Clinical trial results:
A Phase 1b/2, Multicenter, Open-label, Dose-escalation Study of Elotuzumab (Humanized Anti-CS1 Monoclonal IgG1 Antibody) in Combination With Lenalidomide and Dexamethasone in Subjects With Relapsed Multiple Myeloma

Summary

EudraCT number	2007-006677-83
Trial protocol	DE GB
Global end of trial date	20 October 2016

Results information

Result version number	v1 (current)
This version publication date	27 October 2017
First version publication date	27 October 2017

Trial information

Trial identification

Sponsor protocol code	HuLuc631703

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00742560
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB
Public contact	Global Medical Services, AbbVie, 001 800-633-9110,
Scientific contact	Nilou Mobashery, MD, AbbVie, Nilou.mobashery@abbvie.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 October 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 October 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

the purpose of this study is to evaluate the combination of elotuzumab, lenalidomide, and dexamethasone in subjects with relapsed relapsed multiple myeloma.

Protection of trial subjects:

Subject read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 August 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	France: 24
Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	United States: 60
Worldwide total number of subjects	102
EEA total number of subjects	32

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	64
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 101 participants were randomized (intent-to-treat [ITT] population); 1 subject did not receive study drug and is excluded from the analyses.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)

Arm description:

Elotuzumab 5 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.

Arm type	Experimental
Investigational medicinal product name	elotuzumab
Investigational medicinal product code	
Other name	HuLuc63
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Humanized Anti-CS1 Monoclonal IgG1 Antibody (HuLuc63) administered as an intravenous infusion once a week during Cycles 1 and 2, and every other week beginning with Cycle 3.

Investigational medicinal product name	lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide 25 mg administered orally once daily on Days 1 to 21 of each 28-day cycle

Investigational medicinal product name	dexamethasone oral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)

Investigational medicinal product name	dexamethasone injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also

administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)

Arm title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Arm description:	
Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Arm type	Experimental
Investigational medicinal product name	elotuzumab
Investigational medicinal product code	
Other name	HuLuc63
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Humanized Anti-CS1 Monoclonal IgG1 Antibody (HuLuc63) administered as an intravenous infusion once a week during Cycles 1 and 2, and every other week beginning with Cycle 3.	
Investigational medicinal product name	lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Lenalidomide 25 mg administered orally once daily on Days 1 to 21 of each 28-day cycle	
Investigational medicinal product name	dexamethasone oral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use
Dosage and administration details:	
Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)	
Investigational medicinal product name	dexamethasone injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)	
Arm title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Arm description:	
Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Arm type	Experimental
Investigational medicinal product name	elotuzumab
Investigational medicinal product code	
Other name	HuLuc63
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Humanized Anti-CS1 Monoclonal IgG1 Antibody (HuLuc63) administered as an intravenous infusion once a week during Cycles 1 and 2, and every other week beginning with Cycle 3.

Investigational medicinal product name	lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide 25 mg administered orally once daily on Days 1 to 21 of each 28-day cycle

Investigational medicinal product name	dexamethasone oral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)

Investigational medicinal product name	dexamethasone injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)

Arm title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)

Arm description:

Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.

Arm type	Experimental
Investigational medicinal product name	elotuzumab
Investigational medicinal product code	
Other name	HuLuc63
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Humanized Anti-CS1 Monoclonal IgG1 Antibody (HuLuc63) administered as an intravenous infusion once a week during Cycles 1 and 2, and every other week beginning with Cycle 3.

Investigational medicinal product name	lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide 25 mg administered orally once daily on Days 1 to 21 of each 28-day cycle

Investigational medicinal product name	dexamethasone oral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also

administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)

Investigational medicinal product name	dexamethasone injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)

Arm title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)

Arm description:

Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.

Arm type	Experimental
Investigational medicinal product name	elotuzumab
Investigational medicinal product code	
Other name	HuLuc63
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Humanized Anti-CS1 Monoclonal IgG1 Antibody (HuLuc63) administered as an intravenous infusion once a week during Cycles 1 and 2, and every other week beginning with Cycle 3.

Investigational medicinal product name	lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide 25 mg administered orally once daily on Days 1 to 21 of each 28-day cycle

Investigational medicinal product name	dexamethasone oral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)

Investigational medicinal product name	dexamethasone injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Dexamethasone 40 mg administered orally once weekly; during weeks when elotuzumab is also administered, dexamethasone was administered as a split dose (28 mg orally and 8 mg intravenously)

Number of subjects in period 1[1]	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Started	3	3	22
Completed	0	0	0
Not completed	3	3	22
Investigator's decision	-	-	4
Disease progression	1	-	5
Death	-	2	-
Not specified	-	1	8
Subject's decision	1	-	2
New multiple myeloma therapy	1	-	2
Adverse event	-	-	1
Missing	-	-	-

Number of subjects in period 1[1]	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Started	36	37
Completed	0	0
Not completed	36	37
Investigator's decision	1	-
Disease progression	17	16
Death	2	3
Not specified	9	9
Subject's decision	3	3
New multiple myeloma therapy	3	4
Adverse event	1	1
Missing	-	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: A total of 101 participants were randomized (intent-to-treat [ITT] population); 1 subject did not receive study drug and is excluded from the analyses.

Baseline characteristics

Reporting groups	
Reporting group title	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Reporting group description:	
Elotuzumab 5 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Reporting group title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Reporting group description:	
Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Reporting group title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Reporting group description:	
Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Reporting group title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Reporting group description:	
Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Reporting group title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Reporting group description:	
Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	

Reporting group values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Number of subjects	3	3	22
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	68.3	64.7	59.3
standard deviation	± 7.23	± 6.94	± 10.87
Gender categorical			
Units: Subjects			
Female	2	1	10
Male	1	2	12

Reporting group values	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Total
Number of subjects	36	37	101

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	60.6	63.3	
standard deviation	± 9.7	± 9.76	-
Gender categorical Units: Subjects			
Female	19	24	56
Male	17	13	45

End points

End points reporting groups

Reporting group title	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Reporting group description:	
Elotuzumab 5 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Reporting group title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Reporting group description:	
Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Reporting group title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Reporting group description:	
Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Reporting group title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Reporting group description:	
Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Reporting group title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Reporting group description:	
Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Subject analysis set title	Phase 1 Elotuzumab + Lenalidomide and Dexamethasone
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Elotuzumab 5, 10, or 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Subject analysis set title	Total (Phase 2)
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Elotuzumab (10 or 20 mg/kg) administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	
Subject analysis set title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally in Phase 1 and Phase 2.	
Subject analysis set title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally in Phase 1 and Phase 2.	
Subject analysis set title	Total (Phase 1)
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Elotuzumab (5, 10, or 20 mg/kg) administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.	

Primary: Maximum Tolerated Dose (MTD) of Elotuzumab in Combination With Lenalidomide and Dexamethasone (Phase 1)

End point title	Maximum Tolerated Dose (MTD) of Elotuzumab in Combination With Lenalidomide and Dexamethasone (Phase 1)[1]

End point description:

MTD was determined by testing increasing doses up to 20 mg/kg once daily dose escalation cohorts 1 to 3 with 3 patients each. MTD reflects highest dose of drug that did not cause an unacceptable side effect (dose limiting toxicity [DLT]) in more than 30% of patients; e.g., hematologic toxicities like Common Toxicity Criteria for Adverse Events (CTCAE) Grade 4 neutropenia in specific conditions, platelets < 10,000 cells/mm^3 that do not recover to 25,000 cells/mm^3; and specific non-hematologic/biochemical toxicities CTCAE Grade 3 or 4 (except fatigue and Grade 3 infections); CTCAE version 3.0 were used.

End point type	Primary

End point timeframe:

4 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive data are summarized for this end point per protocol.

End point values	Phase 1 Elotuzumab + Lenalidomide and Dexamethasone			
Subject group type	Subject analysis set			
Number of subjects analysed	28[2]			
Units: mg/kg				
number (not applicable)	20			

Notes:

[2] - All randomized participants who received at least 1 dose of study drug in phase 1 escalation cohorts

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (ORR) According to the International Myeloma Working Group Uniform Response Criteria (Phase 2)

End point title	Objective Response Rate (ORR) According to the International Myeloma Working Group Uniform Response Criteria (Phase 2)[3][4]

End point description:

ORR: Percentage of participants with confirmed complete response (CR; negative immunofixation on the serum and urine, disappearance of any soft tissue plasmacytomas, and ≤5% plasma cells in bone marrow), partial response (PR; ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to ≤200 mg per 24 hour; if serum and urine M-protein are unmeasurable, a ≥50% decrease in the difference between involved and uninvolved free light chain (FLC] levels is required in place of the M-protein criteria; if serum and urine M-protein are unmeasurable, and serum FLC is also unmeasurable, a ≥50% reduction in plasma cells is required in place of M-protein, provided baseline bone marrow plasma cell percentage was ≥30%; and, if present at baseline, a ≥50% reduction in the size of soft tissue plasmacytomas), very good PR (VGPR; normal FLC ratio and absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence), or stringent CR (sCR; CR plus VGPR).

End point type	Primary

End point timeframe:

From date of randomization until 60 days following the last infusion (or before initiation of new therapy), up to 101 months

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive data are summarized for this end point per protocol.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The primary end point included subjects enrolled in Phase 2 only.

End point values	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Total (Phase 2)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	36[5]	37[6]	73[7]	
Units: percentage of participants				
number (confidence interval 95%)	91.7 (77.5 to 98.2)	75.7 (58.8 to 88.2)	83.6 (73 to 91.2)	

Notes:

[5] - Safety population: All randomized participants who received at least 1 dose of study drug

[6] - Safety population: All randomized participants who received at least 1 dose of study drug

[7] - Safety population: All randomized participants who received at least 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) According to the International Myeloma Working Group Uniform Response Criteria (Phase 1)

End point title	Objective Response Rate (ORR) According to the International Myeloma Working Group Uniform Response Criteria (Phase 1)[8]

End point description:

ORR: Percentage of participants with confirmed complete response (CR; negative immunofixation on the serum and urine, disappearance of any soft tissue plasmacytomas, and ≤5% plasma cells in bone marrow), partial response (PR; ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to ≤200 mg per 24 hour; if serum and urine M-protein are unmeasurable, a ≥50% decrease in the difference between involved and uninvolved free light chain (FLC] levels is required in place of the M-protein criteria; if serum and urine M-protein are unmeasurable, and serum FLC is also unmeasurable, a ≥50% reduction in plasma cells is required in place of M-protein, provided baseline bone marrow plasma cell percentage was ≥30%; and, if present at baseline, a ≥50% reduction in the size of soft tissue plasmacytomas), very good PR (VGPR; normal FLC ratio and absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence), or stringent CR (sCR; CR plus VGPR).

End point type	Secondary

End point timeframe:

From first dose of elotuzumab until 60 days following the last infusion (or before initiation of new therapy), up to 100.5 months

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The secondary end point included subjects enrolled in Phase 1 only.

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Total (Phase 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3[9]	3[10]	22[11]	28[12]
Units: percentage of participants				
number (confidence interval 95%)	100 (29.2 to 100)	100 (29.2 to 100)	77.3 (54.6 to 92.2)	82.1 (63.1 to 93.9)

Notes:

[9] - Safety population: All randomized participants who received at least 1 dose of study drug

[10] - Safety population: All randomized participants who received at least 1 dose of study drug

[11] - Safety population: All randomized participants who received at least 1 dose of study drug

[12] - Safety population: All randomized participants who received at least 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Participants With Treatment-emergent Adverse Events (TEAEs)

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. The investigator assessed the relationship of each event to the use of study drug as either definitely related, probably related, possibly related or unrelated. A serious adverse event (SAE) is an event that results in death, is life-threatening, requires or prolongs hospitalization, results in a congenital anomaly, persistent or significant disability/incapacity or is an important medical event that, based on medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent any of the outcomes listed above. Treatment-emergent events (TEAEs/TESAEs) are defined as any event that began or worsened in severity after the first dose of study drug. For more details on adverse events please see the Adverse Event section.

End point type	Secondary

End point timeframe:

Treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs) were collected from first dose of study drug until 60 days after the last dose of study drug (up to 95 months)

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[13]	3[14]	22[15]	36[16]
Units: participants				
number (not applicable)				
Any TEAE	3	3	22	36
Any TESAE	0	3	12	21
TEAEs ≥ Grade 3	2	3	19	32
TEAEs related to study drug	3	3	16	29

TESAEs related to study drug	0	0	2	2

Notes:

[13] - Safety population: All randomized participants who received at least 1 dose of study drug

[14] - Safety population: All randomized participants who received at least 1 dose of study drug

[15] - Safety population: All randomized participants who received at least 1 dose of study drug

[16] - Safety population: All randomized participants who received at least 1 dose of study drug

End point values	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)			
Subject group type	Reporting group			
Number of subjects analysed	37[17]			
Units: participants				
number (not applicable)				
Any TEAE	37			
Any TESAE	21			
TEAEs ≥ Grade 3	25			
TEAEs related to study drug	26			
TESAEs related to study drug	5			

Notes:

[17] - Safety population: All randomized participants who received at least 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Infusion Reactions

End point title	Number of Participants With Infusion Reactions

End point description:

During Phase 1, a list of 118 pre-defined MedDRA preferred terms that had been adjudicated to be clinically relevant to infusion reactions by a safety committee was used to search for TEAEs that could potentially be associated with an infusion reaction following elotuzumab administration. Examples of these terms included angioedema, bronchospasm, chills, flushing, pyrexia, rash and urticaria. During Phase 2, the method for capturing TEAEs associated with an infusion reaction was modified to include investigators' designation of AEs judged as clinically relevant infusion reactions. The number of participants infusion reactions are provided overall and by highest toxicity grade (CTCAE v 3.0).

End point type	Secondary

End point timeframe:

Cycles 1 and 2: Days 1, 8, 15, and 22 (day of infusion of elotuzumab) and Days 2, 9, 16, and 23 (day following infusion); and Cycles 3 and greater: Days 1 and 15 (day of infusion) and Days 2 and 16 (day after infusion) (up to 95 months)

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[18]	3[19]	22[20]	36[21]

Units: participants				
number (not applicable)				
Any reaction	2	3	20	5
Grade 5	0	0	0	0
Grade 4	0	0	1	0
Grade 3	0	0	2	1
Grade 2	0	1	5	1
Grade 1	2	2	12	3

Notes:

[18] - Safety population: All randomized participants who received at least 1 dose of study drug

[19] - Safety population: All randomized participants who received at least 1 dose of study drug

[20] - Safety population: All randomized participants who received at least 1 dose of study drug

[21] - Safety population: All randomized participants who received at least 1 dose of study drug

End point values	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)			
Subject group type	Reporting group			
Number of subjects analysed	37[22]			
Units: participants				
number (not applicable)				
Any reaction	3			
Grade 5	0			
Grade 4	0			
Grade 3	0			
Grade 2	1			
Grade 1	2			

Notes:

[22] - Safety population: All randomized participants who received at least 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Serum Concentrations of Elotuzumab During Cycle 1

End point title	Mean Serum Concentrations of Elotuzumab During Cycle 1[23]

End point description:

Blood samples were collected during Phase 1, Cycle 1, prior to elotuzumab infusion (time 0 hours) and 30 minutes (0.5 hours) and 4 hours post-infusion (Day 1), 30 minutes (0.5 hours) post-infusion (Day 8 and Day 15), or 30 minutes (0.5 hours), 2 hours, and 4 hours post-infusion (Day 15). Blood samples were collected during Phase 2, Cycle 1, prior to elotuzumab infusion (time 0 hours) and 30 minutes (0.5 hours), 2 hours, and 4 hours post-infusion (Day 1), 30 minutes (0.5 hours) and 2 hours post-infusion (Day 8 and Day 15), or 30 minutes (0.5 hours), 2 hours, and 4 hours post-infusion (Day 15). The samples were analyzed for the concentration of elotuzumab using validated analytical methods. Mean serum concentrations on Cycle 1, Days 1, 8, 15, and 22 (measured in µg/mL) are reported overall (across Phase 1 and Phase 2) by dose. 55555=The estimated standard deviation of one sample is undefined. 88888=Blood samples not collected at given timepoint.

End point type	Secondary

End point timeframe:

Cycle 1: Days 1 (pre-infusion and 0.5, 2 and 4 hours post-infusion), 8 (pre-infusion and 0.5 and 2 hours post-infusion), 15 (pre-infusion and 0.5 hours and 2 hours post-infusion), and 22 (pre-infusion and 0.5, 2, and 4 hours post-infusion)

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The end point is analyzed by dose (5, 10, and 20 mg/kg).

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	3[24]	39[25]	58[26]	
Units: µg/mL				
arithmetic mean (standard deviation)				
Day 1: 0.5 hours (N=3,39,58)	0 (± 0)	0 (± 0)	0 (± 0)	
Day 1: 0.5 hours (N=3,39,57)	78.48 (± 21.33)	217.9 (± 99.31)	434.2 (± 202.74)	
Day 1: 2 hours (N=0,36,43)	88888 (± 88888)	213.31 (± 91.3)	388.58 (± 112.94)	
Day 1: 4 hours (N=3,3,12)	85.56 (± 23.54)	251.34 (± 31.92)	525.98 (± 188.46)	
Day 8: 0 hours (N=3,37,55)	32.44 (± 8.91)	92.47 (± 61.16)	168.55 (± 56.43)	
Day 8: 0.5 hours(N=3,22,44)	133.37 (± 40.87)	281.53 (± 117.35)	593.8 (± 192.7)	
Day 8: 2 hours (N=0,12,9)	88888 (± 88888)	268.35 (± 107.44)	520.97 (± 207.28)	
Day 15: 0 hours (N=3,37,58)	49.84 (± 28.28)	111.11 (± 56.36)	298.82 (± 231.17)	
Day 15: 0.5 hours (N=3,36,55)	140.09 (± 32.28)	282.29 (± 100.29)	661.91 (± 251.08)	
Day 22: 0 hours (N=3,38,54)	61.93 (± 53.66)	135.92 (± 106.83)	308.02 (± 144.61)	
Day 22: 0.5 hours (N=3,38,54)	168.61 (± 59.31)	310.03 (± 165.14)	699.7 (± 230.41)	
Day 22: 2 hours (N=1,35,40)	268.53 (± 55555)	298.85 (± 114.35)	704.48 (± 234.98)	
Day 22: 4 hours (N=2,3,10)	128.94 (± 42.04)	538.88 (± 195.35)	981.16 (± 280.28)	

Notes:

[24] - All participants in the safety population with evaluable data at given timepoint

[25] - All participants in the safety population with evaluable data at given timepoint

[26] - All participants in the safety population with evaluable data at given timepoint

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Serum Concentration (Cmax) of Elotuzumab

End point title	Maximum Serum Concentration (Cmax) of Elotuzumab[27]

End point description:

The maximum plasma concentration (Cmax; measured in ng/mL) is the highest concentration that a drug achieves in the blood after administration in a dosing interval. The Cmax of elotuzumab was to be estimated using non-compartmental methods and data reported as the mean ± standard deviation. No noncompartmental pharmacokinetic parameters (e.g., AUC, CL, V, t 1/2) were estimated due to sparse serum concentration collections.

End point type	Secondary

End point timeframe:

Cycle 1: Days 1, 8, and 15; Cycle 2: Days 1 and 22; Cycle 3 and beyond: Day 1

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point was to be analyzed by dose (5, 10, and 20 mg/kg).

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[28]	0[29]	0[30]	
Units: ng/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[28] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[29] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[30] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-time Curve From 0 to Infinity (AUC0-inf) of Elotuzumab

End point title	Area Under the Concentration-time Curve From 0 to Infinity (AUC0-inf) of Elotuzumab[31]

End point description:

The area under the plasma concentration-time curve (AUC; measured in ng*hr/mL) is a method of measurement to determine the total exposure of a drug in blood plasma. The AUC24 of elotuzumab was to be estimated using non-compartmental methods and data reported as the mean ± standard deviation. No noncompartmental pharmacokinetic parameters (e.g., AUC, CL, V, t 1/2) were estimated due to sparse serum concentration collections.

End point type	Secondary

End point timeframe:

Cycle 1: Days 1, 8, and 15; Cycle 2: Days 1 and 22; Cycle 3 and beyond: Day 1

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point was to be analyzed by dose (5, 10, and 20 mg/kg).

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[32]	0[33]	0[34]	
Units: ng*hr/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[32] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[33] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[34] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

Statistical analyses

No statistical analyses for this end point

Secondary: Systemic Clearance (CL) of Elotuzumab

End point title	Systemic Clearance (CL) of Elotuzumab[35]

End point description:

Systemic clearance (CL, measured in mL/kg/hr) is a measure of the efficiency with which a drug is irreversibly removed from the body. The CL of elotuzumab was to be estimated using non-compartmental methods and data reported as the mean ± standard deviation. No noncompartmental pharmacokinetic parameters (e.g., AUC, CL, V, t 1/2) were estimated due to sparse serum concentration collections.

End point type	Secondary

End point timeframe:

Cycle 1: Days 1, 8, and 15; Cycle 2: Days 1 and 22; Cycle 3 and beyond: Day 1

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point was to be analyzed by dose (5, 10, and 20 mg/kg).

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[36]	0[37]	0[38]	
Units: mL/kg/hr				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[36] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[37] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[38] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution (V) of Elotuzumab

End point title	Volume of Distribution (V) of Elotuzumab[39]

End point description:

Volume of distribution (V, measured in L/kg) is the hypothetical volume of body fluid that would be required to dissolve the amount of drug needed to achieve the same concentration in the blood. The V of elotuzumab was to be estimated using non-compartmental methods and data reported as the mean ± standard deviation. No noncompartmental pharmacokinetic parameters (e.g., AUC, CL, V, t 1/2) were estimated due to sparse serum concentration collections.

End point type	Secondary

End point timeframe:

Cycle 1: Days 1, 8, and 15; Cycle 2: Days 1 and 22; Cycle 3 and beyond: Day 1

Notes:

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point was to be analyzed by dose (5, 10, and 20 mg/kg).

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[40]	0[41]	0[42]	
Units: L/kg				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[40] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[41] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[42] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Half-life (t1/2) of Elotuzumab

End point title	Serum Half-life (t1/2) of Elotuzumab[43]

End point description:

The serum half-life of a drug (t1/2, measured in hours) is the time necessary to reduce the plasma concentration by half. The t1/2 of elotuzumab was to be estimated using non-compartmental methods and data reported as the mean ± standard deviation. No noncompartmental pharmacokinetic parameters (e.g., AUC, CL, V, t 1/2) were estimated due to sparse serum concentration collections.

End point type	Secondary

End point timeframe:

Cycle 1: Days 1, 8, and 15; Cycle 2: Days 1 and 22; Cycle 3 and beyond: Day 1

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point was to be analyzed by dose (5, 10, and 20 mg/kg).

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[44]	0[45]	0[46]	
Units: hours				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[44] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[45] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

[46] - No pharmacokinetic parameters were estimated due to sparse serum concentration collections

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response

End point description:

Duration of response is defined as the time from the initial objective response to disease progression or death, whichever occurs first. The distribution of duration of response was estimated for each treatment group using Kaplan-Meier methodology. Point estimates and 95% CIs for the median for the duration of response distribution are provided. 77777=Median was not reached (max value was 58.22). 11111=Lower limit not calculable due to insufficient progression events. 99999=upper limit not calculable due to insufficient progression events.

End point type	Secondary

End point timeframe:

From first dose of elotuzumab (phase 1) or randomization (phase 2) until 60 days following the last infusion (or before initiation of new therapy), up to 101 months

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[47]	3[48]	22[49]	36[50]
Units: months				
median (confidence interval 95%)	4.47 (1.45 to 4.47)	9.92 (0 to 99999)	77777 (11111 to 99999)	34.83 (14.6 to 99999)

Notes:

[47] - Safety population: All randomized participants who received at least 1 dose of study drug

[48] - Safety population: All randomized participants who received at least 1 dose of study drug

[49] - Safety population: All randomized participants who received at least 1 dose of study drug

[50] - Safety population: All randomized participants who received at least 1 dose of study drug

End point values	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Total (Phase 2)	Total (Phase 1)	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	37[51]	73[52]	28[53]	
Units: months				

median (confidence interval 95%)	29.01 (15.0 to 99999)	29.24 (18.2 to 99999)	77777 (11111 to 99999)	

Notes:

[51] - Safety population: All randomized participants who received at least 1 dose of study drug

[52] - Safety population: All randomized participants who received at least 1 dose of study drug

[53] - Safety population: All randomized participants who received at least 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Progression (TTP)

End point title	Time to Progression (TTP)

End point description:

TTP is defined as the time from first dose (phase 1) or time from randomization (phase 2) to disease progression. The distribution of TTP was estimated for each treatment group using Kaplan-Meier methodology. Point estimates and 95% CIs for the median for the TTP distribution are provided. 11.111=Lower limit not calculable due to insufficient progression events. 99999=upper limit not calculable due to insufficient progression events

End point type	Secondary

End point timeframe:

From first dose of elotuzumab (phase 1) or randomization (phase 2) until 60 days following the last infusion (or before initiation of new therapy), up to 101 months

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[54]	3[55]	22[56]	36[57]
Units: months				
median (confidence interval 95%)	6.08 (6.05 to 6.08)	11.53 (11.111 to 99999)	52.93 (7.43 to 99999)	32.49 (14.9 to 99999)

Notes:

[54] - Safety population: All randomized participants who received at least 1 dose of study drug

[55] - Safety population: All randomized participants who received at least 1 dose of study drug

[56] - Safety population: All randomized participants who received at least 1 dose of study drug

[57] - Safety population: All randomized participants who received at least 1 dose of study drug

End point values	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Total (Phase 2)	Total (Phase 1)	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	37[58]	73[59]	28[60]	
Units: months				
median (confidence interval 95%)	19.94 (12.9 to 35.7)	28.16 (15.4 to 35.8)	52.93 (7.43 to 99999)	

Notes:

[58] - Safety population: All randomized participants who received at least 1 dose of study drug

[59] - Safety population: All randomized participants who received at least 1 dose of study drug

[60] - Safety population: All randomized participants who received at least 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Treatment-emergent Anti-elotuzumab Antibody (ADA)

End point title	Percentage of Participants With Treatment-emergent Anti-elotuzumab Antibody (ADA)[61]

End point description:

Treatment-emergent (post-dose) positive elotuzumab-specific ADA is differentiated from pre-existing (positive at the predose time point) positive elotuzumab-specific ADA. The percentage of participants with confirmed treatment-emergent ADA overall by dose is provided.

End point type	Secondary

End point timeframe:

From screening through 60-day follow up period (up to 101 months)

Notes:

[61] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is analyzed by dose (5, 10, and 20 mg/kg).

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	3[62]	39[63]	57[64]	
Units: participants				
number (not applicable)	0	6	5	

Notes:

[62] - All participants who received ≥ 1 dose of study drug and ≥ 1 evaluable post-dose sample

[63] - All participants who received ≥ 1 dose of study drug and ≥ 1 evaluable post-dose sample

[64] - All participants who received ≥ 1 dose of study drug and ≥ 1 evaluable post-dose sample

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Cell Myeloma Cytogenetic Subtype

End point title	Plasma Cell Myeloma Cytogenetic Subtype

End point description:

Plasma cell myeloma cytogenetic subtype was assessed at the screening visit using standard karyotyping and/or fluorescence in situ hybridization. The number of participants in each cytogenetic risk category are provided: High Risk (International Staging System [ISS] stage II or III and t(4;14) or del(17p) abnormality); Standard Risk (not high or low risk); and Low Risk (ISS stage I or II and absence of t(4;14), del(17p) and 1q21 abnormalities AND age < 55).

End point type	Secondary

End point timeframe:

Screening (up to 14 days prior to dosing)

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[65]	3[66]	22[67]	36[68]
Units: participants				
number (not applicable)				
High Risk	1	0	0	1
Standard Risk	2	3	17	30
Low Risk	0	0	3	2
Not Reported	0	0	2	3

Notes:

[65] - Safety population: All randomized participants who received at least 1 dose of study drug

[66] - Safety population: All randomized participants who received at least 1 dose of study drug

[67] - Safety population: All randomized participants who received at least 1 dose of study drug

[68] - Safety population: All randomized participants who received at least 1 dose of study drug

End point values	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)			
Subject group type	Reporting group			
Number of subjects analysed	37[69]			
Units: participants				
number (not applicable)				
High Risk	3			
Standard Risk	24			
Low Risk	3			
Not Reported	7			

Notes:

[69] - Safety population: All randomized participants who received at least 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS)

End point title	Progression-free Survival (PFS)

End point description:

PFS is defined as the time from first dose (phase 1) or time from randomization (phase 2) to disease progression or death. The distribution of PFS was estimated for each treatment group using Kaplan-Meier methodology. Point estimates and 95% CIs for the median for the PFS distribution are provided. 77777=Median was not reached (max value was 58.91). 11111=Lower limit not calculable due to insufficient progression events. 99999=upper limit not calculable due to insufficient progression events.

End point type	Secondary

End point timeframe:

From first dose of elotuzumab (phase 1) or randomization (phase 2) until 60 days following the last infusion (or before initiation of new therapy), up to 101 months

End point values	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[70]	3[71]	22[72]	36[73]
Units: months				
median (confidence interval 95%)	6.08 (6.05 to 6.08)	22.23 (11.5 to 32.9)	77777 (11111 to 99999)	32.49 (14.9 to 99999)

Notes:

[70] - Safety population: All randomized participants who received at least 1 dose of study drug

[71] - Safety population: All randomized participants who received at least 1 dose of study drug

[72] - Safety population: All randomized participants who received at least 1 dose of study drug

[73] - Safety population: All randomized participants who received at least 1 dose of study drug

End point values	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Total (Phase 2)	Total (Phase 1)	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	37[74]	73[75]	28[76]	
Units: months				
median (confidence interval 95%)	25.00 (14.0 to 35.7)	28.62 (16.6 to 43.1)	32.92 (7.43 to 99999)	

Notes:

[74] - Safety population: All randomized participants who received at least 1 dose of study drug

[75] - Safety population: All randomized participants who received at least 1 dose of study drug

[76] - Safety population: All randomized participants who received at least 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs) were collected from first dose of study drug until 60 days after the last dose of study drug (up to 95 months).

Adverse event reporting additional description:

TEAEs and TESAEs are defined as any adverse event or serious adverse event that begins or worsens in severity after initiation of study drug until 30 days after the last dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)

Reporting group description:

Elotuzumab 5 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.

Reporting group title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)

Reporting group description:

Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.

Reporting group title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)

Reporting group description:

Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.

Reporting group title	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)

Reporting group description:

Elotuzumab 10 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.

Reporting group title	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)

Reporting group description:

Elotuzumab 20 mg/kg administered as an IV infusion in combination with lenalidomide 25 mg and dexamethasone 40 mg administered orally.

Serious adverse events	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	3 / 3 (100.00%)	12 / 22 (54.55%)
number of deaths (all causes)	0	2	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOBULAR BREAST CARCINOMA IN SITU			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT MELANOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
ACCELERATED HYPERTENSION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PHLEBITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRIDOR			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
GASTROENTERITIS RADIATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRADYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBROVASCULAR ACCIDENT			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERALISED TONIC-CLONIC SEIZURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT GLOBAL AMNESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCYTOPENIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
CONSTIPATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULAR PERFORATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL PERFORATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
HAEMATEMESIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICES OESOPHAGEAL			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLECYSTITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL COLIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 INFLUENZA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENINGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA KLEBSIELLA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA VIRAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VISCERAL LEISHMANIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METABOLIC ACIDOSIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Serious adverse events	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 36 (58.33%)	21 / 37 (56.76%)	
number of deaths (all causes)	1	2	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOBULAR BREAST CARCINOMA IN SITU			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT MELANOMA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYELODYSPLASTIC SYNDROME			

subjects affected / exposed	1 / 36 (2.78%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATE CANCER			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	1 / 36 (2.78%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
ACCELERATED HYPERTENSION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PHLEBITIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PHLEBITIS SUPERFICIAL			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

CHEST PAIN			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
PYREXIA			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATITIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASTHMA			

subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG DISORDER			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONITIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 36 (2.78%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STRIDOR			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
GASTROENTERITIS RADIATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRADYCARDIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TACHYCARDIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERALISED TONIC-CLONIC SEIZURE			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNCOPE			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSIENT GLOBAL AMNESIA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	1 / 36 (2.78%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood and lymphatic system disorders			
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHOPENIA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIA			
subjects affected / exposed	1 / 36 (2.78%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCYTOPENIA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
CONSTIPATION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULAR PERFORATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

GASTROINTESTINAL PERFORATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATEMESIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VARICES OESOPHAGEAL			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLECYSTITIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			

subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL COLIC			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACK PAIN			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BONE PAIN			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			

ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHITIS			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1N1 INFLUENZA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES ZOSTER			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFLUENZA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOCALISED INFECTION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFECTION			

subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENINGITIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	4 / 36 (11.11%)	5 / 37 (13.51%)	
occurrences causally related to treatment / all	0 / 5	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
PNEUMONIA KLEBSIELLA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA VIRAL			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYELONEPHRITIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			
subjects affected / exposed	3 / 36 (8.33%)	2 / 37 (5.41%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
URINARY TRACT INFECTION			

subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VISCERAL LEISHMANIASIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERCALCAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOKALAEMIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METABOLIC ACIDOSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Elotuzumab 5 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 1)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 1)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	22 / 22 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	4
FLUSHING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HOT FLUSH			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
HYPERTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	4
PHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
THROMBOPHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	6 / 22 (27.27%)
occurrences (all)	0	1	12
CHEST DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
CHILLS			

subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	1 / 22 (4.55%)
occurrences (all)	2	3	1
FATIGUE			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	15 / 22 (68.18%)
occurrences (all)	1	2	21
FEELING HOT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
IRRITABILITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	6 / 22 (27.27%)
occurrences (all)	0	2	15
PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	4
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
PYREXIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	10 / 22 (45.45%)
occurrences (all)	0	0	21
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SEASONAL ALLERGY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	2
Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	7 / 22 (31.82%)
occurrences (all)	0	0	11
DYSPHONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	5 / 22 (22.73%)
occurrences (all)	0	0	7
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
EPISTAXIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HICCUPS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LUNG DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	3
NASAL CONGESTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
RALES			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	5
SINUS CONGESTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
THROAT IRRITATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2

Psychiatric disorders			
AGGRESSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	4
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DEPRESSED MOOD			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
INSOMNIA			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	7 / 22 (31.82%)
occurrences (all)	2	1	9
MOOD SWINGS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
BLOOD BICARBONATE DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CARDIAC MURMUR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
IMMUNOGLOBULINS DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PROTEIN TOTAL INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PROTHROMBIN TIME PROLONGED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
WEIGHT INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
FALL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	6
JOINT DISLOCATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LIGAMENT SPRAIN			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
SKIN ABRASION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
STOMA SITE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
SUNBURN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
PALPITATIONS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
BALANCE DISORDER			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
DIZZINESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	6
DYSGEUSIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
HEADACHE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	5 / 22 (22.73%)
occurrences (all)	1	0	8
HYPOAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HYPOGEUSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
NEURALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	7 / 22 (31.82%)
occurrences (all)	0	0	10
PARAESTHESIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	3
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PSYCHOMOTOR HYPERACTIVITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
SOMNOLENCE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	10 / 22 (45.45%)
occurrences (all)	2	3	17
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	2
HAEMOGLOBINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
INCREASED TENDENCY TO BRUISE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	2 / 22 (9.09%)
occurrences (all)	1	3	2
LYMPHADENOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
NEUTROPENIA			
subjects affected / exposed	2 / 3 (66.67%)	3 / 3 (100.00%)	7 / 22 (31.82%)
occurrences (all)	3	8	11

PANCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	5 / 22 (22.73%)
occurrences (all)	3	3	5
Ear and labyrinth disorders			
HYPOACUSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
TINNITUS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
VERTIGO			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
DRY EYE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
EYE IRRITATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	4
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VITREOUS FLOATERS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ABDOMINAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	11 / 22 (50.00%)
occurrences (all)	2	2	13
DIARRHOEA			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	14 / 22 (63.64%)
occurrences (all)	1	3	29
DIVERTICULAR PERFORATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
DRY MOUTH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
FLATULENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
GASTROINTESTINAL MOTILITY DISORDER			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	3
GASTROINTESTINAL PERFORATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HAEMATOCHEZIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
NAUSEA			
subjects affected / exposed	0 / 3 (0.00%)	3 / 3 (100.00%)	11 / 22 (50.00%)
occurrences (all)	0	4	13
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
TOOTH DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
VOMITING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	6 / 22 (27.27%)
occurrences (all)	0	0	6
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLISTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
ECCHYMOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ERYTHEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
HYPERHIDROSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	5
INGROWING NAIL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	3
NIGHT SWEATS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PRURITUS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
RASH			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 22 (13.64%)
occurrences (all)	1	1	7
RASH GENERALISED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1

RASH MACULAR			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
SCAB			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SKIN DISCOLOURATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
URTICARIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	3
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
DYSURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HAEMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	7 / 22 (31.82%)
occurrences (all)	0	2	12
BACK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	7 / 22 (31.82%)
occurrences (all)	0	1	11
BONE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	3
MUSCLE SPASMS			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	10 / 22 (45.45%)
occurrences (all)	2	1	12
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	5 / 22 (22.73%)
occurrences (all)	0	0	8
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
NECK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	5 / 22 (22.73%)
occurrences (all)	0	1	6
PAIN IN JAW			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	2
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	5 / 22 (22.73%)
occurrences (all)	0	0	14
CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	4
EAR INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
GASTROENTERITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
GINGIVITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
HERPES ZOSTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
LOCALISED INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
LUNG INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	4
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	2
ORAL HERPES			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	5
PNEUMONIA VIRAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
SEPSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
SINUSITIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	8
UPPER RESPIRATORY TRACT			

INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	7 / 22 (31.82%)
occurrences (all)	0	2	44
UPPER RESPIRATORY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	19
VIRAL INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DIABETES MELLITUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GOUT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HYPERCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	4
HYPERKALAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HYPERNATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	6 / 22 (27.27%)
occurrences (all)	0	2	13
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
METABOLIC ACIDOSIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

Non-serious adverse events	Elotuzumab 10 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	Elotuzumab 20 mg/kg + Lenalidomide and Dexamethasone (Phase 2)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 36 (100.00%)	37 / 37 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

BASAL CELL CARCINOMA			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	1	2	
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	2	
FLUSHING			
subjects affected / exposed	4 / 36 (11.11%)	2 / 37 (5.41%)	
occurrences (all)	5	3	
HOT FLUSH			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	3	3	
HYPERTENSION			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	5	
HYPOTENSION			
subjects affected / exposed	4 / 36 (11.11%)	4 / 37 (10.81%)	
occurrences (all)	5	8	
PHLEBITIS SUPERFICIAL			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
THROMBOPHLEBITIS SUPERFICIAL			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	7 / 36 (19.44%)	12 / 37 (32.43%)	
occurrences (all)	10	22	
CHEST DISCOMFORT			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	2	2	
CHEST PAIN			
subjects affected / exposed	0 / 36 (0.00%)	3 / 37 (8.11%)	
occurrences (all)	0	3	
CHILLS			

subjects affected / exposed	6 / 36 (16.67%)	2 / 37 (5.41%)	
occurrences (all)	8	4	
FATIGUE			
subjects affected / exposed	24 / 36 (66.67%)	18 / 37 (48.65%)	
occurrences (all)	36	24	
FEELING HOT			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
GAIT DISTURBANCE			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	2	
INFLAMMATION			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
IRRITABILITY			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	3	1	
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	5 / 36 (13.89%)	2 / 37 (5.41%)	
occurrences (all)	5	2	
OEDEMA			
subjects affected / exposed	5 / 36 (13.89%)	1 / 37 (2.70%)	
occurrences (all)	8	1	
OEDEMA PERIPHERAL			
subjects affected / exposed	14 / 36 (38.89%)	9 / 37 (24.32%)	
occurrences (all)	23	14	
PAIN			
subjects affected / exposed	1 / 36 (2.78%)	5 / 37 (13.51%)	
occurrences (all)	1	5	
PERIPHERAL SWELLING			
subjects affected / exposed	5 / 36 (13.89%)	7 / 37 (18.92%)	
occurrences (all)	14	9	
PYREXIA			

subjects affected / exposed	14 / 36 (38.89%)	17 / 37 (45.95%)	
occurrences (all)	22	23	
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
SEASONAL ALLERGY			
subjects affected / exposed	3 / 36 (8.33%)	0 / 37 (0.00%)	
occurrences (all)	3	0	
Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	0 / 36 (0.00%)	3 / 37 (8.11%)	
occurrences (all)	0	3	
VULVOVAGINAL PRURITUS			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
COUGH			
subjects affected / exposed	12 / 36 (33.33%)	13 / 37 (35.14%)	
occurrences (all)	20	20	
DYSPHONIA			
subjects affected / exposed	6 / 36 (16.67%)	3 / 37 (8.11%)	
occurrences (all)	7	4	
DYSPNOEA			
subjects affected / exposed	11 / 36 (30.56%)	10 / 37 (27.03%)	
occurrences (all)	15	15	
DYSPNOEA EXERTIONAL			
subjects affected / exposed	9 / 36 (25.00%)	5 / 37 (13.51%)	
occurrences (all)	11	6	
EPISTAXIS			
subjects affected / exposed	6 / 36 (16.67%)	6 / 37 (16.22%)	
occurrences (all)	6	8	
HICCUPS			

subjects affected / exposed	1 / 36 (2.78%)	3 / 37 (8.11%)	
occurrences (all)	1	3	
LUNG DISORDER			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	1	2	
NASAL CONGESTION			
subjects affected / exposed	2 / 36 (5.56%)	5 / 37 (13.51%)	
occurrences (all)	2	6	
OROPHARYNGEAL PAIN			
subjects affected / exposed	5 / 36 (13.89%)	4 / 37 (10.81%)	
occurrences (all)	8	5	
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
PRODUCTIVE COUGH			
subjects affected / exposed	5 / 36 (13.89%)	2 / 37 (5.41%)	
occurrences (all)	5	3	
PULMONARY EMBOLISM			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	2	
RALES			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
RHINORRHOEA			
subjects affected / exposed	4 / 36 (11.11%)	5 / 37 (13.51%)	
occurrences (all)	4	7	
SINUS CONGESTION			
subjects affected / exposed	4 / 36 (11.11%)	2 / 37 (5.41%)	
occurrences (all)	4	2	
THROAT IRRITATION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences (all)	0	1	
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	

Psychiatric disorders			
AGGRESSION			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
ANXIETY			
subjects affected / exposed	5 / 36 (13.89%)	1 / 37 (2.70%)	
occurrences (all)	5	1	
CONFUSIONAL STATE			
subjects affected / exposed	1 / 36 (2.78%)	3 / 37 (8.11%)	
occurrences (all)	1	3	
DEPRESSED MOOD			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
DEPRESSION			
subjects affected / exposed	4 / 36 (11.11%)	3 / 37 (8.11%)	
occurrences (all)	4	4	
INSOMNIA			
subjects affected / exposed	10 / 36 (27.78%)	15 / 37 (40.54%)	
occurrences (all)	12	16	
MOOD SWINGS			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	1	2	
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	5 / 36 (13.89%)	4 / 37 (10.81%)	
occurrences (all)	8	8	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	3 / 36 (8.33%)	4 / 37 (10.81%)	
occurrences (all)	4	6	
BLOOD ALKALINE PHOSPHATASE INCREASED			

subjects affected / exposed	3 / 36 (8.33%)	1 / 37 (2.70%)	
occurrences (all)	3	2	
BLOOD BICARBONATE DECREASED			
subjects affected / exposed	7 / 36 (19.44%)	4 / 37 (10.81%)	
occurrences (all)	13	9	
BLOOD CREATININE INCREASED			
subjects affected / exposed	5 / 36 (13.89%)	4 / 37 (10.81%)	
occurrences (all)	8	10	
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	4 / 36 (11.11%)	1 / 37 (2.70%)	
occurrences (all)	7	4	
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
BLOOD UREA INCREASED			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	3	
CARDIAC MURMUR			
subjects affected / exposed	3 / 36 (8.33%)	1 / 37 (2.70%)	
occurrences (all)	3	1	
EJECTION FRACTION DECREASED			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
IMMUNOGLOBULINS DECREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	3 / 36 (8.33%)	1 / 37 (2.70%)	
occurrences (all)	7	1	
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	3 / 36 (8.33%)	1 / 37 (2.70%)	
occurrences (all)	3	2	
PROTEIN TOTAL INCREASED			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
PROTHROMBIN TIME PROLONGED			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	3	3	
WEIGHT DECREASED			
subjects affected / exposed	7 / 36 (19.44%)	4 / 37 (10.81%)	
occurrences (all)	9	4	
WEIGHT INCREASED			
subjects affected / exposed	1 / 36 (2.78%)	3 / 37 (8.11%)	
occurrences (all)	1	3	
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	3	
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
CONTUSION			
subjects affected / exposed	4 / 36 (11.11%)	4 / 37 (10.81%)	
occurrences (all)	4	5	
FALL			
subjects affected / exposed	5 / 36 (13.89%)	4 / 37 (10.81%)	
occurrences (all)	5	4	
JOINT DISLOCATION			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
LIGAMENT SPRAIN			

subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences (all)	1	0	
SKIN ABRASION			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
STOMA SITE PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
SUNBURN			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 36 (2.78%)	3 / 37 (8.11%)	
occurrences (all)	1	3	
PALPITATIONS			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	3	2	
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
BALANCE DISORDER			
subjects affected / exposed	1 / 36 (2.78%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
DIZZINESS			
subjects affected / exposed	12 / 36 (33.33%)	7 / 37 (18.92%)	
occurrences (all)	16	12	
DYSGEUSIA			

subjects affected / exposed	9 / 36 (25.00%)	6 / 37 (16.22%)	
occurrences (all)	10	7	
HEADACHE			
subjects affected / exposed	14 / 36 (38.89%)	7 / 37 (18.92%)	
occurrences (all)	20	8	
HYPOAESTHESIA			
subjects affected / exposed	5 / 36 (13.89%)	3 / 37 (8.11%)	
occurrences (all)	5	3	
HYPOGEUSIA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
MEMORY IMPAIRMENT			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	2	
NEURALGIA			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	8 / 36 (22.22%)	7 / 37 (18.92%)	
occurrences (all)	11	8	
PARAESTHESIA			
subjects affected / exposed	6 / 36 (16.67%)	3 / 37 (8.11%)	
occurrences (all)	7	3	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	3 / 36 (8.33%)	5 / 37 (13.51%)	
occurrences (all)	3	5	
PSYCHOMOTOR HYPERACTIVITY			
subjects affected / exposed	3 / 36 (8.33%)	0 / 37 (0.00%)	
occurrences (all)	3	0	
SCIATICA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
SINUS HEADACHE			
subjects affected / exposed	3 / 36 (8.33%)	1 / 37 (2.70%)	
occurrences (all)	3	1	
SOMNOLENCE			

subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
SYNCOPE			
subjects affected / exposed	6 / 36 (16.67%)	1 / 37 (2.70%)	
occurrences (all)	7	1	
TREMOR			
subjects affected / exposed	3 / 36 (8.33%)	5 / 37 (13.51%)	
occurrences (all)	3	6	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	17 / 36 (47.22%)	13 / 37 (35.14%)	
occurrences (all)	29	24	
FEBRILE NEUTROPENIA			
subjects affected / exposed	2 / 36 (5.56%)	3 / 37 (8.11%)	
occurrences (all)	2	3	
HAEMOGLOBINAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
INCREASED TENDENCY TO BRUISE			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
LEUKOPENIA			
subjects affected / exposed	8 / 36 (22.22%)	6 / 37 (16.22%)	
occurrences (all)	13	8	
LYMPHADENOPATHY			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	3	3	
LYMPHOPENIA			
subjects affected / exposed	12 / 36 (33.33%)	8 / 37 (21.62%)	
occurrences (all)	23	11	
NEUTROPENIA			
subjects affected / exposed	12 / 36 (33.33%)	9 / 37 (24.32%)	
occurrences (all)	25	17	

PANCYTOPENIA			
subjects affected / exposed	0 / 36 (0.00%)	3 / 37 (8.11%)	
occurrences (all)	0	3	
THROMBOCYTOPENIA			
subjects affected / exposed	12 / 36 (33.33%)	10 / 37 (27.03%)	
occurrences (all)	21	18	
Ear and labyrinth disorders			
HYPOACUSIS			
subjects affected / exposed	1 / 36 (2.78%)	3 / 37 (8.11%)	
occurrences (all)	1	3	
TINNITUS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
VERTIGO			
subjects affected / exposed	3 / 36 (8.33%)	3 / 37 (8.11%)	
occurrences (all)	3	4	
Eye disorders			
CATARACT			
subjects affected / exposed	4 / 36 (11.11%)	6 / 37 (16.22%)	
occurrences (all)	4	7	
DRY EYE			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
EYE IRRITATION			
subjects affected / exposed	3 / 36 (8.33%)	3 / 37 (8.11%)	
occurrences (all)	3	3	
OCULAR HYPERAEMIA			
subjects affected / exposed	1 / 36 (2.78%)	3 / 37 (8.11%)	
occurrences (all)	1	4	
VISION BLURRED			
subjects affected / exposed	9 / 36 (25.00%)	5 / 37 (13.51%)	
occurrences (all)	14	5	
VISUAL ACUITY REDUCED			
subjects affected / exposed	3 / 36 (8.33%)	1 / 37 (2.70%)	
occurrences (all)	3	1	
VITREOUS FLOATERS			

subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	4 / 36 (11.11%)	2 / 37 (5.41%)	
occurrences (all)	7	2	
ABDOMINAL PAIN			
subjects affected / exposed	7 / 36 (19.44%)	7 / 37 (18.92%)	
occurrences (all)	9	8	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	5 / 36 (13.89%)	4 / 37 (10.81%)	
occurrences (all)	6	6	
CONSTIPATION			
subjects affected / exposed	18 / 36 (50.00%)	19 / 37 (51.35%)	
occurrences (all)	25	22	
DIARRHOEA			
subjects affected / exposed	24 / 36 (66.67%)	25 / 37 (67.57%)	
occurrences (all)	71	56	
DIVERTICULAR PERFORATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
DRY MOUTH			
subjects affected / exposed	3 / 36 (8.33%)	2 / 37 (5.41%)	
occurrences (all)	3	2	
DYSPEPSIA			
subjects affected / exposed	8 / 36 (22.22%)	2 / 37 (5.41%)	
occurrences (all)	10	2	
FLATULENCE			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences (all)	0	1	
GASTROINTESTINAL MOTILITY DISORDER			

subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
GASTROINTESTINAL PERFORATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	3 / 36 (8.33%)	4 / 37 (10.81%)	
occurrences (all)	3	5	
HAEMATOCHEZIA			
subjects affected / exposed	3 / 36 (8.33%)	0 / 37 (0.00%)	
occurrences (all)	5	0	
HAEMORRHOIDS			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
NAUSEA			
subjects affected / exposed	18 / 36 (50.00%)	17 / 37 (45.95%)	
occurrences (all)	35	27	
PARAESTHESIA ORAL			
subjects affected / exposed	3 / 36 (8.33%)	0 / 37 (0.00%)	
occurrences (all)	3	0	
STOMATITIS			
subjects affected / exposed	3 / 36 (8.33%)	1 / 37 (2.70%)	
occurrences (all)	5	1	
TOOTH DISORDER			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
TOOTHACHE			
subjects affected / exposed	3 / 36 (8.33%)	0 / 37 (0.00%)	
occurrences (all)	3	0	
VOMITING			
subjects affected / exposed	11 / 36 (30.56%)	6 / 37 (16.22%)	
occurrences (all)	18	8	
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			

subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	3	0	
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	3 / 36 (8.33%)	0 / 37 (0.00%)	
occurrences (all)	3	0	
BLISTER			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
DRY SKIN			
subjects affected / exposed	1 / 36 (2.78%)	1 / 37 (2.70%)	
occurrences (all)	1	3	
ECCHYMOSIS			
subjects affected / exposed	3 / 36 (8.33%)	3 / 37 (8.11%)	
occurrences (all)	3	3	
ERYTHEMA			
subjects affected / exposed	3 / 36 (8.33%)	4 / 37 (10.81%)	
occurrences (all)	3	5	
HYPERHIDROSIS			
subjects affected / exposed	4 / 36 (11.11%)	5 / 37 (13.51%)	
occurrences (all)	5	5	
INGROWING NAIL			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
NIGHT SWEATS			
subjects affected / exposed	8 / 36 (22.22%)	10 / 37 (27.03%)	
occurrences (all)	12	12	
PRURITUS			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	2	
RASH			
subjects affected / exposed	9 / 36 (25.00%)	9 / 37 (24.32%)	
occurrences (all)	16	15	
RASH GENERALISED			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	3	

RASH MACULAR			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
RASH MACULO-PAPULAR			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	3	1	
SCAB			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
SKIN DISCOLOURATION			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
SKIN LESION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences (all)	0	2	
URTICARIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences (all)	1	0	
DYSURIA			
subjects affected / exposed	4 / 36 (11.11%)	2 / 37 (5.41%)	
occurrences (all)	4	2	
HAEMATURIA			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	1	2	
POLLAKIURIA			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
RENAL FAILURE			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	1	3	
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	12 / 36 (33.33%)	8 / 37 (21.62%)	
occurrences (all)	13	9	
BACK PAIN			
subjects affected / exposed	17 / 36 (47.22%)	14 / 37 (37.84%)	
occurrences (all)	27	15	
BONE PAIN			
subjects affected / exposed	4 / 36 (11.11%)	8 / 37 (21.62%)	
occurrences (all)	5	12	
MUSCLE SPASMS			
subjects affected / exposed	22 / 36 (61.11%)	23 / 37 (62.16%)	
occurrences (all)	28	32	
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	4 / 36 (11.11%)	3 / 37 (8.11%)	
occurrences (all)	7	3	
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	6 / 36 (16.67%)	4 / 37 (10.81%)	
occurrences (all)	8	4	
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	3	1	
MYALGIA			
subjects affected / exposed	6 / 36 (16.67%)	1 / 37 (2.70%)	
occurrences (all)	8	1	
NECK PAIN			
subjects affected / exposed	4 / 36 (11.11%)	3 / 37 (8.11%)	
occurrences (all)	4	4	
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	

PAIN IN EXTREMITY			
subjects affected / exposed	10 / 36 (27.78%)	13 / 37 (35.14%)	
occurrences (all)	10	16	
PAIN IN JAW			
subjects affected / exposed	0 / 36 (0.00%)	1 / 37 (2.70%)	
occurrences (all)	0	1	
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	8 / 36 (22.22%)	10 / 37 (27.03%)	
occurrences (all)	10	15	
CELLULITIS			
subjects affected / exposed	4 / 36 (11.11%)	4 / 37 (10.81%)	
occurrences (all)	8	5	
CONJUNCTIVITIS			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	2	2	
EAR INFECTION			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	4	0	
FUNGAL INFECTION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences (all)	1	0	
GASTROENTERITIS			
subjects affected / exposed	2 / 36 (5.56%)	3 / 37 (8.11%)	
occurrences (all)	4	4	
GASTROENTERITIS VIRAL			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	4	0	
GINGIVITIS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
HERPES ZOSTER			
subjects affected / exposed	4 / 36 (11.11%)	0 / 37 (0.00%)	
occurrences (all)	4	0	
INFLUENZA			

subjects affected / exposed	8 / 36 (22.22%)	3 / 37 (8.11%)	
occurrences (all)	9	4	
LOCALISED INFECTION			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	2	2	
LUNG INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	3 / 37 (8.11%)	
occurrences (all)	0	3	
NASOPHARYNGITIS			
subjects affected / exposed	10 / 36 (27.78%)	9 / 37 (24.32%)	
occurrences (all)	21	15	
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 36 (2.78%)	5 / 37 (13.51%)	
occurrences (all)	1	6	
ORAL HERPES			
subjects affected / exposed	2 / 36 (5.56%)	1 / 37 (2.70%)	
occurrences (all)	2	1	
PHARYNGITIS			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	1	2	
PNEUMONIA			
subjects affected / exposed	7 / 36 (19.44%)	9 / 37 (24.32%)	
occurrences (all)	10	11	
PNEUMONIA VIRAL			
subjects affected / exposed	2 / 36 (5.56%)	0 / 37 (0.00%)	
occurrences (all)	2	0	
RHINITIS			
subjects affected / exposed	5 / 36 (13.89%)	8 / 37 (21.62%)	
occurrences (all)	8	10	
SEPSIS			
subjects affected / exposed	3 / 36 (8.33%)	2 / 37 (5.41%)	
occurrences (all)	3	2	
SINUSITIS			
subjects affected / exposed	5 / 36 (13.89%)	3 / 37 (8.11%)	
occurrences (all)	6	11	
UPPER RESPIRATORY TRACT			

INFECTION			
subjects affected / exposed	19 / 36 (52.78%)	15 / 37 (40.54%)	
occurrences (all)	46	54	
UPPER RESPIRATORY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
URINARY TRACT INFECTION			
subjects affected / exposed	6 / 36 (16.67%)	5 / 37 (13.51%)	
occurrences (all)	13	5	
VIRAL INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	10 / 36 (27.78%)	8 / 37 (21.62%)	
occurrences (all)	12	11	
DEHYDRATION			
subjects affected / exposed	3 / 36 (8.33%)	2 / 37 (5.41%)	
occurrences (all)	4	2	
DIABETES MELLITUS			
subjects affected / exposed	1 / 36 (2.78%)	2 / 37 (5.41%)	
occurrences (all)	1	2	
GOUT			
subjects affected / exposed	0 / 36 (0.00%)	2 / 37 (5.41%)	
occurrences (all)	0	2	
HYPERCALCAEMIA			
subjects affected / exposed	1 / 36 (2.78%)	3 / 37 (8.11%)	
occurrences (all)	1	3	
HYPERGLYCAEMIA			
subjects affected / exposed	9 / 36 (25.00%)	12 / 37 (32.43%)	
occurrences (all)	24	24	
HYPERKALAEMIA			

subjects affected / exposed	3 / 36 (8.33%)	1 / 37 (2.70%)	
occurrences (all)	3	1	
HYPERNATRAEMIA			
subjects affected / exposed	3 / 36 (8.33%)	0 / 37 (0.00%)	
occurrences (all)	3	0	
HYPOALBUMINAEMIA			
subjects affected / exposed	5 / 36 (13.89%)	3 / 37 (8.11%)	
occurrences (all)	6	8	
HYPOCALCAEMIA			
subjects affected / exposed	3 / 36 (8.33%)	3 / 37 (8.11%)	
occurrences (all)	3	3	
HYPOKALAEMIA			
subjects affected / exposed	7 / 36 (19.44%)	7 / 37 (18.92%)	
occurrences (all)	21	12	
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 36 (5.56%)	2 / 37 (5.41%)	
occurrences (all)	4	4	
HYPONATRAEMIA			
subjects affected / exposed	3 / 36 (8.33%)	2 / 37 (5.41%)	
occurrences (all)	3	2	
HYPOPHOSPHATAEMIA			
subjects affected / exposed	2 / 36 (5.56%)	5 / 37 (13.51%)	
occurrences (all)	2	6	
METABOLIC ACIDOSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 37 (0.00%)	
occurrences (all)	0	0	
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 36 (0.00%)	3 / 37 (8.11%)	
occurrences (all)	0	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 August 2008	The primary purpose of this amendment was to add pretreatment with an antihistamine and acetaminophen before or during study drug infusion and to slow the infusion rate of the elotuzumab dose.
23 April 2009	The primary purpose of this amendment was to reduce the maximum number of subjects in phase 1 treated at the maximum tolerated dose (MTD) from 36 to 33 subjects because no dose-limiting toxicities (DLTs) were observed; extend the duration of the treatment period beyond 6 cycles to allow treatment to continue until the subject experienced disease progression or unacceptable toxicity; and increase the flow rate of elotuzumab infusion as the subject was able to tolerate (the rate remained capped at 2 mL/min).
30 September 2009	The primary purpose of this amendment was to expand the study design from phase 1b to phase 1b/2 and to enroll an additional 60 subjects; include pretreatment with IV methylprednisolone, diphenhydramine and acetaminophen before every elotuzumab infusion; and specify that the weekly dose of dexamethasone was to be administered 12 hours before all elotuzumab infusions.
19 March 2010	The primary purpose of this amendment was to revise predosing instructions (change the first weekly 40 mg oral dexamethasone administration from 2 to 4 hours to 1 to 3 hours prior to elotuzumab, and to allow split dosing of dexamethasone prior to the second dose and all subsequent doses of elotuzumab)
29 July 2010	The primary purpose of this amendment was to enroll and additional 10 subjects; update the predose of dexamethasone to a split dose of 28 mg orally (between 3 – 24 hours prior to elotuzumab infusion) and 8 mg IV (at least 45 minutes prior to infusion), and dexamethasone 28 mg orally was given on elotuzumab dosing days to reducing total dexamethasone dosing to a total biologic equivalent dose of 40 mg oral dexamethasone, the standard of care with a maximum 40 mg; and increase the maximum allowable elotuzumab infusion rate to 5 mL/min for subjects who had completed at least 4 cycles without an infusion reaction.
28 January 2011	The primary purpose of this amendment was to allow reduction to 20 mg weekly dexamethasone dose for subjects who developed intolerance to dexamethasone.
23 May 2012	The primary purpose of this amendment was to decrease the frequency of vital sign measurements and blood tests; and to discontinue DMC oversight (safety to be monitored by Bristol-Myers Squibb and Abbott).
20 November 2012	The primary purpose of this amendment was to remove serum soluble SLAMF7 and cytokines at the last cycle Day 28/early termination visit and the 30- and 60-day follow-up visits; and to incorporate changes related to Sponsor changing from Abbott to AbbVie (Abbott separated into 2 publicly traded companies, Abbott and AbbVie).
21 November 2013	The primary purpose of this amendment was to reduce the burden of assessments during treatment and the burden of long-term follow-up.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported