description
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.

Measured Values

	Part 2: VMP (Velcade+Melphalan+Prednisone)	**Part 2: VMP (Velcade+Melphalan+Prednisone)**

		+ Siltuximab
Number of Participants Analyzed [units: participants]	**31**	**25**
Change From Baseline to Cycle 9 in Global Health Status/Quality of Life Subscale of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C30) [units: Scores on a scale] Mean (Standard Deviation)	**14.78 (25.250)**	**8.33 (31.088)**

No statistical analysis provided for Change From Baseline to Cycle 9 in Global Health Status/Quality of Life Subscale of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C30)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 30 days after the last dose of study medication
Additional Description	For Safety analyses all randomized participants who received at least 1 dose of study agents were analyzed. Data are presented for 117 participants in the treatment period (Part 1 and Part 2) and 21 participants who entered maintenance period (after achieving partial response or better in the Part 2 treatment period while receiving VPM+siltuximab)

Reporting Groups

	Description
Part 1: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60

	mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2, Maintenance Period: Siltuximab	Siltuximab 8.3 mg/kg or 11 mg/kg as a 1-hour intravenous infusion every 3 weeks, during the maintenance period

Serious Adverse Events

	Part 1: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Part 2: VMP (Velcade+Melphalan+Prednisone)	Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Part 2, Maintenance Period: Siltuximab
Total, serious adverse events				
# participants affected / at risk	**8/12 (66.67%)**	**27/53 (50.94%)**	**30/52 (57.69%)**	**1/21 (4.76%)**
Blood and lymphatic system disorders				
Anaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Neutropenia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Thrombocytopenia [*1]				

# participants affected / at risk	0/12 (0.00%)	2/53 (3.77%)	2/52 (3.85%)	0/21 (0.00%)
Cardiac disorders				
Atrial Fibrillation [*1]				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Cardiac Arrest [*1]				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Cardiac Failure [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Cardiac Failure Acute [*1]				
# participants affected / at risk	0/12 (0.00%)	0/53 (0.00%)	1/52 (1.92%)	0/21 (0.00%)
Cardio-Respiratory Arrest [*1]				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Myocardial Infarction [*1]				
# participants affected / at risk	0/12 (0.00%)	0/53 (0.00%)	1/52 (1.92%)	0/21 (0.00%)

Endocrine disorders				
Steroid Withdrawal Syndrome [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Gastrointestinal disorders				
Abdominal Pain [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Diarrhoea [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**4/53 (7.55%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Gastritis [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Haemorrhoidal Haemorrhage [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Ileus [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Ileus Paralytic [*1]				

# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	1/52 (1.92%)	0/21 (0.00%)
Rectal Haemorrhage [*1]				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Upper Gastrointestinal Haemorrhage [*1]				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Vomiting [*1]				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
General disorders				
Adverse Drug Reaction [*1]				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Asthenia [*1]				
# participants affected / at risk	0/12 (0.00%)	0/53 (0.00%)	1/52 (1.92%)	0/21 (0.00%)
Pyrexia [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	1/52 (1.92%)	0/21 (0.00%)

Hepatobiliary disorders				
Hepatotoxicity [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Infections and infestations				
Bronchitis [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Bronchopneumonia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**3/53 (5.66%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Gastroenteritis [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Gastroenteritis Escherichia Coli [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
H1n1 Influenza [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**

Hepatitis B [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Lobar Pneumonia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Parotitis [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Pneumonia [*1]				
# participants affected / at risk	**3/12 (25.00%)**	**5/53 (9.43%)**	**7/52 (13.46%)**	**0/21 (0.00%)**
Pneumonia Pneumococcal [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Respiratory Tract Infection [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Septic Shock [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**

Injury, poisoning and procedural complications				
Femur Fracture [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Hip Fracture [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Radius Fracture [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**1/21 (4.76%)**
Spinal Compression Fracture [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Spinal Fracture [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Investigations				
Weight Decreased [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**

Metabolism and nutrition disorders				
Dehydration [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Hypercalcaemia [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Hyperglycaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Hyperkalaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Hyperuricaemia [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Hypoglycaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Hypokalaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**2/52 (3.85%)**	**0/21 (0.00%)**

Hyponatraemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**2/53 (3.77%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Musculoskeletal and connective tissue disorders				
Arthritis [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Back Pain [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**1/53 (1.89%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Bone Lesion [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Pathological Fracture [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Adenocarcinoma Pancreas [*1]				
# participants				

affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Multiple Myeloma * 1				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Myelodysplastic Syndrome * 1				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Rectal Cancer * 1				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Nervous system disorders				
Cerebral Ischaemia * 1				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Cerebrovascular Accident * 1				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Dizziness * 1				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**

Encephalopathy [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Hypoglycaemic Encephalopathy [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Lacunar Infarction [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Metabolic Encephalopathy [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Syncope [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Psychiatric disorders				
Completed Suicide [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**

Depression [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Renal and urinary disorders				
Hydronephrosis [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Renal Failure [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Renal Failure Acute [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Renal Impairment [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**1/53 (1.89%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Urinary Retention [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**2/53 (3.77%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Respiratory, thoracic and mediastinal				

disorders				
Acute Respiratory Failure [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Asthma [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Chronic Obstructive Pulmonary Disease [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Dyspnoea [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Pleural Effusion [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Pulmonary Embolism [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Pulmonary Oedema				

* 1				
# participants affected / at risk	0/12 (0.00%)	0/53 (0.00%)	1/52 (1.92%)	0/21 (0.00%)
Respiratory Failure * 1				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	1/52 (1.92%)	0/21 (0.00%)
Status Asthmaticus * 1				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Skin and subcutaneous tissue disorders				
Leukocytoclastic Vasculitis * 1				
# participants affected / at risk	0/12 (0.00%)	0/53 (0.00%)	1/52 (1.92%)	0/21 (0.00%)
Vascular disorders				
Hypotension * 1				
# participants affected / at risk	0/12 (0.00%)	2/53 (3.77%)	0/52 (0.00%)	0/21 (0.00%)
Hypovolaemic Shock * 1				
# participants				

affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 15.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 30 days after the last dose of study medication
Additional Description	For Safety analyses all randomized participants who received at least 1 dose of study agents were analyzed. Data are presented for 117 participants in the treatment period (Part 1 and Part 2) and 21 participants who entered maintenance period (after achieving partial response or better in the Part 2 treatment period while receiving VPM+siltuximab)

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Part 1: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone)	Velcade 1.3 mg/m2 was administered as an intravenous bolus injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Siltuximab 11 mg/kg as a 1-hour intravenous infusion every 3 weeks along with VMP. VMP: Velcade 1.3 mg/m2 was administered as an intravenous bolus

	injection according to the current approved package inserts. Melphalan 9 mg/m2 and prednisone 60 mg/m2 were taken orally.
Part 2, Maintenance Period: Siltuximab	Siltuximab 8.3 mg/kg or 11 mg/kg as a 1-hour intravenous infusion every 3 weeks, during the maintenance period

Other Adverse Events

	Part 1: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Part 2: VMP (Velcade+Melphalan+Prednisone)	Part 2: VMP (Velcade+Melphalan+Prednisone) + Siltuximab	Part 2, Maintenance Period: Siltuximab
Total, other (not including serious) adverse events				
# participants affected / at risk	**12/12 (100.00%)**	**51/53 (96.23%)**	**51/52 (98.08%)**	**15/21 (71.43%)**
Blood and lymphatic system disorders				
Anaemia [*1]				
# participants affected / at risk	**5/12 (41.67%)**	**19/53 (35.85%)**	**12/52 (23.08%)**	**2/21 (9.52%)**
Leukopenia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**5/53 (9.43%)**	**6/52 (11.54%)**	**0/21 (0.00%)**
Lymphopenia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**3/53 (5.66%)**	**4/52 (7.69%)**	**0/21 (0.00%)**
Neutropenia [*1]				
# participants affected / at risk	**11/12 (91.67%)**	**25/53 (47.17%)**	**34/52 (65.38%)**	**3/21 (14.29%)**

Thrombocytopenia [*1]				
# participants affected / at risk	**8/12 (66.67%)**	**21/53 (39.62%)**	**30/52 (57.69%)**	**5/21 (23.81%)**
Cardiac disorders				
Atrial Fibrillation [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**2/53 (3.77%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Eye disorders				
Conjunctivitis [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**2/53 (3.77%)**	**4/52 (7.69%)**	**0/21 (0.00%)**
Dry Eye [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**4/53 (7.55%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Gastrointestinal disorders				
Abdominal Discomfort [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**3/53 (5.66%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Abdominal Distension [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**2/53 (3.77%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Abdominal Pain [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**6/53 (11.32%)**	**4/52 (7.69%)**	**0/21 (0.00%)**
Abdominal Pain Upper				

* 1				
# participants affected / at risk	0/12 (0.00%)	4/53 (7.55%)	4/52 (7.69%)	0/21 (0.00%)
Constipation * 1				
# participants affected / at risk	8/12 (66.67%)	16/53 (30.19%)	18/52 (34.62%)	2/21 (9.52%)
Diarrhoea * 1				
# participants affected / at risk	7/12 (58.33%)	21/53 (39.62%)	18/52 (34.62%)	2/21 (9.52%)
Dry Mouth * 1				
# participants affected / at risk	0/12 (0.00%)	0/53 (0.00%)	4/52 (7.69%)	0/21 (0.00%)
Dyspepsia * 1				
# participants affected / at risk	0/12 (0.00%)	6/53 (11.32%)	3/52 (5.77%)	1/21 (4.76%)
Gastritis * 1				
# participants affected / at risk	0/12 (0.00%)	3/53 (5.66%)	1/52 (1.92%)	1/21 (4.76%)
Haemorrhoids * 1				
# participants affected / at risk	1/12 (8.33%)	2/53 (3.77%)	4/52 (7.69%)	0/21 (0.00%)
Mouth Ulceration * 1				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	2/52 (3.85%)	0/21 (0.00%)
Nausea * 1				
# participants affected / at risk	4/12 (33.33%)	21/53 (39.62%)	16/52 (30.77%)	0/21 (0.00%)
Stomatitis * 1				

# participants affected / at risk	1/12 (8.33%)	2/53 (3.77%)	1/52 (1.92%)	0/21 (0.00%)
Vomiting [*1]				
# participants affected / at risk	2/12 (16.67%)	15/53 (28.30%)	12/52 (23.08%)	1/21 (4.76%)
General disorders				
Asthenia [*1]				
# participants affected / at risk	10/12 (83.33%)	18/53 (33.96%)	10/52 (19.23%)	0/21 (0.00%)
Chest Pain [*1]				
# participants affected / at risk	0/12 (0.00%)	5/53 (9.43%)	6/52 (11.54%)	1/21 (4.76%)
Chills [*1]				
# participants affected / at risk	1/12 (8.33%)	3/53 (5.66%)	3/52 (5.77%)	0/21 (0.00%)
Fatigue [*1]				
# participants affected / at risk	0/12 (0.00%)	8/53 (15.09%)	12/52 (23.08%)	2/21 (9.52%)
Malaise [*1]				
# participants affected / at risk	1/12 (8.33%)	3/53 (5.66%)	0/52 (0.00%)	0/21 (0.00%)
Mucosal Discolouration [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Oedema [*1]				
# participants affected / at risk	2/12 (16.67%)	4/53 (7.55%)	0/52 (0.00%)	0/21 (0.00%)
Oedema Peripheral [*1]				

# participants affected / at risk	3/12 (25.00%)	4/53 (7.55%)	16/52 (30.77%)	0/21 (0.00%)
Pain * 1				
# participants affected / at risk	0/12 (0.00%)	2/53 (3.77%)	3/52 (5.77%)	1/21 (4.76%)
Pyrexia * 1				
# participants affected / at risk	1/12 (8.33%)	15/53 (28.30%)	9/52 (17.31%)	0/21 (0.00%)
Spinal Pain * 1				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Hepatobiliary disorders				
Hepatic Function Abnormal * 1				
# participants affected / at risk	1/12 (8.33%)	2/53 (3.77%)	6/52 (11.54%)	0/21 (0.00%)
Hepatotoxicity * 1				
# participants affected / at risk	1/12 (8.33%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Jaundice * 1				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Infections and infestations				
Bronchitis * 1				
# participants affected / at risk	0/12 (0.00%)	5/53 (9.43%)	6/52 (11.54%)	0/21 (0.00%)
H1n1 Influenza * 1				

# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Hordeolum [*1]				
# participants affected / at risk	1/12 (8.33%)	3/53 (5.66%)	0/52 (0.00%)	0/21 (0.00%)
Nasopharyngitis [*1]				
# participants affected / at risk	3/12 (25.00%)	5/53 (9.43%)	4/52 (7.69%)	2/21 (9.52%)
Nipple Infection [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Onychomycosis [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Oral Candidiasis [*1]				
# participants affected / at risk	3/12 (25.00%)	3/53 (5.66%)	0/52 (0.00%)	0/21 (0.00%)
Pharyngitis [*1]				
# participants affected / at risk	1/12 (8.33%)	1/53 (1.89%)	0/52 (0.00%)	0/21 (0.00%)
Respiratory Tract Infection [*1]				
# participants affected / at risk	2/12 (16.67%)	1/53 (1.89%)	3/52 (5.77%)	0/21 (0.00%)
Respiratory Tract Infection Viral [*1]				
# participants affected / at risk	0/12 (0.00%)	3/53 (5.66%)	0/52 (0.00%)	0/21 (0.00%)
Sinusitis [*1]				

# participants affected / at risk	0/12 (0.00%)	0/53 (0.00%)	3/52 (5.77%)	0/21 (0.00%)
Upper Respiratory Tract Infection [*1]				
# participants affected / at risk	3/12 (25.00%)	6/53 (11.32%)	5/52 (9.62%)	2/21 (9.52%)
Urinary Tract Infection [*1]				
# participants affected / at risk	1/12 (8.33%)	2/53 (3.77%)	5/52 (9.62%)	0/21 (0.00%)
Injury, poisoning and procedural complications				
Limb Injury [*1]				
# participants affected / at risk	0/12 (0.00%)	0/53 (0.00%)	0/52 (0.00%)	2/21 (9.52%)
Investigations				
Weight Decreased [*1]				
# participants affected / at risk	0/12 (0.00%)	6/53 (11.32%)	6/52 (11.54%)	2/21 (9.52%)
Metabolism and nutrition disorders				
Decreased Appetite [*1]				
# participants affected / at risk	4/12 (33.33%)	18/53 (33.96%)	9/52 (17.31%)	1/21 (4.76%)
Enzyme Abnormality [*1]				
# participants affected / at risk	0/12 (0.00%)	1/53 (1.89%)	4/52 (7.69%)	0/21 (0.00%)

Fluid Retention [*1]				
# participants affected / at risk	**2/12 (16.67%)**	**0/53 (0.00%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Hyperamylasaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Hypercholesterolaemia [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**2/53 (3.77%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Hyperglycaemia [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**3/53 (5.66%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Hyperkalaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Hypoalbuminaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Hypocalcaemia [*1]				
# participants affected / at risk	**2/12 (16.67%)**	**2/53 (3.77%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Hypoglycaemia [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**4/52 (7.69%)**	**0/21 (0.00%)**
Hypokalaemia [*1]				
# participants affected / at risk	**4/12 (33.33%)**	**2/53 (3.77%)**	**7/52 (13.46%)**	**1/21 (4.76%)**
Hypomagnesaemia [*1]				

# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	4/52 (7.69%)	0/21 (0.00%)
Hyponatraemia [*1]				
# participants affected / at risk	0/12 (0.00%)	4/53 (7.55%)	4/52 (7.69%)	0/21 (0.00%)
Musculoskeletal and connective tissue disorders				
Arthralgia [*1]				
# participants affected / at risk	0/12 (0.00%)	6/53 (11.32%)	6/52 (11.54%)	0/21 (0.00%)
Back Pain [*1]				
# participants affected / at risk	2/12 (16.67%)	7/53 (13.21%)	9/52 (17.31%)	0/21 (0.00%)
Bone Pain [*1]				
# participants affected / at risk	1/12 (8.33%)	3/53 (5.66%)	6/52 (11.54%)	0/21 (0.00%)
Muscular Weakness [*1]				
# participants affected / at risk	1/12 (8.33%)	4/53 (7.55%)	3/52 (5.77%)	0/21 (0.00%)
Musculoskeletal Chest Pain [*1]				
# participants affected / at risk	0/12 (0.00%)	2/53 (3.77%)	4/52 (7.69%)	0/21 (0.00%)
Musculoskeletal Pain [*1]				
# participants affected / at risk	0/12 (0.00%)	3/53 (5.66%)	1/52 (1.92%)	3/21 (14.29%)
Myalgia [*1]				

# participants affected / at risk	0/12 (0.00%)	4/53 (7.55%)	2/52 (3.85%)	0/21 (0.00%)
Neck Pain [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	1/52 (1.92%)	2/21 (9.52%)
Pain in Extremity [*1]				
# participants affected / at risk	2/12 (16.67%)	7/53 (13.21%)	10/52 (19.23%)	3/21 (14.29%)
Nervous system disorders				
Dizziness [*1]				
# participants affected / at risk	2/12 (16.67%)	9/53 (16.98%)	11/52 (21.15%)	1/21 (4.76%)
Essential Tremor [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Headache [*1]				
# participants affected / at risk	0/12 (0.00%)	3/53 (5.66%)	4/52 (7.69%)	1/21 (4.76%)
Monoparesis [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Neuralgia [*1]				
# participants affected / at risk	5/12 (41.67%)	16/53 (30.19%)	10/52 (19.23%)	0/21 (0.00%)
Paraesthesia [*1]				
# participants affected / at risk	0/12 (0.00%)	4/53 (7.55%)	4/52 (7.69%)	0/21 (0.00%)
Peripheral Sensory				

Neuropathy [*1]				
# participants affected / at risk	**9/12 (75.00%)**	**34/53 (64.15%)**	**31/52 (59.62%)**	**1/21 (4.76%)**
Somnolence [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**2/53 (3.77%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Syncope [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**3/53 (5.66%)**	**2/52 (3.85%)**	**0/21 (0.00%)**
Tremor [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**1/53 (1.89%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Psychiatric disorders				
Agitation [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**1/53 (1.89%)**	**0/52 (0.00%)**	**0/21 (0.00%)**
Anxiety [*1]				
# participants affected / at risk	**2/12 (16.67%)**	**5/53 (9.43%)**	**4/52 (7.69%)**	**0/21 (0.00%)**
Confusional State [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**3/53 (5.66%)**	**1/52 (1.92%)**	**0/21 (0.00%)**
Depression [*1]				
# participants affected / at risk	**2/12 (16.67%)**	**3/53 (5.66%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Hallucination [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**1/52 (1.92%)**	**1/21 (4.76%)**

Insomnia [*1]				
# participants affected / at risk	**3/12 (25.00%)**	**13/53 (24.53%)**	**10/52 (19.23%)**	**1/21 (4.76%)**
Renal and urinary disorders				
Dysuria [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**2/53 (3.77%)**	**4/52 (7.69%)**	**0/21 (0.00%)**
Renal Impairment [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**1/53 (1.89%)**	**6/52 (11.54%)**	**0/21 (0.00%)**
Reproductive system and breast disorders				
Pelvic Pain [*1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/53 (0.00%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Respiratory, thoracic and mediastinal disorders				
Cough [*1]				
# participants affected / at risk	**2/12 (16.67%)**	**10/53 (18.87%)**	**11/52 (21.15%)**	**1/21 (4.76%)**
Dyspnoea [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**8/53 (15.09%)**	**6/52 (11.54%)**	**0/21 (0.00%)**
Epistaxis [*1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/53 (0.00%)**	**3/52 (5.77%)**	**0/21 (0.00%)**
Nasal Congestion [*1]				

# participants affected / at risk	0/12 (0.00%)	3/53 (5.66%)	2/52 (3.85%)	0/21 (0.00%)
Productive Cough [*1]				
# participants affected / at risk	0/12 (0.00%)	3/53 (5.66%)	4/52 (7.69%)	0/21 (0.00%)
Rhinorrhoea [*1]				
# participants affected / at risk	0/12 (0.00%)	3/53 (5.66%)	2/52 (3.85%)	0/21 (0.00%)
Skin and subcutaneous tissue disorders				
Dermatitis [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Erythema [*1]				
# participants affected / at risk	0/12 (0.00%)	3/53 (5.66%)	2/52 (3.85%)	0/21 (0.00%)
Pruritus [*1]				
# participants affected / at risk	1/12 (8.33%)	5/53 (9.43%)	5/52 (9.62%)	0/21 (0.00%)
Rash [*1]				
# participants affected / at risk	1/12 (8.33%)	4/53 (7.55%)	7/52 (13.46%)	0/21 (0.00%)
Scar [*1]				
# participants affected / at risk	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)
Vascular disorders				
Haematoma [*1]				
# participants	1/12 (8.33%)	0/53 (0.00%)	0/52 (0.00%)	0/21 (0.00%)

affected / at risk				
Hypertension * 1				
# participants affected / at risk	**1/12 (8.33%)**	**7/53 (13.21%)**	**4/52 (7.69%)**	**0/21 (0.00%)**
Hypotension * 1				
# participants affected / at risk	**1/12 (8.33%)**	**2/53 (3.77%)**	**7/52 (13.46%)**	**1/21 (4.76%)**
Orthostatic Hypotension * 1				
# participants affected / at risk	**2/12 (16.67%)**	**2/53 (3.77%)**	**3/52 (5.77%)**	**0/21 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 15.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

San-Miguel J, Bladé J, Shpilberg O, Grosicki S, Maloisel F, Min CK, Polo Zarzuela M, Robak T, Prasad SV, Tee Goh Y, Laubach J, Spencer A, Mateos MV, Palumbo A, Puchalski T, Reddy M, Uhlar C, Qin X, van de Velde H, Xie H, Orlowski RZ. Phase 2 randomized study of bortezomib-melphalan-prednisone with or without siltuximab (anti-IL-6) in multiple myeloma. Blood. 2014 Jun 26;123(26):4136-42. doi: 10.1182/blood-2013-12-546374. Epub 2014 May 15. Erratum in: Blood. 2014 Aug 14;124(7):1201.

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