



Clinical trial results:

A Phase 1/2 Dose Escalation Safety, Pharmacokinetic and Efficacy Study of Multiple Intravenous Administrations of a Humanized Monoclonal Antibody (SAR650984) Against CD38 in Patients With Selected CD38+ Hematological Malignancies

Summary

EudraCT number	2013-001418-13
Trial protocol	IT GR GB FI BE AT
Global end of trial date	13 July 2023

Results information

Result version number	v1
This version publication date	14 July 2024
First version publication date	14 July 2024

Trial information

Trial identification

Sponsor protocol code	TED10893
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01084252
WHO universal trial number (UTN)	U1111-1116-5472

Notes:

Sponsors

Sponsor organisation name	Sanofi aventis recherche & développement
Sponsor organisation address	1 avenue Pierre Brossolette, Chilly-Mazarin, France, 91380
Public contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.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	02 August 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	13 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase 1: To determine the maximum tolerated/administered dose (MTD/MAD) of isatuximab according to the investigational product (IP)-related dose limiting toxicities (DLTs) observed in participants with cluster of differentiation (CD)38+-selected hematological malignancies.

Phase 2 Stage 1: To evaluate the activity of single agent isatuximab at different doses/schedules and to select dose and regimen for Phase 2 Stage 2.

Phase 2 Stage 2: To further evaluate the activity in terms of overall response rate (ORR) of isatuximab (SAR650984) at the selected dose/schedule from Stage 1, as single agent (isatuximab arm) and in combination with dexamethasone in participants with relapsed or relapsed/refractory multiple myeloma (RRMM)

Protection of trial subjects:

Participants were fully informed of all pertinent aspects of clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the participant and considering the local culture. During the course of the trial, participants were provided with individual participant cards indicating the nature of the trial the participant is participating, contact details and any information needed in the event of a medical emergency. Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 May 2010
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	Argentina: 5
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	Brazil: 17
Country: Number of subjects enrolled	Chile: 6
Country: Number of subjects enrolled	Finland: 10
Country: Number of subjects enrolled	France: 12
Country: Number of subjects enrolled	Greece: 21
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	Peru: 7

Country: Number of subjects enrolled	Russian Federation: 13
Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	Türkiye: 9
Country: Number of subjects enrolled	Ukraine: 7
Country: Number of subjects enrolled	United Kingdom: 9
Country: Number of subjects enrolled	United States: 191
Worldwide total number of subjects	350
EEA total number of subjects	78

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)	168
From 65 to 84 years	179
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

Study participants were involved in the study from 11 May 2010 at 59 centers in 18 countries. A total of 418 participants were screened, of which 351 participants were enrolled. A total of 67 participants had screen failures due to failure to meet inclusion criteria. 1 participant was enrolled but not treated.

Pre-assignment

Screening details:

Study consisted 2 phases; Phase 1=dose escalation part of isatuximab to determine MTD. Phase 2=for efficacy and safety evaluation of isatuximab with or without dexamethasone. It consisted of 2 stages: Stage 1 (comprised of 1a and 1b) and Stage 2. Here Completed'=Participants with end of treatment or death from any cause forms completed.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase1: Isatuximab \leq 1 mg/kg every 2 weeks (Q2W)

Arm description:

Participants with CD38+ hematological malignancies (HM), received Isatuximab at any one of the dose less than or equal to (\leq) 1 milligram per kilogram (mg/kg) (i.e. either 0.0001 mg/kg or 0.001 mg/kg or 0.01 mg/kg or 0.03 mg/kg, or 0.1 mg/kg or 0.3 mg/kg or 1 mg/kg) as intravenous (IV) infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal by participant, investigator's decision, and/or availability of study drug.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab \leq 1 mg/kg was administered by IV infusion every week or Q2W in 14-day cycles until protocol defined discontinuation criteria was met.

Arm title	Phase 1: Isatuximab 3mg/kg Q2W
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Arm description:

Participants with CD38+ HM, received Isatuximab 3 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 3 mg/kg was administered by IV infusion every week or Q2W in 14-day cycles until protocol defined discontinuation criteria was met.

Arm title	Phase 1: Isatuximab 5 mg/kg Q2W
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Arm description:

Participants with CD38+ HM, received Isatuximab 5 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 5 mg/kg was administered by IV infusion every week or Q2W in 14-day cycles until protocol defined discontinuation criteria was met.

Arm title	Phase1:Isatuximab (CD38+HM and Standard Risk Multiple Myeloma)
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Arm description:

Participants with CD38+ HM along with participants with standard risk multiple myeloma were included in this arm and, received Isatuximab 10 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 10 mg/kg was administered by IV infusion on Day 1 of each 14-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
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Arm description:

Participants with CD38+ HM along with participants with high risk multiple myeloma were included in this arm and, received Isatuximab 10 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 10 mg/kg was administered by IV infusion on Day 1 of each 14-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 1: Isatuximab 10 mg/kg Every Week (QW)
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Arm description:

Participants with CD38+ HM, received Isatuximab 10 mg/kg, as IV infusion QW, i.e. on Day 1 and 8 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 10 mg/kg was administered by IV infusion on Day 1 and 8 of each 14-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 1: Isatuximab 20 mg/kg Q2W
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Arm description:

Participants with CD38+ HM, received Isatuximab 20 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 20 mg/kg was administered by IV infusion on Day 1 of each 14-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 1: Isatuximab 20 mg/kg QW
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Arm description:

Participants with CD38+ HM, received Isatuximab 20 mg/kg, as IV infusion QW, i.e. on Day 1 and 8 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 20 mg/kg was administered by IV infusion on Day 1 and 8 of each 14-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W
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Arm description:

Participants with multiple Myeloma received Isatuximab 3 mg/kg, as IV infusion on Day 1 and Day 15 of each 28-day cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 3 mg/kg was administered by IV infusion on Day 1 and 15 of each 28-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W
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Arm description:

Participants with multiple Myeloma received Isatuximab 10 mg/kg, as IV infusion on Day 1 and Day 15 of each 28-day cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Arm type	Experimental
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Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 10 mg/kg was administered by IV infusion on Day 1 and 15 of each 28-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W
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Arm description:

Participants with multiple Myeloma received Isatuximab 10 mg/kg, as IV infusion Q2W, i.e. on Day 1 and Day 15 of Cycle 1 and 2 (each cycle 28 days), then every 4 weeks (Q4W), i.e. on Day 1 of each 28-days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 10 mg/kg was administered by IV infusion on Day 1 and 15 of Cycle 1 and 2 (each cycle 28 days) then Q4W on Day 1 of each 28-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
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Arm description:

Participants with multiple Myeloma received Isatuximab 20 mg/kg, as IV infusion QW, i.e. on Day 1, 8, 15 and 22 of Cycle 1 and 2 (each cycle 28 days), then Q2W, i.e. on Day 1 and Day 15 of each 28-days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 20 mg/kg was administered by IV infusion on Days 1, 8, 15 and 22 of Cycle 1 and 2 (each cycle 28 days) then Q2W on Days 1 and 15 of each 28-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 2 Stage 2: Isatuximab alone
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Arm description:

Participants with relapsed or RRMM, received Isatuximab 20 mg/kg, as IV infusion on Day 1, 8, 15 and Day 22 of Cycle 1 (28 days) and then on Day 1 and 15 of each subsequent 28-day cycles until unacceptable AE, disease progression, poor compliance to the study protocol, study termination, lost to follow up or investigator's decision.

Arm type	Experimental
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Isatuximab 20 mg/kg was administered by IV infusion on Days 1, 8, 15 and 22 of Cycle 1 (28 days) then on Days 1 and 15 of each subsequent 28-day cycle until protocol defined discontinuation criteria was met.

Arm title	Phase 2 Stage 2: Isatuximab + Dexamethasone
Arm description:	
Participants with relapsed or RRMM, received Isatuximab 20 mg/kg, as IV infusion on Day 1, 8, 15 and Day 22 of Cycle 1 (28 days) and then on Day 1 and 15 of each subsequent 28-day cycles along with dexamethasone: tablet or as IV infusion (40 mg/day for less than [$<$] 75 years of age; 20 mg/day for greater than or equal to [\geq] 75 years of age) on Days 1, 8, 15 and 22 of each 28 days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination, lost to follow up or investigator's decision.	
Arm type	Experimental
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion, Tablet
Routes of administration	Oral use, Intravenous use
Dosage and administration details:	
Dexamethasone was administered (40 mg/day for <75 years of age; 20 mg/day for ≥ 75 years of age) on Days 1, 8, 15 and 22 of each 28-day cycle until protocol defined discontinuation criteria was met.	
Investigational medicinal product name	Isatuximab
Investigational medicinal product code	SAR650984
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Isatuximab 20 mg/kg was administered by IV infusion on Days 1, 8, 15 and 22 of Cycle 1 (28 days) then on Days 1 and 15 of each subsequent 28-day cycle until protocol defined discontinuation criteria was met.	

Number of subjects in period 1	Phase1: Isatuximab ≤ 1 mg/kg every 2 weeks (Q2W)	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W
Started	16	6	3
All Treated (AT) population	16	6	3
Completed	16	6	3

Number of subjects in period 1	Phase1:Isatuximab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)	Phase 1: Isatuximab 10 mg/kg Every Week (QW)
Started	26	18	6
All Treated (AT) population	26	18	6
Completed	26	18	6

Number of subjects in period 1	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W
Started	7	7	23
All Treated (AT) population	7	7	23
Completed	7	7	23

Number of subjects in period 1	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Started	24	25	25
All Treated (AT) population	24	25	25
Completed	24	25	25

Number of subjects in period 1	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone
Started	109	55
All Treated (AT) population	109	55
Completed	109	55

Baseline characteristics

Reporting groups

Reporting group title	Phase1: Isatuximab ≤1 mg/kg every 2 weeks (Q2W)
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Reporting group description:

Participants with CD38+ hematological malignancies (HM), received Isatuximab at any one of the dose less than or equal to (≤) 1 milligram per kilogram (mg/kg) (i.e. either 0.0001 mg/kg or 0.001 mg/kg or 0.01 mg/kg or 0.03 mg/kg, or 0.1 mg/kg or 0.3 mg/kg or 1 mg/kg) as intravenous (IV) infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal by participant, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 3mg/kg Q2W
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 3 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 5 mg/kg Q2W
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 5 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase1:Isatuximab (CD38+HM and Standard Risk Multiple Myeloma)
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Reporting group description:

Participants with CD38+ HM along with participants with standard risk multiple myeloma were included in this arm and, received Isatuximab 10 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
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Reporting group description:

Participants with CD38+ HM along with participants with high risk multiple myeloma were included in this arm and, received Isatuximab 10 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 10 mg/kg Every Week (QW)
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 10 mg/kg, as IV infusion QW, i.e. on Day 1 and 8 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 20 mg/kg Q2W
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 20 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 20 mg/kg QW
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 20 mg/kg, as IV infusion QW, i.e. on Day 1 and 8 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 3 mg/kg, as IV infusion on Day 1 and Day 15 of each 28-day cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 10 mg/kg, as IV infusion on Day 1 and Day 15 of each 28-day cycle until unacceptable AE, disease progression, poor compliance to the study protocol,

study termination or lost to follow up.

Reporting group title	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 10 mg/kg, as IV infusion Q2W, i.e. on Day 1 and Day 15 of Cycle 1 and 2 (each cycle 28 days), then every 4 weeks (Q4W), i.e. on Day 1 of each 28-days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 20 mg/kg, as IV infusion QW, i.e. on Day 1, 8, 15 and 22 of Cycle 1 and 2 (each cycle 28 days), then Q2W, i.e. on Day 1 and Day 15 of each 28-days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 2: Isatuximab alone
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Reporting group description:

Participants with relapsed or RRMM, received Isatuximab 20 mg/kg, as IV infusion on Day 1, 8, 15 and Day 22 of Cycle 1 (28 days) and then on Day 1 and 15 of each subsequent 28-day cycles until unacceptable AE, disease progression, poor compliance to the study protocol, study termination, lost to follow up or investigator's decision.

Reporting group title	Phase 2 Stage 2: Isatuximab + Dexamethasone
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Reporting group description:

Participants with relapsed or RRMM, received Isatuximab 20 mg/kg, as IV infusion on Day 1, 8, 15 and Day 22 of Cycle 1 (28 days) and then on Day 1 and 15 of each subsequent 28-day cycles along with dexamethasone: tablet or as IV infusion (40 mg/day for less than [$<$] 75 years of age; 20 mg/day for greater than or equal to [\geq] 75 years of age) on Days 1, 8, 15 and 22 of each 28 days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination, lost to follow up or investigator's decision.

Reporting group values	Phase1: Isatuximab ≤ 1 mg/kg every 2 weeks (Q2W)	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W
Number of subjects	16	6	3
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	64.9 ± 11.6	63.5 ± 6.2	62.0 ± 3.5
Sex: Female, Male Units: participants			
Female	5	3	1
Male	11	3	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	14	4	3
More than one race	0	0	0
Unknown or Not Reported	2	1	0

Reporting group values	Phase1:Isatuximab	Phase 1: Isatuximab	Phase 1: Isatuximab
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	(CD38+HM and Standard Risk Multiple Myeloma)	(CD38 + HM and High Risk Multiple Myeloma)	10 mg/kg Every Week (QW)
Number of subjects	26	18	6
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	65.0	60.8	61.7
standard deviation	± 7.2	± 12.6	± 12.7
Sex: Female, Male			
Units: participants			
Female	11	9	2
Male	15	9	4
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	2	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	20	13	4
More than one race	0	0	0
Unknown or Not Reported	6	2	2

Reporting group values	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W
Number of subjects	7	7	23
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	63.3	60.0	63.2
standard deviation	± 10.0	± 8.3	± 8.9
Sex: Female, Male			
Units: participants			
Female	2	3	11
Male	5	4	12
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	6	7	21
More than one race	0	0	0
Unknown or Not Reported	1	0	1

Reporting group values	Phase 2 Stage 1a: Isatuximab 10	Phase 2 Stage 1a: Isatuximab 10mg/kg	Phase 2 Stage 1b: Isatuximab 20mg/kg
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	mg/kg Q2W	Q2W; Then Q4W	QW and Then Q2W
Number of subjects	24	25	25
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	63.9	61.0	61.1
standard deviation	± 8.8	± 7.3	± 10.3
Sex: Female, Male			
Units: participants			
Female	11	7	13
Male	13	18	12
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	2	4	3
White	19	19	21
More than one race	0	0	0
Unknown or Not Reported	2	1	0

Reporting group values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone	Total
Number of subjects	109	55	350
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	66.6	66.3	
standard deviation	± 8.8	± 8.9	-
Sex: Female, Male			
Units: participants			
Female	58	26	162
Male	51	29	188
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	2	0	3
Asian	0	1	4
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	5	3	20
White	91	45	287
More than one race	0	0	0
Unknown or Not Reported	11	6	35

End points

End points reporting groups

Reporting group title	Phase1: Isatuximab <=1 mg/kg every 2 weeks (Q2W)
Reporting group description: Participants with CD38+ hematological malignancies (HM), received Isatuximab at any one of the dose less than or equal to (<=) 1 milligram per kilogram (mg/kg) (i.e. either 0.0001 mg/kg or 0.001 mg/kg or 0.01 mg/kg or 0.03 mg/kg, or 0.1 mg/kg or 0.3 mg/kg or 1 mg/kg) as intravenous (IV) infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal by participant, investigator's decision, and/or availability of study drug.	
Reporting group title	Phase 1: Isatuximab 3mg/kg Q2W
Reporting group description: Participants with CD38+ HM, received Isatuximab 3 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.	
Reporting group title	Phase 1: Isatuximab 5 mg/kg Q2W
Reporting group description: Participants with CD38+ HM, received Isatuximab 5 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.	
Reporting group title	Phase1:Isatuximab (CD38+HM and Standard Risk Multiple Myeloma)
Reporting group description: Participants with CD38+ HM along with participants with standard risk multiple myeloma were included in this arm and, received Isatuximab 10 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.	
Reporting group title	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
Reporting group description: Participants with CD38+ HM along with participants with high risk multiple myeloma were included in this arm and, received Isatuximab 10 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.	
Reporting group title	Phase 1: Isatuximab 10 mg/kg Every Week (QW)
Reporting group description: Participants with CD38+ HM, received Isatuximab 10 mg/kg, as IV infusion QW, i.e. on Day 1 and 8 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.	
Reporting group title	Phase 1: Isatuximab 20 mg/kg Q2W
Reporting group description: Participants with CD38+ HM, received Isatuximab 20 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.	
Reporting group title	Phase 1: Isatuximab 20 mg/kg QW
Reporting group description: Participants with CD38+ HM, received Isatuximab 20 mg/kg, as IV infusion QW, i.e. on Day 1 and 8 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.	
Reporting group title	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W
Reporting group description: Participants with multiple Myeloma received Isatuximab 3 mg/kg, as IV infusion on Day 1 and Day 15 of each 28-day cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.	
Reporting group title	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W
Reporting group description: Participants with multiple Myeloma received Isatuximab 10 mg/kg, as IV infusion on Day 1 and Day 15 of each 28-day cycle until unacceptable AE, disease progression, poor compliance to the study protocol,	

study termination or lost to follow up.

Reporting group title	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 10 mg/kg, as IV infusion Q2W, i.e. on Day 1 and Day 15 of Cycle 1 and 2 (each cycle 28 days), then every 4 weeks (Q4W), i.e. on Day 1 of each 28-days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 20 mg/kg, as IV infusion QW, i.e. on Day 1, 8, 15 and 22 of Cycle 1 and 2 (each cycle 28 days), then Q2W, i.e. on Day 1 and Day 15 of each 28-days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 2: Isatuximab alone
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Reporting group description:

Participants with relapsed or RRMM, received Isatuximab 20 mg/kg, as IV infusion on Day 1, 8, 15 and Day 22 of Cycle 1 (28 days) and then on Day 1 and 15 of each subsequent 28-day cycles until unacceptable AE, disease progression, poor compliance to the study protocol, study termination, lost to follow up or investigator's decision.

Reporting group title	Phase 2 Stage 2: Isatuximab + Dexamethasone
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Reporting group description:

Participants with relapsed or RRMM, received Isatuximab 20 mg/kg, as IV infusion on Day 1, 8, 15 and Day 22 of Cycle 1 (28 days) and then on Day 1 and 15 of each subsequent 28-day cycles along with dexamethasone: tablet or as IV infusion (40 mg/day for less than [$<$] 75 years of age; 20 mg/day for greater than or equal to [\geq] 75 years of age) on Days 1, 8, 15 and 22 of each 28 days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination, lost to follow up or investigator's decision.

Subject analysis set title	Phase 1: Isatuximab 0.3 mg/kg Q2W
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with CD38+ HM, received Isatuximab 0.3 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Subject analysis set title	Phase 1: Isatuximab 1 mg/kg Q2W
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with CD38+ HM, received Isatuximab 1 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal by participant, investigator's decision, and/or availability of study drug

Subject analysis set title	Phase 1: Isatuximab
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Subject analysis set type	Per protocol
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Subject analysis set description:

All participants who were enrolled in Phase 1 and received Isatuximab.

Primary: Phase 1: Number of Participants With Dose Limiting Toxicities (DLTs)

End point title	Phase 1: Number of Participants With Dose Limiting Toxicities (DLTs) ^{[1][2]}
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End point description:

DLTs were assessed using the national cancer institute common terminology criteria for adverse events (NCI-CTCAE) version 4.03. DLTs were defined as any Grade 3 or higher non-hematological toxicity (with the exception of allergic reaction/hypersensitivity), Grade 4 neutropenia and/or Grade 4 thrombocytopenia lasting longer than 5 days, attributed to isatuximab. Any other toxicity that the Investigator and the Sponsor deemed to be dose-limiting, regardless of the grade, was also considered as DLT. DLT evaluable population included participants who gave their informed consent, received at least 1 dose of isatuximab during Phase 1 and had a DLT assessment at the end of Cycle 2. Data was planned not to be collected and analyzed for the arm: Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma).

End point type	Primary
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End point timeframe:

Day 1 of Cycle 1 up to Day 14 of Cycle 2

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: As the endpoint was descriptive in nature, no statistical analysis was reported.

[2] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase1: Isatuximab <=1 mg/kg every 2 weeks (Q2W)	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	6	3	6
Units: participants	1	1	0	0

End point values	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	6	
Units: participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants With Treatment Emergent Adverse Events (TEAEs)

End point title	Phase 1: Number of Participants With Treatment Emergent Adverse Events (TEAEs) ^{[3][4]}
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End point description:

Adverse event (AE) was defined as any untoward medical occurrence in a participant who received study drug and did not necessarily have to have a causal relationship with the treatment. TEAEs were defined as AEs that developed or worsened during the on-treatment period which was defined as the period from the time of first dose of study treatment until 30 days after the last dose of study treatment. Analysis was performed on AT population which included participants who signed informed consent and received at least 1 dose/even incomplete of isatuximab.

End point type	Primary
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End point timeframe:

From Baseline up to 30 days after the last dose (maximum duration: 120 weeks)

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: As the endpoint was descriptive in nature, no statistical analysis was reported.

[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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase1: Isatuximab <=1 mg/kg every 2 weeks (Q2W)	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	6	3	26
Units: participants	16	6	3	26

End point values	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	6	7	7
Units: participants	18	6	7	6

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2 Stage 1: Percentage of Participants With Overall Response (OR) According to International Myeloma Working Group (IMWG) Uniform Response Criteria

End point title	Phase 2 Stage 1: Percentage of Participants With Overall Response (OR) According to International Myeloma Working Group (IMWG) Uniform Response Criteria ^{[5][6]}
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End point description:

OR defined as participants with stringent complete response (sCR) or complete response (CR) or very good partial response (VGPR) or partial response (PR).Based on IMWG, CR: Negative serum and urine on immunofixation, disappearance of any soft tissue plasmacytomas (STP) and <=5% plasma cells in bone marrow; sCR:CR and normal free light chain (FLC) ratio and no clonal cells in bone marrow; VGPR: Serum and urine M-protein detectable by immunofixation but not on electrophoresis or >=90% reduction in serum M-protein and urine M-protein level <100 mg/24 hours;PR: >=50% reduction of serum M-Protein and reduction in urinary M-protein by >=90% or to <200 mg/24 hours;>=50% decrease in difference between involved and uninvolved FLC levels in place of M-protein criteria or >=50% reduction in plasma cells in place of M-protein if present at baseline.Analysis on AT population which included participants who signed informed consent and received at least 1 dose/even incomplete of isatuximab.

End point type	Primary
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End point timeframe:

From the date of randomization until disease progression or death or data cut-off (maximum duration: 77 weeks for Stage 1a arms and 53 weeks for Stage 1b arm)

Notes:

[5] - 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: As the endpoint was descriptive in nature, no statistical analysis was reported.

[6] - 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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	25	25
Units: percentage of participants				
number (not applicable)	4.3	29.2	20.0	24.0

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2 Stage 2: Percentage of Participants With Overall Response According to Updated IMWG Response Criteria

End point title	Phase 2 Stage 2: Percentage of Participants With Overall Response According to Updated IMWG Response Criteria ^{[7][8]}
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End point description:

OR: participants with sCR or CR or VGPR or PR. As per updated IMWG, CR: Negative immunofixation on serum and urine, disappearance of any STP and $\leq 5\%$ plasma cells in bone marrow; normal FLC ratio of 0.26-1.65 in participants with only FLC disease; sCR: CR and normal FLC ratio and no clonal cells in bone marrow; VGPR: Serum and urine M-protein detectable by immunofixation but not on electrophoresis or $\geq 90\%$ reduction in serum M-protein and urine M-protein level < 100 mg/24 hours, $> 90\%$ decrease in the difference between involved and uninvolved FLC levels; PR: $\geq 50\%$ reduction of serum M-Protein and reduction in urinary M-protein by $\geq 90\%$ or to < 200 mg/24 hours; $\geq 50\%$ decrease in the difference between involved and uninvolved FLC levels in place of M-protein criteria or $\geq 50\%$ reduction in plasma cells in place of M-protein if present at baseline. Analysis was performed on AT population.

End point type	Primary
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End point timeframe:

From the date of randomization to date of death from any cause (maximum duration: 97 weeks)

Notes:

[7] - 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: As the endpoint was descriptive in nature, no statistical analysis was reported.

[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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109	55		
Units: percentage of participants				
number (not applicable)	23.9	43.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic (PK) assessment: Phase 1: Plasma Concentration of Isatuximab observed at the end of an Intravenous infusion (Ceoi)

End point title	Pharmacokinetic (PK) assessment: Phase 1: Plasma Concentration of Isatuximab observed at the end of an Intravenous infusion (Ceoi) ^[9]
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End point description:

Ceoi was defined as the plasma concentration of Isatuximab at end of infusion. Data for this outcome measure was planned to be collected and analyzed separately for dose 0.3 mg/kg, 1 mg/kg and not for 0.0001, 0.001, 0.01, 0.03 and 0.1 dose levels (reported under one arm, i.e. Phase 1: Isatuximab <=1mg/kg in participant flow). Analysis was performed on PK population: participants who gave informed consent, received at least one dose (even if incomplete) of isatuximab, had an assessable PK parameter. Here, "Number of Participants analyzed"=participants evaluable for this outcome measure and "99999" signifies none of the participant were evaluable because at Cycle 3, Day 1, only data for reporting arms "Phase 1: Isatuximab 10mg/kg QW" and "Phase 1: Isatuximab 20mg/kg QW" was planned to be collected and analyzed. Analysis was performed on AT population. Here, n= number of participants with data collected for each category.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 and Cycle 3 Day 1: At the end of infusion

Notes:

[9] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	15	5
Units: microgram per milliliter (mcg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n= 4, 2, 15, 5, 3, 3, 6, 6, 3)	44.22500 (± 15.30651)	125.50000 (± 53.03301)	171.43333 (± 50.18853)	148.80000 (± 18.48513)
Cycle 3 Day 1 (n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 0.3 mg/kg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	4	3	6	6
Units: microgram per milliliter (mcg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n= 4, 2, 15, 5, 3, 3, 6, 6, 3)	173.33333 (± 20.64784)	400.33333 (± 52.51984)	334.33333 (± 98.28462)	2.08667 (± 0.65567)
Cycle 3 Day 1 (n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	299.82500 (± 220.83898)	99999 (± 99999)	715.33333 (± 188.01241)	99999 (± 99999)

End point values	Phase 1: Isatuximab 1 mg/kg Q2W			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: microgram per milliliter (mcg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n= 4, 2, 15, 5, 3, 3, 6, 6, 3)	13.18333 (± 5.74464)			
Cycle 3 Day 1 (n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment: Phase 1: Maximum Observed Plasma Concentration (Cmax) of Isatuximab

End point title	PK Assessment: Phase 1: Maximum Observed Plasma Concentration (Cmax) of Isatuximab ^[10]
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End point description:

Data for this outcome measure was planned to be collected and analyzed separately for dose 0.3 mg/kg, 1 mg/kg and not for 0.0001, 0.001, 0.01, 0.03 and 0.1 dose levels (reported under one arm, i.e. Phase 1: Isatuximab ≤1mg/kg in participant flow). Analysis was performed on PK population. Here, "Number of Participants analyzed"=participants evaluable for this outcome measure and "99999" signifies none of the participant were evaluable because at Cycle 3, Day 1, only data for reporting arms "Phase 1: Isatuximab 10mg/kg QW" and "Phase 1: Isatuximab 20mg/kg QW" was planned to be collected and analyzed. 9999=pre-specified not to calculate if n≤2. Here, n= number of participants with data collected for each category.

End point type	Secondary
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End point timeframe:

For Q2W:Cycle 1,Day 1: pre-dose, 15 min after start of infusion, at the end of infusion, 3, 7, 24, 48 and 168 hr post-infusion; For QW: Cycle 1,Day 1: pre-dose, 15 min after start of infusion, at the end of infusion, 4, 24, 48, 72 and 168 hr post-infusion

Notes:

[10] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	11	5
Units: mcg/mL				
geometric mean (geometric coefficient of variation)				

Cycle 1 Day 1 (n= 4, 2, 11, 5, 3, 3, 6, 6, 3)	53.7 (± 28)	126 (± 9999)	181 (± 48)	154 (± 13)
Cycle 3 Day 1 1 (n= n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 0.3 mg/kg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	4	3	6	6
Units: mcg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n= 4, 2, 11, 5, 3, 3, 6, 6, 3)	181 (± 20)	457 (± 28)	343 (± 29)	2.00 (± 31)
Cycle 3 Day 1 1 (n= n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	265 (± 67)	99999 (± 9999)	712 (± 27)	99999 (± 99999)

End point values	Phase 1: Isatuximab 1 mg/kg Q2W			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: mcg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n= 4, 2, 11, 5, 3, 3, 6, 6, 3)	12.4 (± 45)			
Cycle 3 Day 1 1 (n= n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment: Phase 1: Time to reach maximum plasma concentration observed (tmax) of Isatuximab

End point title	PK Assessment: Phase 1: Time to reach maximum plasma concentration observed (tmax) of Isatuximab ^[11]
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End point description:

Data for this outcome measure was planned to be collected and analyzed separately for dose 0.3 mg/kg, 1 mg/kg and not for 0.0001, 0.001, 0.01, 0.03 and 0.1 dose levels (reported under one arm, i.e. Phase 1: Isatuximab ≤1mg/kg in participant flow). Analysis was performed on PK population. Here, "Number of Participants analyzed"=participants evaluable for this outcome measure and "99999" signifies none of the participant were evaluable because at Cycle 3, Day 1, only data for reporting arms "Phase 1: Isatuximab 10mg/kg QW" and "Phase 1: Isatuximab 20mg/kg QW" was planned to be collected and analyzed. Here, n= number of participants with data collected for each category.

End point type	Secondary
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End point timeframe:

For Q2W: Cycle 1, Day 1: pre-dose, 15 min after start of infusion, at the end of infusion, 3, 7, 24, 48 and 168 hr post-infusion; For QW: Cycle 1, Day 1: pre-dose, 15 min after start of infusion, at the end of infusion, 4, 24, 48, 72 and 168 hr post-infusion

Notes:

[11] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	11	5
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (n= 4, 2, 11, 5, 3, 3, 6, 6, 3)	6.99 (4.58 to 8.00)	7.65 (5.13 to 10.17)	4.28 (2.15 to 9.37)	4.92 (2.60 to 30.08)
Cycle 3 Day 1 (n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 0.3 mg/kg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	4	3	6	6
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (n= 4, 2, 11, 5, 3, 3, 6, 6, 3)	2.25 (2.20 to 7.50)	5.87 (5.78 to 9.90)	6.83 (3.98 to 10.53)	2.49 (1.42 to 3.43)
Cycle 3 Day 1 (n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	4.30 (2.57 to 27.48)	99999 (99999 to 99999)	8.07 (2.87 to 29.03)	99999 (99999 to 99999)

End point values	Phase 1: Isatuximab 1 mg/kg Q2W			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (n= 4, 2, 11, 5, 3, 3, 6, 6, 3)	4.35 (3.13 to 6.33)			
Cycle 3 Day 1 (n= 0, 0, 0, 0, 4, 0, 6, 0, 0)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment: Phase 1: Plasma Concentration of Isatuximab at Week 1, 2 and 3

End point title	PK Assessment: Phase 1: Plasma Concentration of Isatuximab at Week 1, 2 and 3 ^[12]
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End point description:

Data for this outcome measure was planned to be collected and analyzed only for dose 1 mg/kg and not for 0.0001, 0.001, 0.01, 0.03, 0.1 and 0.3 mg/kg dose levels (reported under one arm, i.e. Phase 1: Isatuximab ≤1mg/kg in participant flow). Analysis was performed on PK population. Here, 'number analyzed' = number of participants with available data for each category. Here, n= number of participants with data collected for each category.

End point type	Secondary
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End point timeframe:

Week 1, 2 and 3

Notes:

[12] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	18	16
Units: mcg/mL				
geometric mean (geometric coefficient of variation)				
Week 1 (n= 6, 3, 18, 16 6, 6, 7, 3)	1.44 (± 85)	15.3 (± 90)	27.6 (± 81)	44.2 (± 52)
Week 2 (n= 6, 3, 18, 16 6, 6, 7, 3)	0.181 (± 136)	1.39 (± 116)	1.97 (± 145)	8.31 (± 77)
Week 3 (n= 6, 2, 17, 14, 6, 5, 6, 3)	0.460 (± 121)	42.7 (± 73)	4.18 (± 133)	18.6 (± 71)

End point values	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 1 mg/kg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	6	6	7	3
Units: mcg/mL				
geometric mean (geometric coefficient of variation)				
Week 1 (n= 6, 3, 18, 16 6, 6, 7, 3)	20.7 (± 63)	113 (± 37)	108 (± 33)	0.00223 (± 86)
Week 2 (n= 6, 3, 18, 16 6, 6, 7, 3)	55.1 (± 63)	63.9 (± 46)	194.8 (± 36)	0.000800 (± 173)
Week 3 (n= 6, 2, 17, 14, 6, 5, 6, 3)	75.9 (± 78)	91.0 (± 52)	347.3 (± 36)	0.000283 (± 145)

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment: Phase 1: Predicted Cumulative Area under the plasma concentration Curve (AUC) of Isatuximab Over the First Week (0-168 hours) (AUC1W)

End point title	PK Assessment: Phase 1: Predicted Cumulative Area under the plasma concentration Curve (AUC) of Isatuximab Over the First Week (0-168 hours) (AUC1W) ^[13]
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End point description:

Data for this outcome measure was planned to be collected and analyzed only for dose 1 mg/kg and not for 0.0001, 0.001, 0.01, 0.03, 0.1 and 0.3 mg/kg dose levels (reported under one arm, i.e. Phase 1: Isatuximab ≤1mg/kg in participant flow). Analysis was performed on PK population. Here, "Number of Participants Analyzed" = participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

For Q2W: Cycle 1, Day 1: pre-dose, 15 min after start of infusion, at the end of infusion, 3, 7, 24, 48 and 168 hr post-infusion; For QW: Cycle 1, Day 1: pre-dose, 15 min after start of infusion, at the end of infusion, 4, 24, 48, 72 and 168 hr post-infusion

Notes:

[13] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase 1: Isatuximab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	18	16
Units: mcg*hour/mL				
geometric mean (geometric coefficient of variation)	2624 (± 24)	7174 (± 54)	11566 (± 48)	13480 (± 38)

End point values	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 1 mg/kg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	6	6	7	3
Units: mcg*hour/mL				
geometric mean (geometric coefficient of variation)	12680 (± 35)	32739 (± 28)	28405 (± 27)	222 (± 80)

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment: Phase 1: Predicted Cumulative Area Under the Plasma Concentration Curve (AUC) of Isatuximab Over the First 2 Weeks (0-336 hours) (AUC2W)

End point title	PK Assessment: Phase 1: Predicted Cumulative Area Under the Plasma Concentration Curve (AUC) of Isatuximab Over the First 2 Weeks (0-336 hours) (AUC2W) ^[14]
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End point description:

Data for this outcome measure was planned to be collected and analyzed only for dose 1 mg/kg and not for 0.0001, 0.001, 0.01, 0.03, 0.1 and 0.3 mg/kg dose levels (reported under one arm, i.e. Phase 1: Isatuximab ≤1mg/kg in participant flow). Analysis was performed on PK population. Here, "Number of Participants Analyzed" = participants evaluable for this outcome measure

End point type	Secondary
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End point timeframe:

For Q2W: Cycle 1, Day 1: pre-dose, 15 min after start of infusion, at the end of infusion, 3, 7, 24, 48 and 336 hr post-infusion; For QW: Cycle 1, Day 1: pre-dose, 15 min after start of infusion, at the end of infusion, 4, 24, 48, 72 and 336 hr post-infusion

Notes:

[14] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	18	16
Units: mcg*hour/mL				
geometric mean (geometric coefficient of variation)	3076 (± 35)	9546 (± 70)	14876 (± 64)	18967 (± 44)

End point values	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 1 mg/kg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	6	6	7	3
Units: mcg*hour/mL				
geometric mean (geometric coefficient of variation)	30187 (± 40)	48003 (± 31)	71174 (± 29)	222 (± 80)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamic (PD) assessment: Phase 1: Change From Baseline in Serum/Plasma Markers

End point title	Pharmacodynamic (PD) assessment: Phase 1: Change From Baseline in Serum/Plasma Markers ^[15]
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End point description:

Serum/plasma markers included: tumor necrosis factor alpha (TNF- α), interleukin-1 β (IL-1- β), interleukin 6 (IL-6) and interferon-gamma (IFN-Gamma). Due to change in planned analysis, data for high-sensitivity C-reactive protein (hs-CRP) and CD38 was not collected and analyzed. Analysis was performed on all randomized participants who gave their informed consent, had received at least 1 dose (even incomplete) of isatuximab and had an assessable PD parameter. Here, 'n' = number of participants with available data for each category. Here, n= number of participants with data collected for each category.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1

Notes:

[15] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase1: Isatuximab <=1 mg/kg every 2 weeks (Q2W)	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	6	3	26
Units: picogram/milliliter (pg/mL)				
arithmetic mean (standard deviation)				
TNF alpha (n=16, 5, 3, 23, 16, 6, 6, 5)	163.181 (\pm 253.373)	179.783 (\pm 191.455)	352.974 (\pm 220.394)	340.799 (\pm 341.100)
IL-1 Beta (n=15, 4, 3, 21, 16, 6, 6, 5)	64.577 (\pm 227.399)	29.741 (\pm 55.515)	7.527 (\pm 8.118)	299.058 (\pm 572.260)
IL-6 (n=16, 5, 3, 23, 16, 6, 6, 5)	139.234 (\pm 212.385)	261.732 (\pm 270.119)	73.899 (\pm 53.211)	148.594 (\pm 175.719)
IFN Gamma (n=15, 3, 3, 23, 16, 6, 6, 5)	477.116 (\pm 1673.063)	5.376 (\pm 9.312)	25.806 (\pm 44.698)	445.772 (\pm 1043.982)

End point values	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW
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	Myeloma)			
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	6	7	7
Units: picogram/milliliter (pg/mL)				
arithmetic mean (standard deviation)				
TNF alpha (n=16, 5, 3, 23, 16, 6, 6, 5)	503.462 (± 479.813)	342.664 (± 410.245)	307.319 (± 398.025)	412.541 (± 243.169)
IL-1 Beta (n=15, 4, 3, 21, 16, 6, 6, 5)	547.770 (± 1454.175)	327.957 (± 759.305)	305.914 (± 621.754)	293.307 (± 612.746)
IL-6 (n=16, 5, 3, 23, 16, 6, 6, 5)	173.004 (± 433.297)	-8.109 (± 45.845)	274.616 (± 234.752)	165.295 (± 203.451)
IFN Gamma (n=15, 3, 3, 23, 16, 6, 6, 5)	568.806 (± 1022.000)	627.089 (± 1527.647)	448.387 (± 569.499)	1487.097 (± 2693.826)

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity Assessment: Phase 1: Number of Participants With Treatment-Emergent And Treatment-Boosted Anti-drug Antibodies (ADA) Response

End point title	Immunogenicity Assessment: Phase 1: Number of Participants With Treatment-Emergent And Treatment-Boosted Anti-drug Antibodies (ADA) Response ^[16]
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End point description:

ADA response was categorized as: treatment induced and treatment boosted response. Treatment-induced ADA was defined as ADA that developed at any time during the ADA on-study observation period (defined as the time from the first isatuximab administration until end of Phase 1) in participants without preexisting ADA (defined as: ADA that were present in samples drawn before treatment), including participants without pre-treatment (before treatment) samples. Treatment boosted ADA was defined as pre-existing ADA that increased at least 2 titer steps between pre-treatment (before treatment) and post-treatment. Analysis was performed on ADA evaluable population which included all treated participants with at least one ADA assessment with a reportable result during the ADA on-study observation period.

End point type	Secondary
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End point timeframe:

Up to 120 weeks

Notes:

[16] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase1: Isatuximab ≤1 mg/kg every 2 weeks (Q2W)	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuximab (CD38+HM and Standard Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	6	3	26
Units: participants				
Treatment-induced ADA	2	0	0	1
Treatment boosted ADA	0	0	0	0

End point values	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	6	6	7
Units: participants				
Treatment-induced ADA	1	1	1	1
Treatment boosted ADA	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical assessment: Phase 1: Percentage of Participants With Overall Response and Clinical Benefit: Assessed Using European Society for Blood and Marrow Transplantation (EBMT) criteria

End point title	Clinical assessment: Phase 1: Percentage of Participants With Overall Response and Clinical Benefit: Assessed Using European Society for Blood and Marrow Transplantation (EBMT) criteria ^[17]
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End point description:

OR: Participants with CR or PR as best overall response (BOR). Clinical benefit: participants with minimal response (MR) or better as BOR. BOR: best sequential response from start of treatment through the entire study excluding any time point following start of other treatment. CR: negative immunofixation on serum and urine, disappearance of any STP, <5% plasma cells in bone marrow aspirates, no increase in size or number of lytic bone lesions. PR: ≥50% reduction of serum M-protein, reduction in 24 h urinary M-protein by ≥90% or <200mg, ≥50% reduction in size/number of STP, no increase in size or number of lytic bone lesions. MR: 25 to 49% reduction in serum M-protein, 50-89% reduction in 24h urine M-protein, 25-49% reduction in size of STP, no increase in size or number of lytic bone lesions. Analysis was performed on AT population. Here, 'number of participants analyzed' = participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

From the date of randomization to the date of first documentation of progression or death (due to any cause) (maximum duration: 120 weeks)

Notes:

[17] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	25	18
Units: percentage of participants				

number (not applicable)				
OR	0	33.3	28.0	16.7
Clinical benefit	20.0	33.3	28.0	27.8

End point values	Phase 1: Isatuximab 10 mg/kg Every Week (QW)	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 1 mg/kg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	6	7	7	3
Units: percentage of participants				
number (not applicable)				
OR	33.3	14.3	28.6	33.3
Clinical benefit	33.3	28.6	42.9	33.3

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical assessment: Phase 1: Duration of response (DOR)

End point title	Clinical assessment: Phase 1: Duration of response (DOR) ^[18]
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End point description:

DOR: time from first response (PR or better) to first documented tumor progression/death. Progression (EBMT): >25% increase in serum monoclonal paraprotein level also absolute increase of ≥ 5 g/l; >25% increase in 24h urinary light chain excretion also absolute increase of ≥ 200 mg/24 h; >25% increase in plasma cells in a bone marrow aspirate/on trephine biopsy also absolute increase of $\geq 10\%$; definite increase in size of existing bone lesions/STP; development of new bone lesions/STP or hypercalcemia (corrected serum calcium >11.5 mg/dl) not attributable to any other cause. PR: $\geq 50\%$ reduction of serum M-protein, reduction in 24h urinary M-protein by $\geq 90\%$ or <200 mg, $\geq 50\%$ reduction in size/number of STP, no increase in size/number of lytic bone lesions. Analysis only on subset of participants who had response in Phase 1; not for reporting group with no response. 22222=standard deviation cannot be calculated for single participant.

End point type	Secondary
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End point timeframe:

From the date of first response to the date of first documentation of progression or death (due to any cause) (maximum duration: 120 weeks)

Notes:

[18] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)	Phase 1: Isatuximab 10 mg/kg Every Week (QW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	7	3	2
Units: months				
arithmetic mean (standard deviation)	7.16 (\pm 22222)	5.76 (\pm 4.62)	10.70 (\pm	14.31 (\pm 7.50)

End point values	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 1 mg/kg Q2W	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	1	2	1	
Units: months				
arithmetic mean (standard deviation)	3.94 (\pm 22222)	8.82 (\pm 7.83)	20.21 (\pm 22222)	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical assessment: Phase 1: Time to First Response (TTR)

End point title	Clinical assessment: Phase 1: Time to First Response (TTR) ^[19]
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End point description:

TTR was defined as the time from first dose of isatuximab to first response (PR or better). PR: $\geq 50\%$ reduction of serum M-protein, reduction in 24 h urinary M-protein by $\geq 90\%$ or $< 200\text{mg}$, $\geq 50\%$ reduction in size/number of STP, no increase in size or number of lytic bone lesions. Analysis was performed only on subset of participants who had response in Phase 1 and not for the reporting group with no response. 22222=standard deviation cannot be calculated for a single participant.

End point type	Secondary
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End point timeframe:

From the date of first dose administration to the date of first response or death (due to any cause) (maximum duration: 120 weeks)

Notes:

[19] - 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: Only Phase 1 participants were analyzed in this endpoint.

End point values	Phase 1: Isatuximab 5 mg/kg Q2W	Phase1:Isatuxi mab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)	Phase 1: Isatuximab 10 mg/kg Every Week (QW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	7	3	2
Units: months				
arithmetic mean (standard deviation)	6.41 (\pm 22222)	2.52 (\pm 3.77)	1.96 (\pm 1.72)	1.38 (\pm 0.65)

End point values	Phase 1: Isatuximab 20 mg/kg Q2W	Phase 1: Isatuximab 20 mg/kg QW	Phase 1: Isatuximab 1 mg/kg Q2W	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	1	2	1	

Units: months				
arithmetic mean (standard deviation)	1.18 (± 22222)	1.46 (± 0.77)	0.95 (± 22222)	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical assessment: Phase 1: Number of Participants With Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) (Karnofsky performance status)-Shift From Baseline Value to Best Value During Treatment

End point title	Clinical assessment: Phase 1: Number of Participants With Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) (Karnofsky performance status)-Shift From Baseline Value to Best Value During Treatment
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End point description:

ECOG performance status was measured on a 4 point scale to assess participant's performance status. 0=Normal, fully functional; 1=Fatigue without significant decrease in daily activity; 2=Fatigue with significant impairment of daily activities or bed rest <50% of waking hours; 3=Bed rest/sitting >50% of waking hours; 4=Bedridden or unable to care for self, where lower score indicated good performance status. Number of participants with Baseline ECOG PS score and corresponding changes to the best values (categorized as: Baseline ECOG 1, During Treatment ECOG 0; Baseline ECOG 2, During Treatment ECOG 0; Baseline ECOG 2, During Treatment ECOG 1) are reported. Analysis was performed on AT population. Data for this outcome measure was planned to be collected and analyzed for a combined arm of overall Phase 1 AT population.

End point type	Secondary
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End point timeframe:

At baseline, during treatment (Day 1 up to 120 weeks)

End point values	Phase 1: Isatuximab			
Subject group type	Subject analysis set			
Number of subjects analysed	89			
Units: participants				
Baseline ECOG 1, During Treatment ECOG 0	11			
Baseline ECOG 2, During Treatment ECOG 0	2			
Baseline ECOG 2, During Treatment ECOG 1	11			

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical assessment: Phase 1: Number of Participants With Eastern Cooperative Oncology Group Performance Status (Karnofsky performance status)-Shift From Baseline Value to Worst Value During Treatment

End point title	Clinical assessment: Phase 1: Number of Participants With
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End point description:

ECOG performance status was measured on a 4 point scale to assess participant's performance status. 0=Normal, fully functional; 1=Fatigue without significant decrease in daily activity; 2=Fatigue with significant impairment of daily activities or bed rest <50% of waking hours; 3=Bed rest/sitting>50% of waking hours; 4=Bedridden or unable to care for self, where higher score indicated worst performance status. Number of participants with Baseline ECOG PS score and corresponding changes to the worst values (categorized as: Baseline ECOG 0, During Treatment ECOG 1; Baseline ECOG 2, During Treatment ECOG 1; Baseline ECOG 0, During Treatment ECOG 2; Baseline ECOG 1, During Treatment ECOG 2; Baseline ECOG 0, During Treatment ECOG 3; Baseline ECOG 1, During Treatment ECOG 3; Baseline ECOG 2, During Treatment ECOG 3) are reported. Analysis was performed on AT population. Data for this outcome measure was planned to be collected and analyzed for a combined arm of overall Phase 1 AT population.

End point type	Secondary
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End point timeframe:

At baseline, during treatment (up to 120 weeks)

End point values	Phase 1: Isatuximab			
Subject group type	Subject analysis set			
Number of subjects analysed	89			
Units: participants				
Baseline ECOG 0, During Treatment ECOG 1	8			
Baseline ECOG 2, During Treatment ECOG 1	1			
Baseline ECOG 0, During Treatment ECOG 2	3			
Baseline ECOG 1, During Treatment ECOG 2	20			
Baseline ECOG 0, During Treatment ECOG 3	1			
Baseline ECOG 1, During Treatment ECOG 3	2			
Baseline ECOG 2, During Treatment ECOG 3	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 1: Duration of Response

End point title	Phase 2 Stage 1: Duration of Response ^[20]
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End point description:

DOR: Time from date of 1st IAC determined response (\geq PR) that was subsequently confirmed, to date of first IAC determined PD/death, whichever happened earlier. updated IMWG criteria- PR: \geq 50% decrease in difference between involved and uninvolved FLC levels in place of M-protein criteria or a \geq 50% reduction in plasma cells in place of M-protein if baseline was \geq 30%. If present at baseline a \geq 50% reduction in size of STP; PD: Increase of 25% from lowest response value in any of following: Serum M-protein \geq 0.5 g/dL absolute increase and/or urine M-protein \geq 200 mg/24 hours absolute increase and/or $>$ 10 mg/dL absolute increase in difference between involved and uninvolved FLC levels \geq 10% bone marrow plasma cells (PC), development of new or increase in size of bone

lesions/STP, development of hypercalcemia. Analysis was only on subset of population who had response in Phase 2 stage 1. 22222=Standard deviation cannot be calculated for single participant.

End point type	Secondary
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End point timeframe:

From the date of first response until disease progression or death or data cut-off (maximum duration: 77 weeks for Stage 1a arms and 53 weeks for stage 1b arm)

Notes:

[20] - 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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	7	5	6
Units: months				
arithmetic mean (standard deviation)	1.91 (± 22222)	11.17 (± 5.77)	7.31 (± 3.65)	8.11 (± 2.33)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 2: Number of Participants With Treatment Emergent Adverse Events (TEAEs)

End point title	Phase 2 Stage 2: Number of Participants With Treatment Emergent Adverse Events (TEAEs) ^[21]
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End point description:

AE was defined as any untoward medical occurrence in a participant who received study drug and did not necessarily have to have a causal relationship with the treatment. TEAEs were defined as AEs that developed or worsened during the on-treatment period which was defined as the period from the time of first dose of study treatment until 30 days after the last dose of study treatment. Analysis was performed on AT population which included participants who signed informed consent & received at least 1 dose/even incomplete of isatuximab.

End point type	Secondary
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End point timeframe:

From Baseline up to 30 days after the last dose (maximum duration: 301 weeks)

Notes:

[21] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109	55		
Units: participants	101	51		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 1: Number of Participants With Treatment Emergent Adverse Events (TEAEs)

End point title	Phase 2 Stage 1: Number of Participants With Treatment Emergent Adverse Events (TEAEs) ^[22]
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End point description:

Adverse event (AE) was defined as any untoward medical occurrence in a participant who received study drug and did not necessarily have to have a causal relationship with the treatment. TEAEs were defined as AEs that developed or worsened during the on-treatment period which was defined as the period from the time of first dose of study treatment until 30 days after the last dose of study treatment. Analysis was performed on AT population which included participants who signed informed consent & received at least 1 dose/even incomplete of isatuximab.

End point type	Secondary
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End point timeframe:

From Baseline up to 30 days after the last dose (maximum duration: 414 weeks for Stage 1a and 92 weeks for Stage 1b)

Notes:

[22] - 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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	25	25
Units: participants	22	24	25	25

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 2: Duration of Response

End point title	Phase 2 Stage 2: Duration of Response ^[23]
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End point description:

DOR: Time from date of 1st IAC determined response (\geq PR) subsequently confirmed, to date of 1st IAC determined PD or death, whichever happened earlier. As per updated IMWG criteria-PR: \geq 50% reduction of serum M-Protein and reduction in urinary M-protein by \geq 90% or to $<$ 200 mg/24 hours. \geq 50% decrease in difference between involved and uninvolved FLC levels in place of M-protein criteria or \geq 50% reduction in plasma cells in place of M-protein if baseline \geq 30%. If present at baseline \geq 50% reduction in size of STP; PD: Increase of $>$ 25% from lowest response value in any 1 of following: Serum M-component (absolute increase $>$ 0.5 g/dL) and/or Urine M-component (absolute increase 200 mg/24 h) and/or $>$ 10 mg/dL absolute increase in difference between involved and

uninvolved FLC levels, $\geq 10\%$ bone marrow plasma cell, development of hypercalcemia attributed solely to PC proliferative disorder. Analysis was only on subset of population who had response in Phase 2 stage 2.

End point type	Secondary
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End point timeframe:

From the date of first response until disease progression or death or data cut-off (maximum duration: 97 weeks)

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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	24		
Units: months				
arithmetic mean (standard deviation)	8.6 (\pm 5.2)	10.9 (\pm 4.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 2: Percentage of Participants With Clinical Benefit

End point title	Phase 2 Stage 2: Percentage of Participants With Clinical Benefit ^[24]
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End point description:

Clinical benefit: participants with sCR, CR, VGPR, PR or MR, per IMWG criteria, determined by IAC. CR: negative immunofixation on serum & urine, disappearance of any STP, $< 5\%$ plasma cells in bone marrow aspirates, normal FLC ratio (0.26-1.65) in participants with only FLC disease. sCR: CR + normal FLC ratio, absence of clonal cells in bone marrow biopsy. VGPR: serum & urine M-component detectable by immunofixation, not on electrophoresis, $\geq 90\%$ reduction in serum M-component plus urine M-component level $< 100\text{mg}/24\text{h}$, $\geq 90\%$ decrease in difference between involved and uninvolved FLC levels; PR: $\geq 50\%$ reduction of serum M-protein, reduction in 24h urinary M-protein by $\geq 90\%$ / $< 200\text{mg}/24\text{h}$, $> 50\%$ decrease in difference between involved and uninvolved FLC in place of M-protein criteria, $\geq 50\%$ reduction in size/number of STP. MR: ≥ 25 but $< 49\%$ reduction in serum M-protein, reduction in 24h urine M-protein by 50-89%, 25-49% reduction in size of STP. Analysis was on AT population.

End point type	Secondary
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End point timeframe:

From the date of randomization to the date of first documentation of progression or death (maximum duration: 97 weeks)

Notes:

[24] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109	55		
Units: percentage of participants				
number (not applicable)	43.1	54.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 1: Percentage of Participants With Clinical Benefit

End point title	Phase 2 Stage 1: Percentage of Participants With Clinical Benefit ^[25]
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End point description:

Clinical benefit: participants with sCR, CR, VGPR, PR or MR as per IMWG criteria by IAC. CR: negative immunofixation on serum & urine, disappearance of any STP, <5% PCs in bone marrow aspirates. sCR: CR + normal FLC ratio (0.26-1.65), absence of clonal cells in bone marrow biopsy. VGPR: serum & urine M-component detectable by immunofixation, not on electrophoresis, >=90% reduction in serum M-component plus urine M-component level <100mg/24hours; PR: >=50% reduction of serum M-Protein and reduction in urinary M-protein by >=90% or to <200 mg/24 hours, >=50% decrease in difference between involved and uninvolved FLC levels in place of M-protein criteria or >=50% reduction in plasma cells in place of M-protein if baseline >=30%. If present at baseline, >=50% size reduction in STP. MR: >=25 but <49% reduction in serum M-protein, reduction in 24h urine M-protein by 50-89%, 25-49% size reduction in STP. Analysis was on AT population.

End point type	Secondary
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End point timeframe:

From Baseline up to 30 days after the last dose (maximum duration: 77 weeks for Stage 1a arms and 53 weeks for stage 1b arm)

Notes:

[25] - 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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	25	25
Units: percentage of participants				
number (not applicable)	4.3	41.7	32.0	36.0

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 1: Progression free survival (PFS)

End point title	Phase 2 Stage 1: Progression free survival (PFS) ^[26]
End point description: PFS:Time interval from date of first isatuximab administration to date of first IAC-confirmed disease progression (PD) or date of death due to any cause, whichever came first. As per IMWG criteria, PD: Increase of > 25% from lowest response value in any 1 or more of following: Serum M-component and/or (absolute increase> 0.5 g/dL),Urine M-component and/or (absolute increase> 200 mg/24 h), > 10mg/dL decrease in difference between involved and uninvolved FLC levels in place of M-protein criteria,>10% absolute percentage of bone marrow plasma cell, definite development of new bone lesions or STP or definite increase in the size of existing bone lesions or STP, development of hypercalcemia (corrected serum calcium > 11.5 mg/dL or 2.65 mmol/L) attributed solely to PC proliferative disorder. Analysis was performed by Kaplan-Meier method. Analysis was performed on AT population. 55555=Upper limit of confidence interval was not estimable due to less number of participants with event.	
End point type	Secondary
End point timeframe: From the date of the first dose administration until progression or death, whichever occurred first (maximum duration: 77 weeks for Stage 1a arms and 53 weeks for stage 1b arm)	
Notes: [26] - 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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.	

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	25	25
Units: months				
median (confidence interval 95%)	2.1 (1.02 to 5.49)	9.6 (2.23 to 55555)	4.4 (1.84 to 5.82)	3.6 (1.91 to 9.20)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 1: Overall survival (OS)

End point title	Phase 2 Stage 1: Overall survival (OS) ^[27]
End point description: OS was defined as the time interval from the date of first Isatuximab administration to death from any cause. Analysis was performed by Kaplan-Meier method. Analysis was performed on AT population. 55555= Not estimable, due to less number of participants with event.	
End point type	Secondary
End point timeframe: From the date of randomization to date of death from any cause (maximum duration 77 weeks for Stage 1a arms and 53 weeks for stage 1b arm)	
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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.	

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	25	25
Units: months				
median (confidence interval 95%)	15.277 (4.7310 to 55555)	18.628 (7.7536 to 20.1068)	55555 (8.4435 to 55555)	55555 (8.3450 to 55555)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 2: Overall survival

End point title	Phase 2 Stage 2: Overall survival ^[28]
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End point description:

OS was defined as the time interval from the date of first Isatuximab administration to death from any cause. Analysis was performed by Kaplan-Meier method. Analysis was performed on AT population. 55555=Not estimable, due to less number of participants with event.

End point type	Secondary
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End point timeframe:

From the date of randomization to date of death from any cause (maximum duration: 97 weeks)

Notes:

[28] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109	55		
Units: months				
median (confidence interval 95%)	18.92 (13.602 to 23.064)	17.25 (15.409 to 55555)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 2: Progression free survival

End point title	Phase 2 Stage 2: Progression free survival ^[29]
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End point description:

PFS was defined as the time interval from the date of first isatuximab administration to the date of the first IAC-confirmed disease progression or the date of death due to any cause, whichever came first. As per IMWG criteria, PD: Increase of >25% from lowest response value in any one of the following: Serum M-component (the absolute increase must be >0.5 g/dL)4 and/or Urine M-component (the absolute

increase must be >200 mg/24 h) and/or >10 mg/dL decrease in the difference between involved and uninvolved FLC levels in place of the M-protein criteria, ≥10% bone marrow plasma cell, development of hypercalcemia (corrected serum calcium >11.5 mg/dL) attributed solely to the plasma cell proliferative disorder. Analysis was performed by Kaplan-Meier method. Analysis was performed on AT population.

End point type	Secondary
End point timeframe:	
From the date of the first dose administration until progression or death, whichever occurred first (maximum duration: 97 weeks)	

Notes:

[29] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109	55		
Units: months				
median (confidence interval 95%)	4.86 (3.877 to 7.688)	10.15 (4.862 to 17.347)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 1: Change From Baseline in Health Related Quality of Life (HRQL) European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Scores: Global Health Status

End point title	Phase 2 Stage 1: Change From Baseline in Health Related Quality of Life (HRQL) European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Scores: Global Health Status ^[30]
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End point description:

EORTC-QLQ-C30: Cancer-specific instrument with 30 questions for evaluation of new chemotherapy; provides an assessment of participant reported outcome dimensions. 1st 28 questions used 4-point scale (1=not at all, 2=a little, 3=quite a bit, 4=very much) for evaluating 5 functional scales (physical, role, emotional, cognitive, social), 3 symptom scales (fatigue, nausea/vomiting, pain); other single items. For each item, high score=high level of problem. Last 2 questions were participant's assessment of overall health+quality of life (QoL), coded on 7-point scale (1=very poor to 7=excellent). It observed values and change from baseline for global health status (scoring of questions 29 & 30) and 5 functional scales, 3 symptom scales and other single items (scoring of questions 1 to 28). Answers were converted into grading scale, values between 0 and 100. High score: favorable outcome with best QoL. Analysis: AT population. Only those participants with data available for each specified category are reported.

End point type	Secondary
End point timeframe:	
Baseline, Day 1 of Cycles 2, 3, 4, 5, 6, 7, 8, 9, 10 and End of Treatment (EOT: anytime up to 77 weeks for Stage 1a arms and 53 weeks for stage 1b arm)	

Notes:

[30] - 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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	21	24	22
Units: score on a scale				
arithmetic mean (standard deviation)				
Cycle 2 day 1 (n=14, 15, 19, 18)	-8.33 (± 20.15)	2.22 (± 16.51)	-3.95 (± 20.67)	0.00 (± 15.39)
Cycle 3 day 1 (n=7, 11, 14, 12)	0.00 (± 19.25)	-0.76 (± 16.44)	6.55 (± 19.66)	-2.08 (± 15.54)
Cycle 4 day 1 (n=4, 11, 11, 9)	0.00 (± 24.53)	-5.30 (± 21.50)	6.06 (± 21.11)	7.41 (± 8.78)
Cycle 5 day 1 (n=4, 12, 9, 5)	0.00 (± 24.53)	0.69 (± 15.27)	6.48 (± 21.15)	5.00 (± 4.56)
Cycle 6 day 1 (n=4, 9, 7, 4)	12.50 (± 14.43)	-10.19 (± 25.27)	5.95 (± 13.36)	10.42 (± 7.98)
Cycle 7 day 1 (n=2, 7, 4, 5)	12.50 (± 5.89)	-3.57 (± 15.85)	8.33 (± 11.79)	6.67 (± 6.97)
Cycle 8 day 1 (n=2, 6, 4, 4)	0.00 (± 35.36)	-11.11 (± 18.76)	4.17 (± 15.96)	6.25 (± 10.49)
Cycle 9 day 1 (n=2, 5, 4, 4)	-8.33 (± 11.79)	-10.00 (± 19.90)	4.17 (± 14.43)	6.25 (± 10.49)
Cycle 10 day 1 (n=2, 3, 4, 5)	-8.33 (± 35.36)	-16.67 (± 22.05)	8.33 (± 11.79)	3.33 (± 7.45)
End of treatment (n=5, 5, 3, 2)	3.33 (± 33.64)	-11.67 (± 13.94)	-11.11 (± 20.97)	-12.50 (± 5.89)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 1: Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Multiple Myeloma Specific Module With 20 Items (EORTC QLQ-MY20) Scores: Disease Symptom Subscale Score

End point title	Phase 2 Stage 1: Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Multiple Myeloma Specific Module With 20 Items (EORTC QLQ-MY20) Scores: Disease Symptom Subscale Score ^[31]
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End point description:

EORTC QLQ-MY20 is a validated questionnaire to assess the overall quality of life in participants with MM. It has 4 subscales: body image, future perspective), and 2 symptoms scales (disease symptoms and side-effects of treatment). Disease symptoms subscale used 4-point scale ranged from 1= 'Not at All' to 4= 'Very Much'. Scores were averaged, and transformed to 0 -100 scale, where higher scores = more symptoms and lower health-related quality of life (HRQL) and lower score = less symptoms and more HRQL. Analysis was performed on AT population. Here, "Number of Participants Analyzed" = participants evaluable for this outcome measure and 'n' = number of participants with data collected for each category.

End point type	Secondary
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End point timeframe:

Baseline, Day 1 of Cycles 2, 3, 4, 5, 6, 7, 8, 9, 10 and EOT (anytime up to 77 weeks for Stage 1a arms and 53 weeks for stage 1b arm)

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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	21	23	22
Units: score on a scale				
arithmetic mean (standard deviation)				
Cycle 2 day 1 (n=14, 13, 18, 17)	5.56 (± 18.36)	-3.42 (± 11.24)	0.93 (± 13.91)	2.61 (± 18.75)
Cycle 3 day 1 (n=7, 11, 13, 11)	7.94 (± 11.94)	-5.05 (± 14.15)	-5.98 (± 16.89)	-1.52 (± 13.17)
Cycle 4 day 1 (n=4, 10, 10, 9)	8.33 (± 13.22)	-3.89 (± 16.98)	-10.00 (± 16.93)	0.62 (± 30.10)
Cycle 5 day 1 (n=4, 11, 8, 5)	-6.94 (± 10.52)	0.51 (± 19.95)	-9.03 (± 17.04)	-6.67 (± 17.74)
Cycle 6 day 1 (n=4, 9, 7, 4)	8.33 (± 7.17)	1.23 (± 23.53)	-15.08 (± 20.96)	-6.94 (± 10.52)
Cycle 7 day 1 (n=2, 6, 4, 5)	2.78 (± 3.93)	-3.70 (± 22.95)	-18.06 (± 21.93)	-11.11 (± 11.79)
Cycle 8 day 1 (n=2, 6, 4, 4)	-5.56 (± 7.86)	-2.78 (± 23.50)	-15.28 (± 23.30)	-4.17 (± 5.32)
Cycle 9 day 1 (n=2, 5, 4, 4)	5.56 (± 7.86)	-10.00 (± 10.69)	-16.67 (± 29.75)	-6.94 (± 12.32)
Cycle 10 day 1 (n=2, 3, 4, 5)	0.00 (± 0.00)	0.00 (± 19.25)	-15.28 (± 30.56)	-6.67 (± 17.30)
End of treatment (n=4, 5, 3, 2)	-9.72 (± 19.44)	7.78 (± 24.41)	24.07 (± 22.45)	25.00 (± 35.36)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Stage 1: Change From Baseline in Euro Quality of Life 5 Dimension (EQ-5D) Generic Health Status - Visual Analogue Scale Scores

End point title	Phase 2 Stage 1: Change From Baseline in Euro Quality of Life 5 Dimension (EQ-5D) Generic Health Status - Visual Analogue Scale Scores ^[32]
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End point description:

EQ-5D was a standardized HRQL questionnaire consisting of EQ-5D descriptive system and Visual Analogue Scale (VAS). EQ-5D VAS was used to record a participant's rating for his/her current health-related quality of life state and captured on a vertical VAS (0-100), where 0 = worst imaginable health state and 100 = best imaginable health state. Analysis was performed on AT population. Here, "Number of Participants Analyzed" = participants evaluable for this outcome measure and 'n' = number of participants with available data for each category. 22222=Standard deviation cannot be calculated for a single participant. 99999=no evaluable participants

End point type	Secondary
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End point timeframe:

Baseline, Day 1 of Cycles 4, 7, 10, 13, 16, 19, and EOT (anytime up to 77 weeks for Stage 1a arms and 53 weeks for stage 1b arm)

Notes:

[32] - 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: Only Phase 2 Stage 1 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 1a: Isatuximab 3 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10 mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	21	22	22
Units: score on a scale				
arithmetic mean (standard deviation)				
Cycle 4 day 1 (n=4, 9, 9, 9)	-5.75 (± 18.55)	2.00 (± 16.88)	-4.78 (± 15.71)	4.89 (± 16.02)
Cycle 7 day 1 (n=2, 6, 3, 5)	-2.50 (± 0.71)	-6.00 (± 27.39)	9.00 (± 18.25)	1.00 (± 7.94)
Cycle 10 day 1 (n=2, 3, 3, 5)	0.50 (± 2.12)	-10.33 (± 9.29)	10.33 (± 24.38)	-2.60 (± 8.11)
Cycle 13 day 1 (n=2, 3, 1, 1)	14.00 (± 19.80)	-5.00 (± 4.00)	-9.00 (± 22222)	-5.00 (± 22222)
Cycle 16 day 1 (n=2, 3, 0, 0)	5.00 (± 5.66)	0.67 (± 23.71)	99999 (± 99999)	99999 (± 99999)
Cycle 19 day 1 (n=0, 2, 0, 0)	99999 (± 99999)	-5.50 (± 4.95)	99999 (± 99999)	99999 (± 99999)
End of treatment (n=4, 5, 3, 2)	-18.50 (± 16.98)	-11.60 (± 11.37)	-10.00 (± 9.54)	-9.00 (± 0.00)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic assessment: Phase 2 Stage 2: Area under the plasma concentration versus time curve of Isatuximab over 2 weeks interval

End point title	Pharmacokinetic assessment: Phase 2 Stage 2: Area under the plasma concentration versus time curve of Isatuximab over 2 weeks interval ^[33]
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End point description:

Analysis was performed on PK population.

End point type	Secondary
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End point timeframe:

Cycle 1, Day 1: pre-dose, at the end of infusion, 168 and 336 hours post-infusion

Notes:

[33] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	52		
Units: mcg*hour/mL				
geometric mean (geometric coefficient of variation)	91271 (± 78)	86761 (± 77)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic assessment: Phase 2 Stage 2: Area under the plasma concentration versus time curve of Isatuximab over 1 week interval

End point title	Pharmacokinetic assessment: Phase 2 Stage 2: Area under the plasma concentration versus time curve of Isatuximab over 1 week interval ^[34]
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End point description:

Analysis was performed on PK population which included participants who gave informed consent, received at least one dose (even if incomplete) of isatuximab, had an assessable PK parameter.

End point type	Secondary
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End point timeframe:

Pre-dose, at the end of infusion, 1 hour and 168 hours post dose on Day 1 of Cycle 1

Notes:

[34] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	52		
Units: mcg*hour/mL				
geometric mean (geometric coefficient of variation)	37096 (\pm 80)	35423 (\pm 88)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic assessment: Phase 2 Stage 2: Area under the plasma concentration versus time curve of Isatuximab over 4 weeks interval

End point title	Pharmacokinetic assessment: Phase 2 Stage 2: Area under the plasma concentration versus time curve of Isatuximab over 4 weeks interval ^[35]
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End point description:

Analysis was performed on PK population.

End point type	Secondary
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End point timeframe:

Cycle 1, Day 1: pre-dose, at the end of infusion, 168, 336, and 672 hours post-infusion

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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	52		
Units: mcg*hour/mL				
geometric mean (geometric coefficient of variation)	236360 (\pm 72)	226372 (\pm 66)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic assessment: Phase 2 Stage 2: plasma concentration of Isatuximab before treatment administration (Ctrough)

End point title	Pharmacokinetic assessment: Phase 2 Stage 2: plasma concentration of Isatuximab before treatment administration (Ctrough) ^[36]
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End point description:

Analysis was performed on PK population.

End point type	Secondary
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End point timeframe:

At Days 7, 14, 28

Notes:

[36] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	52		
Units: mcg/mL				
geometric mean (geometric coefficient of variation)				
Day 7	137 (\pm 75)	128 (\pm 54)		
Day 14	230 (\pm 70)	214 (\pm 57)		
Day 28	360 (\pm 63)	305 (\pm 66)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic assessment: Phase 2 Stage 2: Accumulation ratio of Isatuximab based on Ctrough

End point title	Pharmacokinetic assessment: Phase 2 Stage 2: Accumulation ratio of Isatuximab based on Ctrough ^[37]
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End point description:

Ctrough is the plasma concentration observed before treatment administration. For 1st category, the accumulation ratio was calculated by dividing Ctrough value of Cycle 2 Day 1 by Cycle 1 Day 8 and for second category, accumulation ratio was calculated by dividing Ctrough value of Cycle 4 Day 1 by Cycle 1 Day 8. Analysis was performed on PK population. Here, 'number of participants analyzed' = participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Cycle 2, Day 1; Cycle 1, Day 8; Cycle 4, Day 1

Notes:

[37] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	48		
Units: ratio				
arithmetic mean (standard deviation)				
Cycle 2 Day 1/Cycle 1 Day 8	521.38338 (± 4891.63390)	3.24370 (± 1.73860)		
Cycle 4 Day 1/Cycle 1 Day 8	3.58378 (± 2.77398)	3.95950 (± 3.19310)		

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity assessment: Phase 2 Stage 2: Number of participants with anti-drug antibodies to Isatuximab

End point title	Immunogenicity assessment: Phase 2 Stage 2: Number of participants with anti-drug antibodies to Isatuximab ^[38]
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End point description:

ADA response was categorized as: treatment induced and treatment boosted response. Treatment-induced ADA was defined as ADA that developed at any time during the ADA on-study observation period (defined as the time from the first isatuximab administration until end of Phase 2 Stage 2) in participants without preexisting ADA (defined as: ADA that were present in samples drawn before treatment), including participants without pre-treatment (before treatment) samples. Treatment boosted ADA was defined as pre-existing ADA that increased at least 2 titer steps between pre-treatment (before treatment) and post-treatment. Analysis was performed on ADA evaluable population which included all treated participants with at least one ADA assessment with a reportable result during the ADA on-study observation period.

End point type	Secondary
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End point timeframe:

Up to 97 weeks

Notes:

[38] - 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: Only Phase 2 Stage 2 participants were analyzed in this endpoint.

End point values	Phase 2 Stage 2: Isatuximab alone	Phase 2 Stage 2: Isatuximab + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	53		
Units: participants				
Treatment induced ADA	1	0		
Treatment boosted ADA	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs=from signing of informed consent up to 30 days from last administration of IP(maximum exposure:up to 120 weeks-Phase 1, 414 weeks-Phase 2 Stage 1a,92 weeks-Phase 2 Stage 1b, 301 weeks-Phase 2 Stage 2).Deaths=for entire study duration, 683 weeks

Adverse event reporting additional description:

Reported AEs and deaths were TEAEs which was defined as an AE that developed or worsened during the 'on treatment period' (time from the first dose of any study treatment up to 30 days after the last administration of the study treatment). Analysis was performed on AT population. Phase 1 MedDRA version was 19.1. Phase 2 MedDRA version was 26.0.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Phase 1: Isatuximab <=1mg/kg Q2W
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Reporting group description:

Participants with CD38+ HM, received Isatuximab at any one of the dose <=1 mg/kg (i.e. either 0.0001 mg/kg or 0.001 mg/kg or 0.01 mg/kg or 0.03 mg/kg, or 0.1 mg/kg or 0.3 mg/kg or 1 mg/kg) as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal by participant, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 3mg/kg Q2W
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 3 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 5mg/kg Q2W
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 5 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase1:Isatuximab (CD38+HM and Standard Risk Multiple Myeloma)
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Reporting group description:

Participants with CD38+ HM along with participants with standard risk multiple myeloma were included in this arm and, received Isatuximab 10 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)
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Reporting group description:

Participants with CD38+ HM along with participants with high risk multiple myeloma were included in this arm and, received Isatuximab 10 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 10mg/kg QW
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 10 mg/kg, as IV infusion QW, i.e. on Day 1 and 8 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 20mg/kg Q2W
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 20 mg/kg, as IV infusion on Day 1 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent

withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 1: Isatuximab 20mg/kg QW
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Reporting group description:

Participants with CD38+ HM, received Isatuximab 20 mg/kg, as IV infusion QW, i.e. on Day 1 and 8 of each 14-day treatment cycle until occurrence of unacceptable toxicity, disease progression, death, consent withdrawal, investigator's decision, and/or availability of study drug.

Reporting group title	Phase 2 Stage 1a: Isatuximab 3mg/kg Q2W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 3 mg/kg, as IV infusion on Day 1 and Day 15 of each 28-day cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 10 mg/kg, as IV infusion on Day 1 and Day 15 of each 28-day cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 10 mg/kg, as IV infusion Q2W, i.e. on Day 1 and Day 15 of Cycle 1 and 2 (each cycle 28 days), then every 4 weeks (Q4W), i.e. on Day 1 of each 28-days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
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Reporting group description:

Participants with multiple Myeloma received Isatuximab 20 mg/kg, as IV infusion QW, i.e. on Day 1, 8, 15 and 22 of Cycle 1 and 2 (each cycle 28 days), then Q2W, i.e. on Day 1 and Day 15 of each 28-days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination or lost to follow up.

Reporting group title	Phase 2 Stage 2: Isatuximab Alone
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Reporting group description:

Participants with relapsed or relapsed/refractory multiple myeloma (RRMM), received Isatuximab 20 mg/kg, as IV infusion on Day 1, 8, 15 and Day 22 of Cycle 1 (28 days) and then on Day 1 and 15 of each subsequent 28-day cycles until unacceptable AE, disease progression, poor compliance to the study protocol, study termination, lost to follow up or investigator's decision.

Reporting group title	Phase 2 Stage 2: Isatuximab + Dexamethasone
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Reporting group description:

Participants with relapsed or RRMM, received Isatuximab 20 mg/kg, as IV infusion on Day 1, 8, 15 and Day 22 of Cycle 1 (28 days) and then on Day 1 and 15 of each subsequent 28-day cycles along with dexamethasone: tablet or as IV infusion (40 mg/day for <75 years of age; 20 mg/day for ≥75 years of age) on Days 1, 8, 15 and 22 of each 28 days cycle until unacceptable AE, disease progression, poor compliance to the study protocol, study termination, lost to follow up or investigator's decision.

Serious adverse events	Phase 1: Isatuximab ≤1mg/kg Q2W	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5mg/kg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 16 (18.75%)	3 / 6 (50.00%)	1 / 3 (33.33%)
number of deaths (all causes)	5	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Colon Cancer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Plasma Cell Leukaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 The Oral Cavity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Aortic Aneurysm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Extrinsic Iliac Vein Compression			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Hypertensive Crisis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Chills			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Asthenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Disease Progression			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Feeling Cold			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Hyperpyrexia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Physical Health Deterioration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Physical Deconditioning			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Performance Status Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Sudden Death			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Pelvic Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Bronchospasm			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Apnoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Dyspnoea At Rest			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Dyspnoea Exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Laryngeal Oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Laryngospasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Pharyngeal Swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Pleural Effusion			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Tract Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Alkalosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Fibrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Product issues			
Device Malfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Device Occlusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Investigations			
Blood Creatinine Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Pressure Increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Infusion Related Reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Joint Injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Road Traffic Accident			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Post Procedural Complication			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Traumatic Fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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

Acute Myocardial Infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Stress Cardiomyopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Cardiac Failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Cerebral Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Dizziness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Headache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Sciatica			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Ischaemic Stroke			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Seizure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Spinal Cord Compression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Febrile Neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Hyperviscosity Syndrome			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Thrombocytopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Eye disorders			
Eye Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Cataract			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Visual Impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Diverticular Perforation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Amyloidosis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Intussusception			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Ileus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Mechanical Ileus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Nausea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Obstruction Gastric			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Hyperbilirubinaemia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Cholestasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Kidney Disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Endocrine disorders			
Hypercalcaemia Of Malignancy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Pathological Fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Spinal Stenosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Acute Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Abdominal Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (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
Atypical Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Bronchiolitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Campylobacter Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Covid-19 Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Device Related Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Escherichia Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Gastroenteritis Rotavirus			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Haemophilus Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Infectious Colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Infective Aortitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Intervertebral Discitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Lower Respiratory Tract Infection Viral			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Bacterial			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Meningococcal Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Otitis Media			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Pneumococcal Bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Aspiration			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Mycoplasmal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Respiratory Syncytial Viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Streptococcal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Syncytial Virus Infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Septic Shock			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Tracheobronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Urinary Tract Infection			

subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (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
Varicella			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Varicella Zoster Virus Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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			
Decreased Appetite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Electrolyte Imbalance			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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	1 / 16 (6.25%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour Lysis Syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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
Hyperuricaemia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (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

Serious adverse events	Phase1:Isatuximab (CD38+HM and Standard Risk Multiple Myeloma)	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple Myeloma)	Phase 1: Isatuximab 10mg/kg QW
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 26 (38.46%)	10 / 18 (55.56%)	3 / 6 (50.00%)
number of deaths (all causes)	0	2	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Plasma Cell Leukaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (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
Squamous Cell Carcinoma Of The Oral Cavity			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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			
Aortic Aneurysm			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Extrinsic Iliac Vein Compression			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Hypertensive Crisis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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			
Chills			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Asthenia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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

Disease Progression				
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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	
Fatigue				
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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	
Feeling Cold				
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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	
Hyperpyrexia				
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Physical Health Deterioration				
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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	
Non-Cardiac Chest Pain				
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Malaise				
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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				
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Pyrexia				

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Physical Deconditioning			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Performance Status Decreased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (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
Pelvic Pain			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Dyspnoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Bronchospasm			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Apnoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Dyspnoea At Rest			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Dyspnoea Exertional			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Haemoptysis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Laryngeal Oedema			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Laryngospasm			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Pharyngeal Swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Pleural Effusion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Tract Haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Alkalosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Fibrosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Product issues			
Device Malfunction			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Device Occlusion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Investigations			
Blood Creatinine Increased			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Pressure Increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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			
Fall			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Infusion Related Reaction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Joint Injury			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (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
Road Traffic Accident			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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

Post Procedural Complication subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Traumatic Fracture subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Cardiac disorders			
Acute Coronary Syndrome subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Myocardial Infarction subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Cardiomyopathy subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Cardiac Failure subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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			

Cerebral Haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Dizziness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Headache			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Sciatica			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Ischaemic Stroke			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Seizure			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Spinal Cord Compression			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Somnolence			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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			
Anaemia			
subjects affected / exposed	1 / 26 (3.85%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperviscosity Syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Thrombocytopenia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Eye disorders			
Eye Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Cataract			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Visual Impairment			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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			

Diarrhoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Diverticular Perforation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Amyloidosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Intussusception			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Ileus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Mechanical Ileus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Nausea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction Gastric			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Cholestasis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Chronic Kidney Disease			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Endocrine disorders			

Hypercalcaemia Of Malignancy subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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			
Musculoskeletal Chest Pain subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (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
Back Pain subjects affected / exposed	0 / 26 (0.00%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Pathological Fracture subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (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
Pain In Extremity subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Spinal Stenosis subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Acute Sinusitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 18 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
Abdominal Sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 18 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
Atypical Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 18 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
Bronchiolitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 18 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
Bronchitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 26 (3.85%) 0 / 1 0 / 0	0 / 18 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
Campylobacter Gastroenteritis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 18 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
Covid-19 Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 18 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
Cellulitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 18 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
Device Related Infection			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Escherichia Sepsis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Gastroenteritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Gastroenteritis Rotavirus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Haemophilus Sepsis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious Colitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (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
Herpes Zoster			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective Aortitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Intervertebral Discitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Lower Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (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
Meningitis Bacterial			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Meningococcal Sepsis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Otitis Media			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae Virus Infection			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Pneumococcal Bacteraemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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	4 / 26 (15.38%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	2 / 4	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Bacterial			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Mycoplasmal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Respiratory Syncytial Viral			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Streptococcal			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Sepsis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Syncytial Virus Infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 Tract Infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Septic Shock			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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	2 / 26 (7.69%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Tracheobronchitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Varicella			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella Zoster Virus Infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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			
Decreased Appetite			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Dehydration			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Electrolyte Imbalance			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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
Tumour Lysis Syndrome			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (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

Serious adverse events	Phase 1: Isatuximab 20mg/kg Q2W	Phase 1: Isatuximab 20mg/kg QW	Phase 2 Stage 1a: Isatuximab 3mg/kg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 7 (42.86%)	3 / 7 (42.86%)	13 / 23 (56.52%)
number of deaths (all causes)	2	0	11
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Colon Cancer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma Cell Leukaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 The Oral Cavity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Aortic Aneurysm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Extrinsic Iliac Vein Compression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Hypertensive Crisis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Hypotension			

subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease Progression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	4 / 23 (17.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	4 / 4
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Feeling Cold			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Hyperpyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Physical Health Deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Non-Cardiac Chest Pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Physical Deconditioning			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Performance Status Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Sudden Death			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Social circumstances			

Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Pelvic Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (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
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Bronchospasm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Apnoea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea At Rest			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Dyspnoea Exertional			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Haemoptysis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal Oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (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
Laryngospasm			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (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
Pharyngeal Swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Pleural Effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Alkalosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Fibrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Product issues			
Device Malfunction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Device Occlusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Investigations			
Blood Creatinine Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Pressure Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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

Infusion Related Reaction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Road Traffic Accident			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Post Procedural Complication			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Traumatic Fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Acute Myocardial Infarction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Stress Cardiomyopathy			

subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (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
Cardiac Failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Cerebral Haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Sciatica			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Ischaemic Stroke			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Seizure			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Anaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperviscosity Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Eye Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Cataract			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Visual Impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Diverticular Perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Amyloidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Intussusception			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Mechanical Ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction Gastric			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Cholestasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Kidney Disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypercalcaemia Of Malignancy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Back Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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

Pathological Fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Spinal Stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Acute Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Abdominal Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Atypical Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter Gastroenteritis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Covid-19 Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Device Related Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Escherichia Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Gastroenteritis Rotavirus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Haemophilus Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Infectious Colitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Infective Aortitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Intervertebral Discitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Lower Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Bacterial			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Meningococcal Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Otitis Media			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (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
Pneumococcal Bacteraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Aspiration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
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 Bacterial			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Mycoplasmal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Respiratory Syncytial Viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Streptococcal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (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
Pulmonary Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Syncytial Virus Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 Tract Infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Septic Shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	4 / 23 (17.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Tracheobronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 23 (8.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Varicella			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Varicella Zoster Virus Infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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			
Decreased Appetite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Electrolyte Imbalance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Tumour Lysis Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (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

Serious adverse events	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 24 (45.83%)	10 / 25 (40.00%)	9 / 25 (36.00%)
number of deaths (all causes)	13	11	11
number of deaths resulting from			

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Colon Cancer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Plasma Cell Leukaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 The Oral Cavity			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Vascular disorders			
Aortic Aneurysm			

subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrinsic Iliac Vein Compression			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Hypertensive Crisis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Hypotension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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			
Chills			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Asthenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Disease Progression			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 1
Fatigue			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Feeling Cold			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Hyperpyrexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Physical Health Deterioration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Malaise			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Physical Deconditioning			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance Status Decreased			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Sudden Death			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Pelvic Pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Dyspnoea			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Bronchospasm			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Dyspnoea At Rest			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Dyspnoea Exertional			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Haemoptysis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Laryngeal Oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Laryngospasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Pharyngeal Swelling			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Pleural Effusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Tract Haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Alkalosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Fibrosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Product issues			
Device Malfunction			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Device Occlusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Investigations			

Blood Creatinine Increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Pressure Increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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			
Fall			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Infusion Related Reaction			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Road Traffic Accident			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Post Procedural Complication			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Traumatic Fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
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			
Acute Coronary Syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Acute Myocardial Infarction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Stress Cardiomyopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Cardiac Failure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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			
Cerebral Haemorrhage			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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

Headache			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Sciatica			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Ischaemic Stroke			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Seizure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Spinal Cord Compression			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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			
Anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Febrile Neutropenia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Hyperviscosity Syndrome			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Thrombocytopenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Eye disorders			
Eye Pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Cataract			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Visual Impairment			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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 disorders			
Diarrhoea			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Haemorrhage			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Amyloidosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Ileus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical Ileus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Nausea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Obstruction Gastric			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Cholestasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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	1 / 24 (4.17%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Kidney Disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Endocrine disorders			
Hypercalcaemia Of Malignancy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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			
Musculoskeletal Chest Pain			

subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Bone Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
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 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Pathological Fracture			
subjects affected / exposed	1 / 24 (4.17%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain In Extremity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Spinal Stenosis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acute Sinusitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Abdominal Sepsis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Atypical Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Bronchiolitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Bronchitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Campylobacter Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Covid-19 Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Device Related Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Escherichia Sepsis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Rotavirus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus Sepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Infectious Colitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective Aortitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Discitis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Lower Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Bacterial			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Meningococcal Sepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis Media			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Pneumococcal Bacteraemia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Aspiration			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	4 / 24 (16.67%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Bacterial			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Mycoplasmal			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Respiratory Syncytial Viral			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Streptococcal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Sepsis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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 Tract Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Septic Shock			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Tracheobronchitis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
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 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Varicella			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Varicella Zoster Virus Infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Dehydration			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour Lysis Syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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
Hyperuricaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (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

Serious adverse events	Phase 2 Stage 2: Isatuximab Alone	Phase 2 Stage 2: Isatuximab + Dexamethasone	
Total subjects affected by serious adverse events			
subjects affected / exposed	52 / 109 (47.71%)	27 / 55 (49.09%)	
number of deaths (all causes)	56	25	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Cancer			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic Syndrome			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma			

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma Cell Leukaemia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Cancer			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma Of The Oral Cavity			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrinsic Iliac Vein Compression			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Crisis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

Chills			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease Progression			
subjects affected / exposed	7 / 109 (6.42%)	2 / 55 (3.64%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	6 / 7	2 / 2	
Fatigue			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Feeling Cold			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperpyrexia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General Physical Health Deterioration			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			

subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Physical Deconditioning			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Performance Status Decreased			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden Death			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic Pain			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	2 / 109 (1.83%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apnoea			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea At Rest			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea Exertional			

subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Oedema			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal Swelling			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural Effusion			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Respiratory Tract Haemorrhage			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Respiratory Alkalosis			

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Fibrosis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device Malfunction			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Occlusion			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood Creatinine Increased			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Pressure Increased			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion Related Reaction			
subjects affected / exposed	6 / 109 (5.50%)	2 / 55 (3.64%)	
occurrences causally related to treatment / all	6 / 6	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Joint Injury			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road Traffic Accident			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Procedural Complication			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic Fracture			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Myocardial Infarction			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Fibrillation			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress Cardiomyopathy			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Failure			

subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (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 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral Haemorrhage			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Stroke			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Seizure			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Cord Compression			

subjects affected / exposed	2 / 109 (1.83%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (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	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 109 (3.67%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile Neutropenia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperviscosity Syndrome			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Eye Pain			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			

subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual Impairment			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular Perforation			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Amyloidosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical Ileus			

subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			
subjects affected / exposed	0 / 109 (0.00%)	2 / 55 (3.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction Gastric			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (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	4 / 109 (3.67%)	3 / 55 (5.45%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	1 / 1	1 / 2	
Chronic Kidney Disease			

subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (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 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hypercalcaemia Of Malignancy			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Pain			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (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 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological Fracture			
subjects affected / exposed	3 / 109 (2.75%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pain In Extremity			
subjects affected / exposed	1 / 109 (0.92%)	2 / 55 (3.64%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Stenosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Acute Sinusitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Sepsis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical Pneumonia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 109 (0.92%)	3 / 55 (5.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter Gastroenteritis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Covid-19 Pneumonia			

subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Related Infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Sepsis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Rotavirus			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus Sepsis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious Colitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes Zoster			

subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective Aortitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Discitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection Viral			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (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 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis Bacterial			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningococcal Sepsis			

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis Media			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal Bacteraemia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Aspiration			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	8 / 109 (7.34%)	5 / 55 (9.09%)	
occurrences causally related to treatment / all	4 / 10	1 / 5	
deaths causally related to treatment / all	0 / 1	1 / 1	
Pneumonia Bacterial			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Mycoplasmal			

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Respiratory Syncytial Viral			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Streptococcal			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Sepsis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
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	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Syncytial Virus Infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection			
subjects affected / exposed	3 / 109 (2.75%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	2 / 3	0 / 1	
deaths causally related to treatment / all	1 / 1	1 / 1	
Septic Shock			

subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Sepsis			
subjects affected / exposed	3 / 109 (2.75%)	2 / 55 (3.64%)	
occurrences causally related to treatment / all	1 / 3	1 / 3	
deaths causally related to treatment / all	2 / 2	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella Zoster Virus Infection			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased Appetite			

subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte Imbalance			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour Lysis Syndrome			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperuricaemia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	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	Phase 1: Isatuximab ≤1mg/kg Q2W	Phase 1: Isatuximab 3mg/kg Q2W	Phase 1: Isatuximab 5mg/kg Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	6 / 6 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour Pain			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	1 / 3 (33.33%) 1
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hot Flush			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Coldness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	4 / 16 (25.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	6	1	0
Face Oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Fatigue			

subjects affected / exposed	8 / 16 (50.00%)	2 / 6 (33.33%)	1 / 3 (33.33%)
occurrences (all)	10	2	1
Implant Site Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling Hot			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Injection Site Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oedema Peripheral			
subjects affected / exposed	2 / 16 (12.50%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	4 / 16 (25.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	1
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Reproductive system and breast disorders			
Nipple Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea Exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 16 (12.50%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	4	1	0
Cough			
subjects affected / exposed	3 / 16 (18.75%)	2 / 6 (33.33%)	1 / 3 (33.33%)
occurrences (all)	5	2	1
Hypoxia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Laryngeal Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Laryngospasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oropharyngeal Pain			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rhinitis Allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat Lesion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Throat Tightness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Congestion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat Irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tracheal Stenosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Abnormal Dreams			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Agitation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Confusional State			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bradyphrenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Restlessness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Investigations			
Carbon Monoxide Diffusing Capacity Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			

subjects affected / exposed	2 / 16 (12.50%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Electrocardiogram T Wave Abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	2 / 16 (12.50%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Qrs Axis Abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	2 / 16 (12.50%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Infusion Related Reaction			
subjects affected / exposed	5 / 16 (31.25%)	3 / 6 (50.00%)	2 / 3 (66.67%)
occurrences (all)	7	4	2
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint Injury			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	1 / 3 (33.33%) 1
Procedural Pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Sports Injury subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Scapula Fracture subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Cardiac disorders Bundle Branch Block Right subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Right Ventricular Hypertrophy subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Angina Pectoris subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Sinus Tachycardia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Nervous system disorders Balance Disorder			

subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Amnesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 16 (6.25%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Cranial Nerve Paralysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 6 (16.67%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Head Discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	5 / 16 (31.25%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	8	0	1
Paraesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mental Impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vith Nerve Paralysis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toxic Encephalopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 16 (37.50%)	2 / 6 (33.33%)	0 / 3 (0.00%)
occurrences (all)	6	2	0
Thrombocytopenia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scleral Discolouration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dry Eye			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			

subjects affected / exposed	2 / 16 (12.50%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Visual Impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain Upper			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal Tenderness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Mouth			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	3 / 16 (18.75%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	1
Constipation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	2
Dyspepsia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Dysphagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Glossitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 16 (25.00%)	2 / 6 (33.33%)	1 / 3 (33.33%)
occurrences (all)	6	2	1
Mouth Ulceration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 16 (12.50%)	1 / 6 (16.67%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Toothache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Actinic Keratosis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dermatitis Acneiform			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain Of Skin			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-Papular			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash Macular			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0
Rash Erythematous subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Rash Pruritic subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Skin Disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Skin Ulcer subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0
Renal and urinary disorders Acute Kidney Injury subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Urinary Incontinence subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Back Pain subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 6 (0.00%) 0	1 / 3 (33.33%) 1
Bone Pain subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	0 / 6 (0.00%) 0	2 / 3 (66.67%) 2
Bursitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank Pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Groin Pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Joint Swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb Discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Muscle Fatigue			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Muscular Weakness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neck Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			

subjects affected / exposed	2 / 16 (12.50%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Pathological Fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Gastroenteritis Viral			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Angular Cheilitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes Simplex			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis Media			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pyuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tooth Abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	2 / 16 (12.50%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 16 (6.25%)	1 / 6 (16.67%)	1 / 3 (33.33%)
occurrences (all)	4	1	1

Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Hypokalaemia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 6 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	3
Hypocalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pseudohyponatraemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Phase1:Isatuximab (CD38+HM and Standard Risk	Phase 1: Isatuximab (CD38 + HM and High Risk Multiple	Phase 1: Isatuximab 10mg/kg QW
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	Multiple Myeloma)	Myeloma)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 26 (100.00%)	18 / 18 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Tumour Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 26 (3.85%)	2 / 18 (11.11%)	1 / 6 (16.67%)
occurrences (all)	1	2	2
Hot Flush			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Peripheral Coldness			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 26 (15.38%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	4	2	0
Chest Discomfort			
subjects affected / exposed	1 / 26 (3.85%)	1 / 18 (5.56%)	2 / 6 (33.33%)
occurrences (all)	1	1	3

Chills			
subjects affected / exposed	3 / 26 (11.54%)	1 / 18 (5.56%)	2 / 6 (33.33%)
occurrences (all)	3	1	3
Face Oedema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	8 / 26 (30.77%)	5 / 18 (27.78%)	4 / 6 (66.67%)
occurrences (all)	10	6	7
Implant Site Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Feeling Hot			
subjects affected / exposed	1 / 26 (3.85%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Influenza Like Illness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Injection Site Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	2 / 26 (7.69%)	3 / 18 (16.67%)	1 / 6 (16.67%)
occurrences (all)	3	3	1
Pain			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Pyrexia subjects affected / exposed occurrences (all)	5 / 26 (19.23%) 6	3 / 18 (16.67%) 4	1 / 6 (16.67%) 1
Immune system disorders Cytokine Release Syndrome subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Reproductive system and breast disorders Nipple Pain subjects affected / exposed occurrences (all) Vulvovaginal Pain subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0 0 / 26 (0.00%) 0	0 / 18 (0.00%) 0 0 / 18 (0.00%) 0	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Bronchospasm subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all) Dyspnoea Exertional subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Hypoxia subjects affected / exposed occurrences (all) Laryngeal Discomfort subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2 3 / 26 (11.54%) 3 0 / 26 (0.00%) 0 4 / 26 (15.38%) 5 6 / 26 (23.08%) 6 1 / 26 (3.85%) 1 0 / 26 (0.00%) 0	1 / 18 (5.56%) 1 0 / 18 (0.00%) 0 0 / 18 (0.00%) 0 5 / 18 (27.78%) 7 2 / 18 (11.11%) 3 0 / 18 (0.00%) 0 0 / 18 (0.00%) 0	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 1 / 6 (16.67%) 2 3 / 6 (50.00%) 4 1 / 6 (16.67%) 1 0 / 6 (0.00%) 0

Laryngospasm			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Productive Cough			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	4
Rhinitis Allergic			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 26 (0.00%)	3 / 18 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	3	1
Throat Lesion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Throat Tightness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus Congestion			
subjects affected / exposed	0 / 26 (0.00%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Sneezing			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Throat Irritation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Tracheal Stenosis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	1 / 6 (16.67%) 1
Wheezing subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	2 / 18 (11.11%) 2	0 / 6 (0.00%) 0
Psychiatric disorders			
Abnormal Dreams subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Agitation subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Confusional State subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	1 / 18 (5.56%) 1	1 / 6 (16.67%) 1
Bradyphrenia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 18 (5.56%) 1	1 / 6 (16.67%) 1
Depression subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	3 / 26 (11.54%) 3	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Restlessness subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	1 / 6 (16.67%) 3
Nightmare subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Irritability			

subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Investigations			
Carbon Monoxide Diffusing Capacity Decreased subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Blood Creatinine Increased subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	1 / 6 (16.67%) 1
Electrocardiogram T Wave Abnormal subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Lymphocyte Count Decreased subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Platelet Count Decreased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Neutrophil Count Decreased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Qrs Axis Abnormal subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Weight Decreased subjects affected / exposed occurrences (all)	3 / 26 (11.54%) 3	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Injury, poisoning and procedural complications			
Accidental Overdose subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Infusion Related Reaction			

subjects affected / exposed	12 / 26 (46.15%)	10 / 18 (55.56%)	4 / 6 (66.67%)
occurrences (all)	12	13	4
Fall			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Joint Injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sports Injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scapula Fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bundle Branch Block Right			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Right Ventricular Hypertrophy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Angina Pectoris			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Sinus Tachycardia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Nervous system disorders			
Balance Disorder subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Amnesia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 3	1 / 18 (5.56%) 1	1 / 6 (16.67%) 1
Cranial Nerve Paralysis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Cognitive Disorder subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Head Discomfort subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	5 / 26 (19.23%) 5	2 / 18 (11.11%) 2	0 / 6 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Mental Impairment subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	1 / 6 (16.67%) 1
Hypoaesthesia			

subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vith Nerve Paralysis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Toxic Encephalopathy			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Restless Legs Syndrome			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	5
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 26 (38.46%)	4 / 18 (22.22%)	1 / 6 (16.67%)
occurrences (all)	13	7	2
Thrombocytopenia			
subjects affected / exposed	3 / 26 (11.54%)	1 / 18 (5.56%)	1 / 6 (16.67%)
occurrences (all)	4	2	2
Neutropenia			
subjects affected / exposed	1 / 26 (3.85%)	1 / 18 (5.56%)	1 / 6 (16.67%)
occurrences (all)	2	2	2
Eye disorders			
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Scleral Discolouration			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry Eye			

subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Lacrimation Increased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	1 / 6 (16.67%) 1
Vision Blurred subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Visual Impairment subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	1 / 6 (16.67%) 1
Gastrointestinal disorders			
Abdominal Discomfort subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Abdominal Distension subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	1 / 18 (5.56%) 1	1 / 6 (16.67%) 1
Abdominal Pain subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 4	1 / 18 (5.56%) 1	1 / 6 (16.67%) 1
Abdominal Pain Upper subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Abdominal Tenderness subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Dry Mouth subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	1 / 6 (16.67%) 1
Diarrhoea subjects affected / exposed occurrences (all)	6 / 26 (23.08%) 9	4 / 18 (22.22%) 6	1 / 6 (16.67%) 1
Constipation subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	1 / 18 (5.56%) 1	2 / 6 (33.33%) 2

Dyspepsia			
subjects affected / exposed	1 / 26 (3.85%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Gastrointestinal Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	10 / 26 (38.46%)	6 / 18 (33.33%)	4 / 6 (66.67%)
occurrences (all)	13	8	6
Mouth Ulceration			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	6 / 26 (23.08%)	4 / 18 (22.22%)	1 / 6 (16.67%)
occurrences (all)	7	5	2
Toothache			
subjects affected / exposed	1 / 26 (3.85%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	1	1	0

Stomatitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Dermatitis Contact			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis Acneiform			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 26 (3.85%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Hair Texture Abnormal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	2 / 26 (7.69%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Pain Of Skin			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Onychoclasia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash			

subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rash Maculo-Papular			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Rash Macular			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rash Erythematous			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rash Pruritic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin Disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin Ulcer			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 26 (3.85%)	2 / 18 (11.11%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Back Pain			

subjects affected / exposed	6 / 26 (23.08%)	7 / 18 (38.89%)	1 / 6 (16.67%)
occurrences (all)	6	7	2
Bone Pain			
subjects affected / exposed	4 / 26 (15.38%)	3 / 18 (16.67%)	0 / 6 (0.00%)
occurrences (all)	5	4	0
Bursitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Flank Pain			
subjects affected / exposed	2 / 26 (7.69%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Groin Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint Swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Limb Discomfort			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle Fatigue			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Muscle Spasms			
subjects affected / exposed	3 / 26 (11.54%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	3
Musculoskeletal Pain			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 26 (3.85%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Muscular Weakness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Myalgia			

subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	3
Neck Pain			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pain In Extremity			
subjects affected / exposed	3 / 26 (11.54%)	0 / 18 (0.00%)	2 / 6 (33.33%)
occurrences (all)	3	0	3
Pathological Fracture			
subjects affected / exposed	2 / 26 (7.69%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Spinal Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Gastroenteritis Viral			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 26 (3.85%)	3 / 18 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	5	0
Angular Cheilitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Herpes Simplex			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Influenza			
subjects affected / exposed	1 / 26 (3.85%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Otitis Media			
subjects affected / exposed	1 / 26 (3.85%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Oral Candidiasis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 26 (7.69%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Rhinitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth Abscess			
subjects affected / exposed	0 / 26 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Tooth Infection			
subjects affected / exposed	2 / 26 (7.69%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0

Urinary Tract Infection subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	1 / 6 (16.67%) 2
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	7 / 26 (26.92%) 11	3 / 18 (16.67%) 3	3 / 6 (50.00%) 4
Metabolism and nutrition disorders			
Decreased Appetite subjects affected / exposed occurrences (all)	5 / 26 (19.23%) 5	3 / 18 (16.67%) 4	1 / 6 (16.67%) 1
Dehydration subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 18 (5.56%) 1	1 / 6 (16.67%) 1
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	2 / 18 (11.11%) 2	0 / 6 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	1 / 18 (5.56%) 1	0 / 6 (0.00%) 0
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 18 (0.00%) 0	1 / 6 (16.67%) 1
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0
Hyperkalaemia			

subjects affected / exposed	3 / 26 (11.54%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Pseudohyponatraemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: Isatuximab 20mg/kg Q2W	Phase 1: Isatuximab 20mg/kg QW	Phase 2 Stage 1a: Isatuximab 3mg/kg Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 7 (85.71%)	6 / 7 (85.71%)	22 / 23 (95.65%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tumour Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	3 / 23 (13.04%)
occurrences (all)	0	0	3
Hot Flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 7 (0.00%)	2 / 7 (28.57%)	4 / 23 (17.39%)
occurrences (all)	0	39	4
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	3 / 23 (13.04%)
occurrences (all)	0	0	3
Pallor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Peripheral Coldness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Chest Discomfort			
subjects affected / exposed	2 / 7 (28.57%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	2	0	1
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	3 / 23 (13.04%)
occurrences (all)	0	0	5
Face Oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 7 (57.14%)	1 / 7 (14.29%)	5 / 23 (21.74%)
occurrences (all)	6	1	5
Implant Site Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Feeling Hot			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Injection Site Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	2 / 23 (8.70%) 3
Pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	1 / 23 (4.35%) 1
Peripheral Swelling subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	3 / 23 (13.04%) 3
Immune system disorders Cytokine Release Syndrome subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Reproductive system and breast disorders Nipple Pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Vulvovaginal Pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Bronchospasm subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Dyspnoea Exertional subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 23 (4.35%) 1
Dyspnoea subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	0 / 7 (0.00%) 0	5 / 23 (21.74%) 6
Cough			

subjects affected / exposed	1 / 7 (14.29%)	2 / 7 (28.57%)	2 / 23 (8.70%)
occurrences (all)	1	2	3
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Laryngeal Discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Laryngospasm			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Nasal Congestion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Productive Cough			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Rhinitis Allergic			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Throat Lesion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Throat Tightness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Sinus Congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Sneezing			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Throat Irritation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tracheal Stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 23 (4.35%)
occurrences (all)	1	1	1
Psychiatric disorders			
Abnormal Dreams			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Confusional State			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Bradyphrenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 23 (4.35%)
occurrences (all)	0	1	1

Restlessness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Investigations			
Carbon Monoxide Diffusing Capacity Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	2 / 23 (8.70%)
occurrences (all)	1	0	2
Electrocardiogram T Wave Abnormal			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Platelet Count Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	5 / 23 (21.74%)
occurrences (all)	0	0	9
Neutrophil Count Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Qrs Axis Abnormal			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Weight Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			

Accidental Overdose subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1	1 / 23 (4.35%) 1
Infusion Related Reaction subjects affected / exposed occurrences (all)	4 / 7 (57.14%) 4	3 / 7 (42.86%) 74	9 / 23 (39.13%) 11
Fall subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Joint Injury subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Procedural Pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1	0 / 23 (0.00%) 0
Sports Injury subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Scapula Fracture subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Cardiac disorders Bundle Branch Block Right subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Right Ventricular Hypertrophy			

subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Angina Pectoris			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Cranial Nerve Paralysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Head Discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 7 (28.57%)	1 / 7 (14.29%)	4 / 23 (17.39%)
occurrences (all)	4	33	4

Paraesthesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Mental Impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Vith Nerve Paralysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Toxic Encephalopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 23 (4.35%)
occurrences (all)	0	2	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	9 / 23 (39.13%)
occurrences (all)	0	0	14
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Scleral Discolouration			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Lacrimation Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Abdominal Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Abdominal Pain Upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Abdominal Tenderness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dry Mouth			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1

Diarrhoea			
subjects affected / exposed	1 / 7 (14.29%)	2 / 7 (28.57%)	5 / 23 (21.74%)
occurrences (all)	1	2	7
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	6 / 23 (26.09%)
occurrences (all)	0	0	6
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	6 / 23 (26.09%)
occurrences (all)	4	1	6
Mouth Ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Vomiting			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 23 (4.35%)
occurrences (all)	2	1	1
Toothache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dermatitis Acneiform			
subjects affected / exposed	2 / 7 (28.57%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
Pain Of Skin			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Rash Maculo-Papular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash Macular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash Erythematous			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash Pruritic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Skin Disorder			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Skin Ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
Urinary Incontinence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	3 / 23 (13.04%)
occurrences (all)	0	0	3
Back Pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	2 / 23 (8.70%)
occurrences (all)	0	5	2
Bone Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Flank Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Groin Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Joint Swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Limb Discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Muscle Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal Chest Pain			

subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	3 / 23 (13.04%)
occurrences (all)	0	3	3
Muscular Weakness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Neck Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Pain In Extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Pathological Fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Gastroenteritis Viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Angular Cheilitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Herpes Simplex			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 23 (4.35%)
occurrences (all)	0	8	1
Otitis Media			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Oral Candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Respiratory Tract Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1

Tooth Abscess subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Tooth Infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Urinary Tract Infection subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	1 / 23 (4.35%) 1
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 4	1 / 7 (14.29%) 1	4 / 23 (17.39%) 5
Metabolism and nutrition disorders			
Decreased Appetite subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 7 (14.29%) 1	4 / 23 (17.39%) 4
Dehydration subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	3 / 23 (13.04%) 5
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 23 (4.35%) 1
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 23 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 23 (4.35%) 1
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	1 / 23 (4.35%) 1
Hypocalcaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	3 / 23 (13.04%)
occurrences (all)	0	0	3
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pseudohyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W	Phase 2 Stage 1a: Isatuximab 10mg/kg Q2W; Then Q4W	Phase 2 Stage 1b: Isatuximab 20mg/kg QW and Then Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 24 (95.83%)	25 / 25 (100.00%)	24 / 25 (96.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Tumour Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 24 (8.33%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	8	1	0
Hot Flush			
subjects affected / exposed	0 / 24 (0.00%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Flushing			
subjects affected / exposed	1 / 24 (4.17%)	3 / 25 (12.00%)	4 / 25 (16.00%)
occurrences (all)	1	4	5
Hypotension			
subjects affected / exposed	2 / 24 (8.33%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	2	1	1
Pallor			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Peripheral Coldness			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Chest Discomfort			
subjects affected / exposed	4 / 24 (16.67%)	3 / 25 (12.00%)	6 / 25 (24.00%)
occurrences (all)	4	3	6
Chills			
subjects affected / exposed	5 / 24 (20.83%)	8 / 25 (32.00%)	2 / 25 (8.00%)
occurrences (all)	6	12	2
Face Oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	7 / 24 (29.17%)	11 / 25 (44.00%)	9 / 25 (36.00%)
occurrences (all)	7	12	9
Implant Site Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Feeling Hot			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Influenza Like Illness			
subjects affected / exposed	2 / 24 (8.33%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	2	2	0
Malaise			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Injection Site Pain			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Non-Cardiac Chest Pain			
subjects affected / exposed	3 / 24 (12.50%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	4	0	2
Oedema Peripheral			
subjects affected / exposed	5 / 24 (20.83%)	1 / 25 (4.00%)	2 / 25 (8.00%)
occurrences (all)	6	1	3
Pain			
subjects affected / exposed	1 / 24 (4.17%)	2 / 25 (8.00%)	4 / 25 (16.00%)
occurrences (all)	2	2	5
Peripheral Swelling			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	5 / 24 (20.83%)	4 / 25 (16.00%)	3 / 25 (12.00%)
occurrences (all)	6	4	3
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Nipple Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	1 / 24 (4.17%)	4 / 25 (16.00%)	3 / 25 (12.00%)
occurrences (all)	1	4	3
Dyspnoea Exertional			

subjects affected / exposed	2 / 24 (8.33%)	3 / 25 (12.00%)	1 / 25 (4.00%)
occurrences (all)	2	3	1
Dyspnoea			
subjects affected / exposed	5 / 24 (20.83%)	8 / 25 (32.00%)	4 / 25 (16.00%)
occurrences (all)	6	8	4
Cough			
subjects affected / exposed	10 / 24 (41.67%)	7 / 25 (28.00%)	8 / 25 (32.00%)
occurrences (all)	14	10	11
Hypoxia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Laryngeal Discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Laryngospasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	3 / 24 (12.50%)	4 / 25 (16.00%)	3 / 25 (12.00%)
occurrences (all)	5	5	3
Oropharyngeal Pain			
subjects affected / exposed	4 / 24 (16.67%)	4 / 25 (16.00%)	0 / 25 (0.00%)
occurrences (all)	5	5	0
Productive Cough			
subjects affected / exposed	3 / 24 (12.50%)	3 / 25 (12.00%)	1 / 25 (4.00%)
occurrences (all)	3	3	2
Rhinitis Allergic			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	1 / 24 (4.17%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Throat Lesion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Throat Tightness			

subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Sinus Congestion			
subjects affected / exposed	2 / 24 (8.33%)	2 / 25 (8.00%)	3 / 25 (12.00%)
occurrences (all)	2	3	3
Sneezing			
subjects affected / exposed	1 / 24 (4.17%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	1	2	0
Throat Irritation			
subjects affected / exposed	1 / 24 (4.17%)	1 / 25 (4.00%)	2 / 25 (8.00%)
occurrences (all)	2	1	2
Upper-Airway Cough Syndrome			
subjects affected / exposed	2 / 24 (8.33%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	3	1	0
Tracheal Stenosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 24 (0.00%)	5 / 25 (20.00%)	3 / 25 (12.00%)
occurrences (all)	0	5	3
Psychiatric disorders			
Abnormal Dreams			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Confusional State			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	3 / 25 (12.00%)
occurrences (all)	0	0	3
Bradyphrenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 24 (4.17%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	1	1	1

Depression			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	6 / 24 (25.00%)	2 / 25 (8.00%)	3 / 25 (12.00%)
occurrences (all)	7	2	3
Restlessness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Investigations			
Carbon Monoxide Diffusing Capacity Decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	2 / 24 (8.33%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	2	2	0
Electrocardiogram T Wave Abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 24 (0.00%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Neutrophil Count Decreased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Qrs Axis Abnormal			

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Weight Decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	2 / 25 (8.00%) 2	2 / 25 (8.00%) 2
Injury, poisoning and procedural complications			
Accidental Overdose subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 25 (4.00%) 1	1 / 25 (4.00%) 1
Infusion Related Reaction subjects affected / exposed occurrences (all)	13 / 24 (54.17%) 17	14 / 25 (56.00%) 14	15 / 25 (60.00%) 16
Fall subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2	0 / 25 (0.00%) 0	3 / 25 (12.00%) 5
Joint Injury subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Procedural Pain subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Sports Injury subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Scapula Fracture subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Cardiac disorders			
Bundle Branch Block Right subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Palpitations			

subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Right Ventricular Hypertrophy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Angina Pectoris			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Sinus Tachycardia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance Disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 24 (4.17%)	1 / 25 (4.00%)	3 / 25 (12.00%)
occurrences (all)	1	1	3
Cranial Nerve Paralysis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1

Head Discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	5 / 24 (20.83%)	7 / 25 (28.00%)	7 / 25 (28.00%)
occurrences (all)	6	8	8
Paraesthesia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Mental Impairment			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Peripheral Sensory Neuropathy			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	4 / 25 (16.00%)
occurrences (all)	2	0	4
Vith Nerve Paralysis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Toxic Encephalopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
subjects affected / exposed	2 / 24 (8.33%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 24 (12.50%)	8 / 25 (32.00%)	8 / 25 (32.00%)
occurrences (all)	3	11	12
Thrombocytopenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	6 / 25 (24.00%)
occurrences (all)	0	0	9
Neutropenia			

subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 25 (0.00%) 0	3 / 25 (12.00%) 4
Eye disorders			
Conjunctival Haemorrhage subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Scleral Discolouration subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Diplopia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Dry Eye subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Lacrimation Increased subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 25 (0.00%) 0	1 / 25 (4.00%) 2
Vision Blurred subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Visual Impairment subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Gastrointestinal disorders			
Abdominal Discomfort subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Abdominal Distension subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	1 / 25 (4.00%) 1
Abdominal Pain subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	3 / 25 (12.00%) 3	2 / 25 (8.00%) 2
Abdominal Pain Upper			

subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Abdominal Tenderness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dry Mouth			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Diarrhoea			
subjects affected / exposed	7 / 24 (29.17%)	9 / 25 (36.00%)	5 / 25 (20.00%)
occurrences (all)	13	11	9
Constipation			
subjects affected / exposed	4 / 24 (16.67%)	2 / 25 (8.00%)	2 / 25 (8.00%)
occurrences (all)	4	3	2
Dyspepsia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 24 (4.17%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Glossitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 24 (0.00%)	2 / 25 (8.00%)	2 / 25 (8.00%)
occurrences (all)	0	3	2
Nausea			

subjects affected / exposed	9 / 24 (37.50%)	11 / 25 (44.00%)	7 / 25 (28.00%)
occurrences (all)	14	16	8
Mouth Ulceration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 24 (16.67%)	7 / 25 (28.00%)	6 / 25 (24.00%)
occurrences (all)	7	9	10
Toothache			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Stomatitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Dermatitis Contact			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Dermatitis Acneiform			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Hyperhidrosis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Pruritus			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Pain Of Skin			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Rash Maculo-Papular			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Rash Macular			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rash Erythematous			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rash Pruritic			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Skin Disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin Ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			

subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Urinary Incontinence			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	2
Pollakiuria			
subjects affected / exposed	0 / 24 (0.00%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 24 (20.83%)	3 / 25 (12.00%)	5 / 25 (20.00%)
occurrences (all)	7	5	5
Back Pain			
subjects affected / exposed	7 / 24 (29.17%)	3 / 25 (12.00%)	3 / 25 (12.00%)
occurrences (all)	8	3	3
Bone Pain			
subjects affected / exposed	3 / 24 (12.50%)	1 / 25 (4.00%)	2 / 25 (8.00%)
occurrences (all)	3	1	2
Bursitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Flank Pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Groin Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Joint Swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Limb Discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Muscle Fatigue			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 24 (4.17%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	1	2	1
Muscular Weakness			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Myalgia			
subjects affected / exposed	4 / 24 (16.67%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	7	1	1
Neck Pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Pain In Extremity			
subjects affected / exposed	2 / 24 (8.33%)	4 / 25 (16.00%)	4 / 25 (16.00%)
occurrences (all)	2	5	4
Pathological Fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Gastroenteritis Viral			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0

Bronchitis			
subjects affected / exposed	2 / 24 (8.33%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	2	1	1
Angular Cheilitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Herpes Simplex			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 24 (4.17%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	1	2	0
Hordeolum			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 24 (8.33%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	3	2	0
Otitis Media			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oral Candidiasis			
subjects affected / exposed	3 / 24 (12.50%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	3	3	1
Sinusitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0

Respiratory Tract Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tooth Abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Urinary Tract Infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Upper Respiratory Tract Infection			
subjects affected / exposed	7 / 24 (29.17%)	9 / 25 (36.00%)	6 / 25 (24.00%)
occurrences (all)	17	20	9
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	3 / 24 (12.50%)	3 / 25 (12.00%)	5 / 25 (20.00%)
occurrences (all)	4	3	5
Dehydration			
subjects affected / exposed	4 / 24 (16.67%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	4	0	1
Hypercalcaemia			
subjects affected / exposed	3 / 24 (12.50%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	3	0	2
Hyperglycaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			

subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Hypomagnesaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Hypokalaemia			
subjects affected / exposed	3 / 24 (12.50%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	3	1	0
Hypocalcaemia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	1 / 24 (4.17%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	2	1	1
Pseudohyponatraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 2 Stage 2: Isatuximab Alone	Phase 2 Stage 2: Isatuximab + Dexamethasone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	92 / 109 (84.40%)	47 / 55 (85.45%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Tumour Pain			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 109 (0.92%)	4 / 55 (7.27%)	
occurrences (all)	1	4	
Hot Flush			

subjects affected / exposed	3 / 109 (2.75%)	1 / 55 (1.82%)	
occurrences (all)	3	1	
Flushing			
subjects affected / exposed	5 / 109 (4.59%)	1 / 55 (1.82%)	
occurrences (all)	5	1	
Hypotension			
subjects affected / exposed	5 / 109 (4.59%)	1 / 55 (1.82%)	
occurrences (all)	5	1	
Pallor			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Peripheral Coldness			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	8 / 109 (7.34%)	7 / 55 (12.73%)	
occurrences (all)	9	7	
Chest Discomfort			
subjects affected / exposed	1 / 109 (0.92%)	2 / 55 (3.64%)	
occurrences (all)	1	2	
Chills			
subjects affected / exposed	9 / 109 (8.26%)	4 / 55 (7.27%)	
occurrences (all)	10	5	
Face Oedema			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	18 / 109 (16.51%)	11 / 55 (20.00%)	
occurrences (all)	106	17	
Implant Site Pain			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Feeling Hot			

subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Influenza Like Illness subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2	2 / 55 (3.64%) 2	
Malaise subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	2 / 55 (3.64%) 2	
Injection Site Pain subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Non-Cardiac Chest Pain subjects affected / exposed occurrences (all)	3 / 109 (2.75%) 3	0 / 55 (0.00%) 0	
Oedema Peripheral subjects affected / exposed occurrences (all)	5 / 109 (4.59%) 5	5 / 55 (9.09%) 5	
Pain subjects affected / exposed occurrences (all)	5 / 109 (4.59%) 5	3 / 55 (5.45%) 3	
Peripheral Swelling subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	1 / 55 (1.82%) 1	
Pyrexia subjects affected / exposed occurrences (all)	4 / 109 (3.67%) 4	7 / 55 (12.73%) 7	
Immune system disorders Cytokine Release Syndrome subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Reproductive system and breast disorders Nipple Pain subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Vulvovaginal Pain			

subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	5 / 109 (4.59%)	1 / 55 (1.82%)	
occurrences (all)	5	1	
Epistaxis			
subjects affected / exposed	6 / 109 (5.50%)	1 / 55 (1.82%)	
occurrences (all)	6	1	
Dyspnoea Exertional			
subjects affected / exposed	3 / 109 (2.75%)	0 / 55 (0.00%)	
occurrences (all)	3	0	
Dyspnoea			
subjects affected / exposed	17 / 109 (15.60%)	7 / 55 (12.73%)	
occurrences (all)	19	7	
Cough			
subjects affected / exposed	19 / 109 (17.43%)	12 / 55 (21.82%)	
occurrences (all)	22	16	
Hypoxia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Laryngeal Discomfort			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Laryngospasm			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Nasal Congestion			
subjects affected / exposed	9 / 109 (8.26%)	2 / 55 (3.64%)	
occurrences (all)	10	2	
Oropharyngeal Pain			
subjects affected / exposed	3 / 109 (2.75%)	4 / 55 (7.27%)	
occurrences (all)	3	4	
Productive Cough			

subjects affected / exposed	5 / 109 (4.59%)	0 / 55 (0.00%)	
occurrences (all)	5	0	
Rhinitis Allergic			
subjects affected / exposed	3 / 109 (2.75%)	1 / 55 (1.82%)	
occurrences (all)	3	1	
Rhinorrhoea			
subjects affected / exposed	3 / 109 (2.75%)	1 / 55 (1.82%)	
occurrences (all)	3	1	
Throat Lesion			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Throat Tightness			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Sinus Congestion			
subjects affected / exposed	1 / 109 (0.92%)	3 / 55 (5.45%)	
occurrences (all)	1	4	
Sneezing			
subjects affected / exposed	2 / 109 (1.83%)	1 / 55 (1.82%)	
occurrences (all)	2	1	
Throat Irritation			
subjects affected / exposed	5 / 109 (4.59%)	3 / 55 (5.45%)	
occurrences (all)	5	3	
Upper-Airway Cough Syndrome			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Tracheal Stenosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Psychiatric disorders			
Abnormal Dreams			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	

Agitation			
subjects affected / exposed	1 / 109 (0.92%)	2 / 55 (3.64%)	
occurrences (all)	1	2	
Confusional State			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Bradyphrenia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	4 / 109 (3.67%)	1 / 55 (1.82%)	
occurrences (all)	4	1	
Depression			
subjects affected / exposed	3 / 109 (2.75%)	1 / 55 (1.82%)	
occurrences (all)	3	1	
Insomnia			
subjects affected / exposed	2 / 109 (1.83%)	14 / 55 (25.45%)	
occurrences (all)	4	19	
Restlessness			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Nightmare			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Investigations			
Carbon Monoxide Diffusing Capacity Decreased			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Blood Creatinine Increased			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences (all)	2	1	
Electrocardiogram T Wave Abnormal			

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Platelet Count Decreased			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Neutrophil Count Decreased			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Qrs Axis Abnormal			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Weight Decreased			
subjects affected / exposed	2 / 109 (1.83%)	2 / 55 (3.64%)	
occurrences (all)	2	2	
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	2 / 109 (1.83%)	1 / 55 (1.82%)	
occurrences (all)	3	1	
Infusion Related Reaction			
subjects affected / exposed	38 / 109 (34.86%)	20 / 55 (36.36%)	
occurrences (all)	41	21	
Fall			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Joint Injury			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Procedural Pain			

subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 55 (0.00%) 0	
Sports Injury subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Scapula Fracture subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Cardiac disorders Bundle Branch Block Right subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Palpitations subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	2 / 55 (3.64%) 3	
Bradycardia subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 55 (0.00%) 0	
Right Ventricular Hypertrophy subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Angina Pectoris subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Tachycardia subjects affected / exposed occurrences (all)	3 / 109 (2.75%) 3	3 / 55 (5.45%) 3	
Sinus Tachycardia subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	1 / 55 (1.82%) 1	
Nervous system disorders Balance Disorder subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Amnesia			

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Dizziness		
subjects affected / exposed	3 / 109 (2.75%)	4 / 55 (7.27%)
occurrences (all)	3	5
Cranial Nerve Paralysis		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Cognitive Disorder		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Dysgeusia		
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	1
Head Discomfort		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Headache		
subjects affected / exposed	15 / 109 (13.76%)	8 / 55 (14.55%)
occurrences (all)	22	9
Paraesthesia		
subjects affected / exposed	2 / 109 (1.83%)	1 / 55 (1.82%)
occurrences (all)	3	1
Mental Impairment		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Hypoaesthesia		
subjects affected / exposed	4 / 109 (3.67%)	0 / 55 (0.00%)
occurrences (all)	5	0
Peripheral Sensory Neuropathy		
subjects affected / exposed	2 / 109 (1.83%)	5 / 55 (9.09%)
occurrences (all)	2	5
Vith Nerve Paralysis		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Toxic Encephalopathy		

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Restless Legs Syndrome			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 109 (3.67%)	1 / 55 (1.82%)	
occurrences (all)	4	1	
Thrombocytopenia			
subjects affected / exposed	3 / 109 (2.75%)	1 / 55 (1.82%)	
occurrences (all)	3	2	
Neutropenia			
subjects affected / exposed	5 / 109 (4.59%)	0 / 55 (0.00%)	
occurrences (all)	5	0	
Eye disorders			
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Scleral Discolouration			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Diplopia			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Dry Eye			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Lacrimation Increased			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Vision Blurred			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Visual Impairment			

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Abdominal Distension			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Abdominal Pain			
subjects affected / exposed	7 / 109 (6.42%)	1 / 55 (1.82%)	
occurrences (all)	8	2	
Abdominal Pain Upper			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Abdominal Tenderness			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Dry Mouth			
subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Diarrhoea			
subjects affected / exposed	23 / 109 (21.10%)	11 / 55 (20.00%)	
occurrences (all)	37	17	
Constipation			
subjects affected / exposed	11 / 109 (10.09%)	4 / 55 (7.27%)	
occurrences (all)	13	4	
Dyspepsia			
subjects affected / exposed	2 / 109 (1.83%)	5 / 55 (9.09%)	
occurrences (all)	2	7	
Gastrointestinal Pain			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Dysphagia			
subjects affected / exposed	0 / 109 (0.00%)	2 / 55 (3.64%)	
occurrences (all)	0	2	

Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Glossitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Glossodynia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	16 / 109 (14.68%)	7 / 55 (12.73%)	
occurrences (all)	18	32	
Mouth Ulceration			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Rectal Haemorrhage			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	13 / 109 (11.93%)	3 / 55 (5.45%)	
occurrences (all)	15	3	
Toothache			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Stomatitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Dermatitis Contact			

subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Dermatitis Acneiform		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Alopecia		
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)
occurrences (all)	1	0
Erythema		
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	1
Hair Texture Abnormal		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Hyperhidrosis		
subjects affected / exposed	1 / 109 (0.92%)	3 / 55 (5.45%)
occurrences (all)	1	3
Pruritus		
subjects affected / exposed	3 / 109 (2.75%)	2 / 55 (3.64%)
occurrences (all)	4	2
Pain Of Skin		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Onychoclasia		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Rash		
subjects affected / exposed	5 / 109 (4.59%)	1 / 55 (1.82%)
occurrences (all)	5	1
Rash Maculo-Papular		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Rash Macular		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Rash Erythematous		

subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Rash Pruritic subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Skin Disorder subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Skin Ulcer subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Renal and urinary disorders Acute Kidney Injury subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Urinary Incontinence subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Pollakiuria subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	12 / 109 (11.01%) 15	5 / 55 (9.09%) 10	
Back Pain subjects affected / exposed occurrences (all)	20 / 109 (18.35%) 23	9 / 55 (16.36%) 10	
Bone Pain subjects affected / exposed occurrences (all)	10 / 109 (9.17%) 12	1 / 55 (1.82%) 1	
Bursitis subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	0 / 55 (0.00%) 0	
Flank Pain			

subjects affected / exposed	1 / 109 (0.92%)	1 / 55 (1.82%)
occurrences (all)	1	1
Groin Pain		
subjects affected / exposed	3 / 109 (2.75%)	0 / 55 (0.00%)
occurrences (all)	3	0
Joint Swelling		
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)
occurrences (all)	1	0
Limb Discomfort		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Muscle Fatigue		
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)
occurrences (all)	2	0
Muscle Spasms		
subjects affected / exposed	4 / 109 (3.67%)	1 / 55 (1.82%)
occurrences (all)	5	1
Musculoskeletal Pain		
subjects affected / exposed	3 / 109 (2.75%)	2 / 55 (3.64%)
occurrences (all)	5	2
Musculoskeletal Chest Pain		
subjects affected / exposed	9 / 109 (8.26%)	5 / 55 (9.09%)
occurrences (all)	9	5
Muscular Weakness		
subjects affected / exposed	2 / 109 (1.83%)	1 / 55 (1.82%)
occurrences (all)	2	2
Myalgia		
subjects affected / exposed	8 / 109 (7.34%)	3 / 55 (5.45%)
occurrences (all)	10	3
Neck Pain		
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	1
Pain In Extremity		
subjects affected / exposed	8 / 109 (7.34%)	10 / 55 (18.18%)
occurrences (all)	8	13
Pathological Fracture		

subjects affected / exposed	4 / 109 (3.67%)	1 / 55 (1.82%)	
occurrences (all)	4	1	
Spinal Osteoarthritis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Spinal Pain			
subjects affected / exposed	1 / 109 (0.92%)	2 / 55 (3.64%)	
occurrences (all)	1	3	
Infections and infestations			
Gastroenteritis Viral			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	2	
Bronchitis			
subjects affected / exposed	6 / 109 (5.50%)	2 / 55 (3.64%)	
occurrences (all)	8	4	
Angular Cheilitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Gingivitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Herpes Simplex			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Lower Respiratory Tract Infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Influenza			
subjects affected / exposed	4 / 109 (3.67%)	4 / 55 (7.27%)	
occurrences (all)	6	5	
Hordeolum			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	4 / 109 (3.67%)	7 / 55 (12.73%)	
occurrences (all)	7	8	

Otitis Media			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Oral Candidiasis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Sinusitis			
subjects affected / exposed	5 / 109 (4.59%)	3 / 55 (5.45%)	
occurrences (all)	5	5	
Rhinitis			
subjects affected / exposed	5 / 109 (4.59%)	1 / 55 (1.82%)	
occurrences (all)	5	1	
Respiratory Tract Infection			
subjects affected / exposed	3 / 109 (2.75%)	3 / 55 (5.45%)	
occurrences (all)	4	3	
Pyuria			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	5 / 109 (4.59%)	3 / 55 (5.45%)	
occurrences (all)	5	3	
Tooth Abscess			
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Tooth Infection			
subjects affected / exposed	2 / 109 (1.83%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Urinary Tract Infection			
subjects affected / exposed	8 / 109 (7.34%)	2 / 55 (3.64%)	
occurrences (all)	9	2	
Upper Respiratory Tract Infection			
subjects affected / exposed	14 / 109 (12.84%)	8 / 55 (14.55%)	
occurrences (all)	16	9	
Metabolism and nutrition disorders			
Decreased Appetite			

subjects affected / exposed	11 / 109 (10.09%)	4 / 55 (7.27%)
occurrences (all)	11	4
Dehydration		
subjects affected / exposed	3 / 109 (2.75%)	0 / 55 (0.00%)
occurrences (all)	3	0
Hypercalcaemia		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Hyperglycaemia		
subjects affected / exposed	3 / 109 (2.75%)	3 / 55 (5.45%)
occurrences (all)	8	3
Hypophosphataemia		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Hypomagnesaemia		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Hypokalaemia		
subjects affected / exposed	1 / 109 (0.92%)	0 / 55 (0.00%)
occurrences (all)	2	0
Hypocalcaemia		
subjects affected / exposed	0 / 109 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	4
Hyperuricaemia		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Hyperkalaemia		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0
Pseudohyponatraemia		
subjects affected / exposed	0 / 109 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 December 2009	The definition of DLT was revised to include hematological toxicities. A procedure to notify investigators of DLTs and SAEs within 24 hours of occurrence was provided. Clarifications and revisions were incorporated to ensure the first 2 participants in a multiple-dose cohort would not receive study treatment on the same day. Updates were incorporated to remove participants from the study who had dose delays >2 weeks for an AE from study. The definition of participants who were considered unsuitable for standard first-line treatment but suitable for treatment with study treatment was clarified. An assessment of vital signs 6 hours following the first infusion of study treatment was added.
07 April 2010	Information regarding the Clinical Study Director was updated. The clinical trial summary, assessment schedule, and disease response evaluation were corrected. The PK/PD flowcharts were revised and corrections/updates were made. Clarifications were provided regarding the secondary endpoint(s) for PK samples. Appendix C was revised to reflect central labs. Minor edits for consistency in formatting were incorporated.
11 October 2010	The study design was revised to include intra-participant dose escalation. The main selection criteria were revised to exclude participants whose platelet counts were $<50 \times 10^9 /L$ for all indications. The study treatment infusion rate was clarified for all participants. The study flowcharts were revised. Minor edits for formatting consistency were incorporated.
05 January 2011	The study design was revised to remove intra-participant dose escalation. The main selection criteria for multiple myeloma were clarified to include participants with free light-chain disease. The main selection criteria were revised to exclude participants with platelet counts $<50 \times 10^9/L$ for all indications. The IP dilution and rate of infusion for participants were clarified. The study flowcharts were revised. Minor edits for formatting consistency were incorporated.
10 September 2012	The definition for DLT was modified to remove Grade 2 or higher allergic reaction/hypersensitivity attributed to SAR650984. The study flowchart for basic dose escalation was modified. The Guidelines for Management of Hypersensitivity Reactions were changed to include clarification for the management of hypersensitivity reactions in the setting of routine premedication with methylprednisolone, diphenhydramine, and acetaminophen. The dose of drug per administration was clarified to indicate that actual body weight was to be measured at each cycle and should be used for dose escalation. Routine premedication with dexamethasone and diphenhydramine for mild hypersensitivity reactions previously observed was instituted. It was clarified that the selection of disease assessment parameter was based on clinical indication and the judgment of the investigator. The timing of safety evaluations, including laboratory assessments and electrocardiograms, was clarified to be consistent with the study flowcharts. Minor edits for formatting and consistency were incorporated.
05 April 2013	Dose escalation and expansion cohorts were added. Updates were made to the eligibility criteria. New infusion rate information was added for the 20 mg/kg dose escalation cohort. Assessments schedules were added or updated. Other administrative changes and clarifications were incorporated.
13 August 2013	Exclusion criterion was clarified/added to better define required contraception. Information for the Clinical Study Director was updated.

19 March 2014	The dose modification guidance was changed to enable participants in the Phase 1 part of the study to be considered for intra-participant dose modifications if they had received treatment for at least 12 weeks on the current dose level and had no study treatment related AE >Grade 1. The frequency of chest X-ray, spirometry, and diffusion capacity was reduced to only being required during the first 2 cycles, and thereafter as clinically indicated. Minor edits for formatting and consistency were incorporated. Phase 2 was added to the study to allow seamless enrollment of participants after the standard risk expansion cohort had completed enrollment; a few changes related to Phase 2 were made.
08 April 2014	Phase 1 exclusion criterion and Phase 2 exclusion criterion: Clarified wording related to excipients to match Investigator's Brochure (IB). A time window for the collection of PK samples was included. Minor edits for formatting and consistency were incorporated.
22 August 2014	Cohort 13 was added to the Phase 1 part of the study to enable evaluation of the 20 mg/kg weekly dose level. MRD and tumor cell CD38 messenger ribonucleic acid were added to the exploratory endpoints. The collection of an optional pharmacogenetics sample was added. The definition of adverse events of special interest (AESI) and overdose was clarified and updated based on the ongoing safety review. The definition of the high risk cohort was clarified (prior therapy inclusion requirements were clarified). The follow-up for related AEs and all SAEs ongoing at the time of study treatment discontinuation was clarified. The required assessments at 60 days and post-60 days after the last study treatment administration were clarified and harmonized. The guidelines for managing potential hypersensitivity reactions and potential tumor lysis syndrome (TLS) were clarified and harmonized with updated AESI language. The PK software used and PK parameters to be assessed were clarified. Minor edits for formatting and consistency were incorporated. An additional cohort was added to the Phase 2 part of the study to evaluate the dose of 20 mg/kg QW for 4 weeks followed by Q2W in 24 patients. Hereafter, there were 3 parts to the Phase 2 study. Clarified that Phase 1 and Phase 2 data were to be analyzed separately. Changed dose modification guidance to allow participants receiving 3/mg kg who had disease progression to escalate their dose if safety criteria were met. Immunoglobulin (Ig) D and IgE analyses were added. Study flowcharts were added/updated. Definitions added/clarified for AESIs, overdose, refractory disease, AESI, pregnancy.
22 April 2016	Serum pregnancy tests were added to the beginning of each cycle. A new section of contraceptive measures was added. The assessment of the study treatment was updated with general guidelines to be implements for infusion associated reactions and TLS. Appendix K was added to provide Investigators with background information and guidance regarding anti-CD38 interference with serologic testing. Minor edits for formatting and consistency were incorporated. Added a Phase 2 Stage 2 part: isatuximab alone (105 participants) or in combination with dexamethasone (55 participants). A few changes were applied to Stage 2.
12 July 2017	Estimated glomerular filtration rate exclusion criterion was changed. Permitted participants in Phase 2 Stage 1 to switch formulation after the study cutoff. Clarified data collection for participants continuing treatment after analysis cut off date. Clarified timing and assessments at follow-up visits. Modified schedule and /or analyses for PK, ADA, and urinalysis. Modified definition of infusion associated reaction and AESI. Clarified intervals for dose delays/modifications. Clarified instructions when eliminating premedications could be reconsidered. Clarified definition of treatment exposure. Appendices added/deleted/modified to support changes in the protocol. Clarified dose delay management during Cycle 1 QW dosing. Added exception to dose delay criteria resulting in permanent treatment discontinuation if a participant had objective clinical benefit and after Investigator and Sponsor discussion. Added assessment for blood type, phenotype, and antibody screen pretreatment.
11 June 2019	Based on updated PK characterization of isatuximab, the plasma half-life was re-estimated to 28 days. As duration of contraceptive measures was required to last for 5 half-lives, a revised duration of contraceptive measures and pregnancy testing of 5 months after the last isatuximab dose was required.

22 July 2020	A risk of hepatitis reactivation was identified in the SAR650984 IB edition 11 and the respective updates were made. Treatment supply option (oral dexamethasone provided to the participant via a Sponsor-approved courier company) for participants who were unable to come to the study site because of a regional or national emergency declared by a governmental agency. Clarification was added for only necessary copies of medical records (hospitalization and examination reports for SAEs were not to be systematically requested) to be shared with Sponsor. Since ADA were not tested beyond final analysis cutoff date, 30-day follow up sampling (30 days following last use of study drug) was considered sufficient.
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported