Clinical trial results:
An Open-label, Phase 1/2 Study of MEDI-551, a Humanized Monoclonal Antibody Directed Against CD19, in Adult Subjects With Relapsed or Refractory Advanced B-cell Malignancies

Summary

EudraCT number	2009-016378-34
Trial protocol	BE FR
Global end of trial date	21 March 2019

Results information

Result version number	v2 (current)
This version publication date	20 June 2020
First version publication date	05 April 2020
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	MI-CP204

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00983619
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedImmune, LLC
Sponsor organisation address	One MedImmune Way, Gaithersburg, United States, 20878
Public contact	Shahram Rahimian, MedImmune, LLC, +1 800-236-9933, information.center@astrazeneca.com
Scientific contact	Shahram Rahimian, MedImmune, LLC, +1 800-236-9933, information.center@astrazeneca.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	12 April 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 March 2019
Global end of trial reached?	Yes
Global end of trial date	21 March 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability, describe any dose-limiting toxicities (DLTs), and determine the maximum tolerated dose (MTD) or optimum biological dose (OBD) or highest protocol-defined doses (in the absence of exceeding the MTD) for MEDI-551 as monotherapy and in combination with rituximab in participants with relapsed or refractory advanced B-cell malignancies (chronic lymphocytic leukemia [CLL], including small lymphocytic lymphoma [SLL], diffuse large B-cell lymphoma [DLBCL], and follicular lymphoma [FL]).

Protection of trial subjects:

The conduct of this clinical study met all local and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with International Conference on Harmonization guideline: Good Clinical Practice, and applicable regulatory requirements. Participants signed an informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 April 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	6 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 115
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Belgium: 11
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Spain: 4
Worldwide total number of subjects	136
EEA total number of subjects	20

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)	54
From 65 to 84 years	76
85 years and over	6

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 137 participants were screened, out of which 1 participant never received the study treatment. A total of 136 participants received study treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A-MEDI-551 0.5 mg/kg

Arm description:

Participants received intravenous (IV) infusion of MEDI 551 0.5 mg/kg once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 0.5 mg/kg administered intravenously (IV) once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part A-MEDI-551 1 mg/kg

Arm description:

Participants received IV infusion of MEDI 551 1 mg/kg once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 1 mg/kg administered IV once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part A-MEDI-551 2 mg/kg

Arm description:

Participants received IV infusion of MEDI 551 2 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental

Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 2 mg/kg administered IV on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part A-MEDI-551 4 mg/kg

Arm description:

Participants received IV infusion of MEDI 551 4 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 4 mg/kg administered IV on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part A-MEDI-551 8 mg/kg

Arm description:

Participants received IV infusion of MEDI 551 8 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 8 mg/kg administered IV on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part A-MEDI-551 12 mg/kg

Arm description:

Participants received IV infusion of MEDI 551 12 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 12 mg/kg administered IV on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part B-MEDI-551 6 mg/kg

Arm description:

Participants received IV infusion of MEDI- 551 6 mg/kg weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 6 mg/kg administered IV weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part B-MEDI-551 12 mg/kg

Arm description:

Participants received IV infusion of MEDI- 551 12 mg/kg weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 12 mg/kg administered IV weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part B-MEDI-551 24 mg/kg

Arm description:

Participants received IV infusion of MEDI- 551 24 mg/kg weekly for 4 weeks during Cycle 1 (over 2 days on Day 1 and Day 2, and on Days 8, 15, and 22) and thereafter from Cycle 2, on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 24 mg/kg administered IV weekly for 4 weeks during Cycle 1 (over 2 days on Day 1 and Day 2, and on Days 8, 15, and 22) and thereafter from Cycle 2, on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Arm title	Part C-MEDI-551 8 mg/kg + rituximab

Arm description:

Participants received IV infusion of MEDI- 551 8 mg/kg on Days 2 and 8 during Cycle 1 and on Day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m^2 on Days 1, 8, 15, and 22. From Cycle 3 onwards, only MEDI- 551 8 mg/kg was administered on Day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdrew consent.

Arm type	Experimental

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab 375 mg/m^2 administered IV on Days 1, 8, 15, and 22 (28- day cycle). The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdraws consent.

Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 8 mg/kg administered IV on Days 2 and 8 during Cycle 1 and thereafter on Day 1 from Cycle 2 of each 28-day cycle until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdraws consent.

Arm title	Part C-MEDI-551 12 mg/kg + rituximab

Arm description:

Participants received IV infusion of MEDI- 551 12 mg/kg on Days 2 and 8 during Cycle 1 and on Day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m^2 on Days 1, 8, 15, and 22. From Cycle 3 onwards, only MEDI- 551 8 mg/kg was administered on Day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdrew consent.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 12 mg/kg administered IV on Days 2 and 8 during Cycle 1 and thereafter on Day 1 from Cycle 2 of each 28-day cycle until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdraws.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab 375 mg/m^2 administered IV on Days 1, 8, 15, and 22 (28- day cycle). The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdraws consent.

Arm title	Part D-MEDI-551 12 mg/kg

Arm description:

Participants received IV infusion of MEDI-551 12 mg/kg on Days 1 and 8 of Cycle 1 and thereafter Day 1 of 28- day cycles from Cycle 2 onwards. Treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached CR or withdrew consent.

Arm type	Experimental
Investigational medicinal product name	MEDI-551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

MEDI-551 12 mg/kg administered IV on Days 1 and 8 of Cycle 1 and thereafter Day 1 of 28- day cycles from Cycle 2 onwards. Treatment was continued until the participants experiences unacceptable toxicity, disease progression, reached CR or consent withdrawal.

Number of subjects in period 1	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg
Started	3	4	3
Completed	0	0	0
Not completed	3	4	3
Adverse event, serious fatal	-	2	2
Consent withdrawn by subject	2	1	1
Not specified	1	-	-
Lost to follow-up	-	1	-

Number of subjects in period 1	Part A-MEDI-551 4 mg/kg	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg
Started	6	3	76
Completed	1	0	9
Not completed	5	3	67
Adverse event, serious fatal	1	2	30
Consent withdrawn by subject	3	1	23
Not specified	1	-	12
Lost to follow-up	-	-	2

Number of subjects in period 1	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg
Started	3	3	1
Completed	0	1	0
Not completed	3	2	1
Adverse event, serious fatal	1	-	1
Consent withdrawn by subject	-	-	-
Not specified	2	2	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Started	3	17	14
Completed	0	6	3
Not completed	3	11	11
Adverse event, serious fatal	2	9	8
Consent withdrawn by subject	-	1	1
Not specified	1	1	-

Lost to follow-up	-	-	2

Reporting groups

Reporting group title	Part A-MEDI-551 0.5 mg/kg

Reporting group description:

Participants received intravenous (IV) infusion of MEDI 551 0.5 mg/kg once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 1 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 1 mg/kg once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 2 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 2 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 4 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 4 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 8 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 8 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 12 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 12 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part B-MEDI-551 6 mg/kg

Reporting group description:

Participants received IV infusion of MEDI- 551 6 mg/kg weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part B-MEDI-551 12 mg/kg

Reporting group description:

Participants received IV infusion of MEDI- 551 12 mg/kg weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part B-MEDI-551 24 mg/kg

Reporting group description:

Participants received IV infusion of MEDI- 551 24 mg/kg weekly for 4 weeks during Cycle 1 (over 2 days on Day 1 and Day 2, and on Days 8, 15, and 22) and thereafter from Cycle 2, on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part C-MEDI-551 8 mg/kg + rituximab

Reporting group description:

Participants received IV infusion of MEDI- 551 8 mg/kg on Days 2 and 8 during Cycle 1 and on Day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m^2 on Days 1, 8, 15, and 22. From Cycle 3 onwards, only MEDI- 551 8 mg/kg was administered on Day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdrew consent.

Reporting group title	Part C-MEDI-551 12 mg/kg + rituximab

Reporting group description:

Participants received IV infusion of MEDI- 551 12 mg/kg on Days 2 and 8 during Cycle 1 and on Day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m^2 on Days 1, 8, 15, and 22. From Cycle 3 onwards, only MEDI- 551 8 mg/kg was administered on Day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdrew consent.

Reporting group title	Part D-MEDI-551 12 mg/kg

Reporting group description:

Participants received IV infusion of MEDI-551 12 mg/kg on Days 1 and 8 of Cycle 1 and thereafter Day 1 of 28- day cycles from Cycle 2 onwards. Treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached CR or withdrew consent.

Reporting group values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg
Number of subjects	3	4	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	1	1
From 65-84 years	1	2	2
85 years and over	1	1	0
Age Continuous			
Here, the arbitrary number "999" signifies standard deviation not reported as only one participant was evaluable for the specified arm.			
Units: years			
arithmetic mean	66.0	69.5	64.7
standard deviation	± 19.5	± 12.5	± 18.3
Sex: Female, Male Units:			
Male	1	4	2
Female	2	0	1
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	3	3	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	4	3
Unknown or Not Reported	0	0	0

Reporting group values	Part A-MEDI-551 4 mg/kg	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg
Number of subjects	6	3	76
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	2	35
From 65-84 years	2	1	39
85 years and over	0	0	2
Age Continuous			
Here, the arbitrary number "999" signifies standard deviation not reported as only one participant was evaluable for the specified arm.			
Units: years			
arithmetic mean	63.8	60.0	64.4
standard deviation	± 12.7	± 12.1	± 11.2
Sex: Female, Male Units:			
Male	4	2	46
Female	2	1	30
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	1	0	5
White	5	3	68
More than one race	0	0	0
Unknown or Not Reported	0	0	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	6
Not Hispanic or Latino	6	3	70
Unknown or Not Reported	0	0	0

Reporting group values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg
Number of subjects	3	3	1
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0

Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	0	0
From 65-84 years	1	3	1
85 years and over	0	0	0
Age Continuous			
Here, the arbitrary number "999" signifies standard deviation not reported as only one participant was evaluable for the specified arm.			
Units: years			
arithmetic mean	61.3	70.0	78.0
standard deviation	± 20.8	± 7.0	± 999
Sex: Female, Male			
Units:			
Male	2	2	0
Female	1	1	1
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	3	2	1
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	1
Unknown or Not Reported	0	0	0

Reporting group values	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Number of subjects	3	17	14
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	3	4
From 65-84 years	2	12	10
85 years and over	0	2	0
Age Continuous			
Here, the arbitrary number "999" signifies standard deviation not reported as only one participant was evaluable for the specified arm.			
Units: years			
arithmetic mean	68.0	69.4	67.9
standard deviation	± 11.8	± 10.8	± 11.0

Sex: Female, Male Units:			
Male	2	7	9
Female	1	10	5
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	15	14
More than one race	0	0	0
Unknown or Not Reported	1	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	17	14
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	136		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	54		
From 65-84 years	76		
85 years and over	6		
Age Continuous			
Here, the arbitrary number "999" signifies standard deviation not reported as only one participant was evaluable for the specified arm.			
Units: years arithmetic mean standard deviation	- -		
Sex: Female, Male Units:			
Male	81		
Female	55		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	1		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	8		
White	122		

More than one race	0		
Unknown or Not Reported	5		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	6		
Not Hispanic or Latino	130		
Unknown or Not Reported	0		

End points reporting groups

Reporting group title	Part A-MEDI-551 0.5 mg/kg
Reporting group description:	
Participants received intravenous (IV) infusion of MEDI 551 0.5 mg/kg once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part A-MEDI-551 1 mg/kg
Reporting group description:	
Participants received IV infusion of MEDI 551 1 mg/kg once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part A-MEDI-551 2 mg/kg
Reporting group description:	
Participants received IV infusion of MEDI 551 2 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part A-MEDI-551 4 mg/kg
Reporting group description:	
Participants received IV infusion of MEDI 551 4 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part A-MEDI-551 8 mg/kg
Reporting group description:	
Participants received IV infusion of MEDI 551 8 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part A-MEDI-551 12 mg/kg
Reporting group description:	
Participants received IV infusion of MEDI 551 12 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part B-MEDI-551 6 mg/kg
Reporting group description:	
Participants received IV infusion of MEDI- 551 6 mg/kg weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part B-MEDI-551 12 mg/kg
Reporting group description:	
Participants received IV infusion of MEDI- 551 12 mg/kg weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part B-MEDI-551 24 mg/kg
Reporting group description:	
Participants received IV infusion of MEDI- 551 24 mg/kg weekly for 4 weeks during Cycle 1 (over 2 days on Day 1 and Day 2, and on Days 8, 15, and 22) and thereafter from Cycle 2, on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.	
Reporting group title	Part C-MEDI-551 8 mg/kg + rituximab
Reporting group description:	
Participants received IV infusion of MEDI- 551 8 mg/kg on Days 2 and 8 during Cycle 1 and on Day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m^2 on Days 1, 8, 15, and 22. From Cycle 3 onwards, only MEDI- 551 8 mg/kg was administered on Day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdrew consent.	
Reporting group title	Part C-MEDI-551 12 mg/kg + rituximab

Reporting group description:

Participants received IV infusion of MEDI- 551 12 mg/kg on Days 2 and 8 during Cycle 1 and on Day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m^2 on Days 1, 8, 15, and 22. From Cycle 3 onwards, only MEDI- 551 8 mg/kg was administered on Day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdrew consent.

Reporting group title	Part D-MEDI-551 12 mg/kg

Reporting group description:

Participants received IV infusion of MEDI-551 12 mg/kg on Days 1 and 8 of Cycle 1 and thereafter Day 1 of 28- day cycles from Cycle 2 onwards. Treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached CR or withdrew consent.

Subject analysis set title	Part A-MEDI-551
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received IV infusion of MEDI 551 0.5 or 1 mg/kg (both, once every week in 4-week cycles), or 2, or 4, or 8, or 12 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Subject analysis set title	Part B-MEDI-551
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received IV infusion of MEDI- 551 6 or 12 mg/kg weekly for 4 weeks during Cycle 1 (both from Days 1, 8, 15, and 22) or 24 mg/kg weekly for 4 weeks during Cycle 1 (over 2 days on Day 1 and Day 2, and on Days 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Subject analysis set title	Part C-MEDI-551 + Rituximab
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received IV infusion of MEDI- 551 8 or 12 mg/kg on Days 2 and 8 during Cycle 1 and on Day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m^2 on Days 1, 8, 15, and 22. From Cycle 3 onwards, only MEDI- 551 8 or 12 mg/kg was administered on Day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdraws consent.

Subject analysis set title	Part A-MEDI-551 12 mg/kg (expansion)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received IV infusion of MEDI 551 12 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Primary: Optimal Biologic Dose of MEDI-551 for Part A

End point title	Optimal Biologic Dose of MEDI-551 for Part A[1]

End point description:

Optimal biologic dose (OBD) was defined as the dose lower than the maximum tolerated dose (MTD), used for dose expansion. The MTD is defined as the highest dose at which less than equal to (<=) 1 out of 6 participants experience a dose limiting toxicities (DLT) from the time of first administration of MEDI-551 through the first 28-day cycle. The DLT evaluable population was analysed for this endpoint, which included all participants in the dose-escalation phase who received at least 1 full cycle of MEDI-551 and completed safety follow-up through the DLT evaluable period (from the time of first administration of MEDI-551 through the first 28-day of cycle 1).

End point type	Primary

End point timeframe:

Day 1 to Day 28 of Cycle 1

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	Part A-MEDI-551			
Subject group type	Subject analysis set			
Number of subjects analysed	95			
Units: mg/Kg	12			

Statistical analyses

No statistical analyses for this end point

Primary: Highest protocol-defined dose for Part B

End point title	Highest protocol-defined dose for Part B[2]

End point description:

Highest protocol-defined dose is dose of MEDI-551 in the absence of exceeding the MTD in participants with relapsed or rituximab-refractory chronic lymphocytic leukemia (defined as those with less than a partial response (PR) or progression within 6 months after completing therapy with rituximab). The MTD is defined as the highest dose at which <= 1 out of 6 participants experience a DLT from the time of first administration of MEDI-551 through the first 28-day cycle.

End point type	Primary

End point timeframe:

Day 1 to Day 28 of Cycle 1

Notes:

[2] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	Part B-MEDI-551			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: mg/Kg	24			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-emergent Adverse Events (TEAEs) and Treatment-emergent Serious Adverse Events (TESAEs) for Part A, Part B, and Part C

End point title	Number of Participants With Treatment-emergent Adverse Events (TEAEs) and Treatment-emergent Serious Adverse Events (TESAEs) for Part A, Part B, and Part C[3][4]

End point description:

An adverse event (AE) is any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. A serious adverse event (SAE) is an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. TEAEs are defined as events present at baseline that worsened in intensity after administration of study drug or events absent at baseline that emerged after administration of study drug. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.

End point type	Primary

End point timeframe:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: Participants				
TEAEs	3	4	3	6
TESAEs	1	1	2	1

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	76	3	3
Units: Participants				
TEAEs	3	76	3	3
TESAEs	1	23	1	2

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	17	
Units: Participants				
TEAEs	1	3	17	
TESAEs	1	1	9	

Statistical analyses

No statistical analyses for this end point

Primary: Highest protocol-defined dose for Part C

End point title	Highest protocol-defined dose for Part C[5]

End point description:

Highest protocol-defined dose is the dose of MEDI-551 in combination with rituximab at the MTD or the highest protocol-defined dose in the absence of exceeding the MTD in participants with aggressive lymphomas. The MTD is defined as the highest dose at which <= 1 out of 6 participants experience a

DLT from the time of first administration of MEDI-551 through the first 28-day cycle.

End point type	Primary

End point timeframe:

Day 1 to Day 28 of Cycle 1

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	Part C-MEDI-551 + Rituximab			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: mg/kg	12			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Dose Limiting Toxicities of MEDI-551 in Part A, Part B, and Part C

End point title	Number of Participants With Dose Limiting Toxicities of MEDI-551 in Part A, Part B, and Part C[6][7]

End point description:

A dose limiting toxicities (DLT) for arm A, B, and C was defined as MEDI-551 (or rituximab for Arm C) treatment-related AE of any toxicity grade that led to an inability to receive a full cycle of MEDI-551 (or rituximab for Arm C) or any Grade 3 or higher toxicity (except Grade 3 fever, transient Grade 3 rigors or chills, Grade 3 tumor lysis syndrome, any Grade 3 or 4 electrolyte alteration, any Grade 3 liver function test elevation,>= Grade 3 or 4 lymphopenia or leukopenia, <= Grade 4 neutropenia, <= Grade 4 thrombocytopenia, <= Grade 4 anemia, and Grade 3 infusion-related reaction and infusion reaction), during DLT evaluable period.

End point type	Primary

End point timeframe:

Day 1 to Day 28 of Cycle 1

Notes:

[6] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[7] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: Participants	0	0	0	0

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	76	3	3
Units: Participants	0	1	0	0

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	17	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Clinical Laboratory Abnormalities Reported as TEAEs in Part A, Part B, and Part C

End point title	Number of Participants With Clinical Laboratory Abnormalities Reported as TEAEs in Part A, Part B, and Part C[8][9]

End point description:

Number of participants with clinical laboratory abnormalities reported as TEAEs are reported. Clinical laboratory abnormalities are defined as any abnormal findings in analysis of serum chemistry, hematology, and urine. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.

End point type	Primary

End point timeframe:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

Notes:

[8] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: Participants				
Anemia	0	2	0	0
Blood fibrinogen decreased	0	1	0	0
Blood fibrinogen increased	0	1	0	0
Febrile neutropenia	0	0	0	0
Hematocrit decreased	0	1	0	0
Hemoglobin increased	0	0	0	0
Leukopenia	0	0	0	0

Lymphocyte count decreased	0	1	0	0
Lymphopenia	0	0	0	0
Myelocytosis	0	0	0	0
Neutropenia	0	0	0	1
Neutrophil count abnormal	0	1	0	0
Neutrophil count decreased	1	1	0	1
Platelet count decreased	0	0	0	0
Red blood cell count decreased	0	1	0	0
Reticulocytosis	0	0	0	0
Thrombocytopenia	0	1	0	3
White blood cell count decreased	0	0	0	1
Hypergammaglobulinemia	0	0	0	0
Activated PTT prolonged	0	0	0	0
Leukocytosis	0	0	0	0
Alanine aminotransferase increased	0	1	0	0
Aspartate aminotransferase increased	0	1	0	0
Blood alkaline phosphatase increased	0	0	0	0
Blood chloride decreased	0	1	0	0
Blood creatinine increased	0	0	1	0
Blood glucose decreased	0	0	0	0
Blood glucose increased	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0
Blood potassium decreased	0	0	0	0
Blood urea increased	0	1	0	0
Blood uric acid increased	0	0	0	0
Gamma-glutamyl transferase increased	0	0	0	0
Hyperbilirubinemia	0	0	0	1
Hypercalcemia	0	0	0	0
Hyperglycemia	0	0	0	1
Hyperkalemia	0	2	0	0
Hyperuricemia	1	1	0	0
Hypocalcemia	0	2	0	0
Hypoglycemia	0	1	0	0
Hypokalemia	0	0	0	0
Hypomagnesemia	0	0	0	0
Hyponatremia	0	1	0	1
Protein total decreased	0	0	0	1
Blood albumin decreased	0	0	0	0
Hypernatremia	0	0	0	0
Hypoalbuminemia	0	0	0	0
Haematuria	0	0	0	0
Dysuria	0	0	0	0
Pollakiuria	0	0	0	0
Hemoglobinuria	0	0	0	0
Hydronephrosis	0	0	0	0
Urinary incontinence	0	0	0	0

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	76	3	3
Units: Participants				
Anemia	1	6	0	1
Blood fibrinogen decreased	0	0	0	1
Blood fibrinogen increased	0	1	0	1
Febrile neutropenia	0	2	0	1
Hematocrit decreased	0	0	0	0
Hemoglobin increased	0	1	0	0
Leukopenia	0	1	0	1
Lymphocyte count decreased	0	0	0	0
Lymphopenia	0	2	0	1
Myelocytosis	0	1	0	0
Neutropenia	1	14	1	1
Neutrophil count abnormal	0	0	0	0
Neutrophil count decreased	0	5	0	1
Platelet count decreased	0	2	0	1
Red blood cell count decreased	0	0	0	0
Reticulocytosis	0	1	0	0
Thrombocytopenia	0	6	0	1
White blood cell count decreased	1	3	0	2
Hypergammaglobulinemia	0	0	1	0
Activated PTT prolonged	0	0	0	0
Leukocytosis	0	0	0	0
Alanine aminotransferase increased	0	3	0	0
Aspartate aminotransferase increased	0	4	0	0
Blood alkaline phosphatase increased	0	1	0	0
Blood chloride decreased	0	0	0	0
Blood creatinine increased	0	1	0	1
Blood glucose decreased	0	1	0	0
Blood glucose increased	0	1	0	0
Blood lactate dehydrogenase increased	0	2	0	0
Blood potassium decreased	0	1	0	0
Blood urea increased	0	0	0	0
Blood uric acid increased	0	1	0	0
Gamma-glutamyl transferase increased	0	3	0	0
Hyperbilirubinemia	0	0	0	0
Hypercalcemia	0	4	0	0
Hyperglycemia	0	1	0	0
Hyperkalemia	0	0	0	0
Hyperuricemia	0	2	0	0
Hypocalcemia	0	0	0	1
Hypoglycemia	0	1	0	0
Hypokalemia	0	1	0	1
Hypomagnesemia	0	2	0	1
Hyponatremia	0	0	0	0
Protein total decreased	0	0	0	1
Blood albumin decreased	0	0	0	1
Hypernatremia	0	0	0	0
Hypoalbuminemia	0	0	0	0
Haematuria	0	2	0	0
Dysuria	0	1	0	0

Pollakiuria	0	2	0	0
Hemoglobinuria	0	2	0	0
Hydronephrosis	0	0	0	0
Urinary incontinence	0	1	0	0

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	17	
Units: Participants				
Anemia	1	0	4	
Blood fibrinogen decreased	0	0	0	
Blood fibrinogen increased	0	0	0	
Febrile neutropenia	0	0	1	
Hematocrit decreased	0	0	0	
Hemoglobin increased	0	0	0	
Leukopenia	0	0	0	
Lymphocyte count decreased	1	0	2	
Lymphopenia	0	0	0	
Myelocytosis	0	0	0	
Neutropenia	0	1	2	
Neutrophil count abnormal	0	0	0	
Neutrophil count decreased	1	0	2	
Platelet count decreased	1	0	1	
Red blood cell count decreased	0	0	0	
Reticulocytosis	0	0	0	
Thrombocytopenia	0	0	2	
White blood cell count decreased	1	0	2	
Hypergammaglobulinemia	0	0	0	
Activated PTT prolonged	0	0	1	
Leukocytosis	0	0	1	
Alanine aminotransferase increased	1	0	1	
Aspartate aminotransferase increased	1	0	1	
Blood alkaline phosphatase increased	1	0	2	
Blood chloride decreased	0	0	0	
Blood creatinine increased	1	0	2	
Blood glucose decreased	0	0	0	
Blood glucose increased	0	0	0	
Blood lactate dehydrogenase increased	1	0	1	
Blood potassium decreased	0	0	0	
Blood urea increased	0	0	0	
Blood uric acid increased	0	0	0	
Gamma-glutamyl transferase increased	0	0	0	
Hyperbilirubinemia	0	0	1	
Hypercalcemia	0	0	1	
Hyperglycemia	0	0	2	
Hyperkalemia	0	0	0	
Hyperuricemia	1	0	1	
Hypocalcemia	1	0	2	

Hypoglycemia	0	0	1	
Hypokalemia	0	0	1	
Hypomagnesemia	0	0	1	
Hyponatremia	0	0	2	
Protein total decreased	0	0	0	
Blood albumin decreased	0	0	0	
Hypernatremia	1	0	2	
Hypoalbuminemia	1	0	2	
Haematuria	0	0	2	
Dysuria	0	0	2	
Pollakiuria	0	0	0	
Hemoglobinuria	0	0	0	
Hydronephrosis	0	0	2	
Urinary incontinence	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Abnormal Vital Signs Reported as TEAEs in Part A, Part B, and Part C

End point title	Number of Participants With Abnormal Vital Signs Reported as TEAEs in Part A, Part B, and Part C[10][11]

End point description:

Number of participants with abnormal vital signs reported as TEAEs are reported. Abnormal vital signs are defined as any abnormal findings in the vital signs parameters (temperature, blood pressure, pulse rate, respiratory rate, and pulse oximetry). The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.

End point type	Primary

End point timeframe:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

Notes:

[10] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: Participants				
Bradycardia	1	0	0	0
Chills	0	0	0	1
Dyspnea	0	1	1	1
Hypertension	2	1	0	0
Hypotension	1	3	1	0
Orthostatic hypotension	0	0	1	0

Palpitations	0	0	0	0
Pyrexia	0	0	1	2
Systolic hypertension	0	0	0	0
Tachycardia	0	0	0	0

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	76	3	3
Units: Participants				
Bradycardia	0	0	0	0
Chills	0	5	0	1
Dyspnea	0	10	0	2
Hypertension	0	8	0	2
Hypotension	0	4	0	0
Orthostatic hypotension	0	0	0	0
Palpitations	0	1	0	0
Pyrexia	0	16	1	1
Systolic hypertension	0	2	0	0
Tachycardia	0	6	1	0

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	17	
Units: Participants				
Bradycardia	0	0	0	
Chills	0	0	1	
Dyspnea	1	0	4	
Hypertension	0	0	2	
Hypotension	1	0	2	
Orthostatic hypotension	0	0	0	
Palpitations	0	0	1	
Pyrexia	0	0	3	
Systolic hypertension	0	0	0	
Tachycardia	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Abnormal Electrocardiograms Reported as TEAEs in Part A, Part B, and Part C

End point title	Number of Participants With Abnormal Electrocardiograms

	Reported as TEAEs in Part A, Part B, and Part C[12][13]

End point description:

Number of participants with abnormal electrocardiograms (ECGs) reported as TEAEs are reported. Abnormal ECGs are defined as any abnormal findings in heart rate, RR interval, PR interval, QRS, axis, and QT intervals from the primary lead of the digital 12-lead ECG. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.

End point type	Primary

End point timeframe:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

Notes:

[12] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: Participants				
Sinus bradycardia	0	1	0	0
Atrial fibrillation	0	0	0	0
Mitral valve incompetence	0	0	0	0
Supraventricular extrasystoles	0	0	0	0
Tricuspid valve incompetence	0	0	0	0
ECG QT prolonged	0	0	1	0
Atrial flutter	0	0	0	0
Atrial tachycardia	0	0	0	0
supraventricular tachycardia	0	0	0	0

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	76	3	3
Units: Participants				
Sinus bradycardia	0	0	0	0
Atrial fibrillation	0	3	0	1
Mitral valve incompetence	0	1	0	0
Supraventricular extrasystoles	0	1	0	0
Tricuspid valve incompetence	0	1	0	0
ECG QT prolonged	0	1	0	0
Atrial flutter	0	0	0	1
Atrial tachycardia	0	0	0	1
supraventricular tachycardia	0	0	0	1

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	17	
Units: Participants				
Sinus bradycardia	0	0	0	
Atrial fibrillation	0	0	0	
Mitral valve incompetence	0	1	0	
Supraventricular extrasystoles	0	0	0	
Tricuspid valve incompetence	0	0	0	
ECG QT prolonged	0	0	1	
Atrial flutter	0	0	0	
Atrial tachycardia	0	0	0	
supraventricular tachycardia	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Complete Response for Part B, Part C, and Part D

End point title	Percentage of Participants With Complete Response for Part B, Part C, and Part D[14][15]

End point description:

Complete response (CR) is defined as disappearance of all evidence of disease according to International Working Group criteria (IWG). For nodal masses; fluorodeoxyglucose (FDG)-avid or polyethylene terephthalate (PET) positive prior to therapy; mass of any size permitted if PET negative .Variably FDG-avid or PET negative; regression to normal size on computed tomography (CT). For spleen; not palpable, nodules disappeared. For bone marrow; infiltrate cleared on repeat biopsy; if indeterminate by morphology, immunohistochemistry (IHC) was negative. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (EOT) (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[14] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0[16]	3
Units: Percentage of Participants				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	0 (0.0 to 70.8)	(to)	33.3 (0.8 to 90.6)

Notes:

[16] - No participants were analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13		
Units: Percentage of Participants				
number (confidence interval 95%)	18.8 (4.0 to 45.6)	0 (0.0 to 24.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Partial Response for Part B, Part C, and Part D

End point title	Percentage of Participants With Partial Response for Part B, Part C, and Part D[17][18]

End point description:

The partial response (PR) is defined as regression of measurable disease and no new sites according to IWG criteria. Nodal masses: >= 50% decrease in sum of the product diameters (SPD) of up to 6 largest dominant masses; no increase in size of other nodes (a) FDG-avid or PET positive prior to therapy; one or more PET positive at previously involved site (b) FDG-avid or PET negative; regression on CT. Spleen and liver: >= 50% decrease in SPD of nodules (for single nodule in greatest transverse diameter); no increase in size of liver or spleen. Bone marrow: irrelevant if positive prior to therapy. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[17] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0[19]	3
Units: Percentage of Participants				
number (not applicable)	33.3	33.3		33.3

Notes:

[19] - No participants were analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13		
Units: Percentage of Participants				
number (not applicable)	25.0	23.1		

Statistical analyses

No statistical analyses for this end point

Primary: Duration of Complete Response for Part B, Part C, and Part D

End point title	Duration of Complete Response for Part B, Part C, and Part

End point description:

Duration of CR is from the first documentation of a CR to the time of progressive disease/relapse according to IWG criteria. The CR is disappearance of all evidence of disease according to IWG criteria. For nodal masses; FDG-avid or PET positive prior to therapy; mass of any size permitted if PET negative. Variably FDG-avid or PET negative; regression to normal size on CT. For spleen; not palpable, nodules disappeared. For bone marrow; infiltrate cleared on repeat biopsy; if indeterminate by morphology, IHC was negative. Kaplan-Meier method was used to evaluate duration of CR. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment. Duration of CR is calculated for participants with CR. Here, the arbitrary number "20.999" signifies that median was not estimable because insufficient number of participants had events.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[20] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[22]	0[23]	0[24]	1[25]
Units: Months				
median (full range (min-max))	5.6 (5.6 to 5.6)	(to)	(to)	0.3 (0.3 to 0.3)

Notes:

[22] - An arbitrary value for median is reported as 5.6 (Median was not calculated, as < 3 participants).

[23] - No participants were analysed, as no response was observed in this specified arm.

[24] - No participants were analysed for the specified arm.

[25] - An arbitrary value for median is reported as 0.3 (Median was not calculated, as < 3 participants).

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	0[26]		
Units: Months				
median (full range (min-max))	20.999 (20.0 to 38.4)	(to)		

Notes:

[26] - No participants were analysed, as no response was observed in this specified arm.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Objective Response Rate for Part B, Part C, and Part D

End point title	Percentage of Participants With Objective Response Rate for Part B, Part C, and Part D[27][28]

End point description:

ORR is proportion of participants with CR or partial response (PR) as per IWG criteria. CR is disappearance of all evidence of disease (Nodal masses: FDG-avid/PET positive prior to therapy; mass of any size permitted if PET negative; FDG-avid or PET negative - regression to normal size on CT; spleen nodules disappeared; cleared bone marrow infiltrate on repeat biopsy; IHC was negative if unknown by morphology). PR is regression of measurable disease and no new sites as: Nodal masses: >= 50% decrease in sum of the product diameters (SPD) of up to 6 largest dominant masses; no increase in size of other nodes: a) FDG-avid or PET positive prior to therapy; one or more PET positive at previously involved site; b) FDG-avid or PET negative; regression on CT. Spleen and liver: >= 50% decrease in SPD of nodules. Bone marrow: irrelevant if positive prior to therapy. Evaluable population for efficacy is used for this endpoint.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[27] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0[29]	3
Units: Percentage of participants				
number (confidence interval 95%)	66.7 (9.4 to 99.2)	33.3 (0.8 to 90.6)	(to)	66.7 (9.4 to 99.2)

Notes:

[29] - No participant was analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13		
Units: Percentage of participants				
number (confidence interval 95%)	43.8 (19.8 to 70.1)	23.1 (5.0 to 53.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Duration of Objective Response for Part B, Part C, and Part D

End point title	Duration of Objective Response for Part B, Part C, and Part

End point description:

Duration of objective response (DOR) is the first documentation of objective response to the first documented progressive disease (PD) or relapse according to IWG criteria. PD is defined as any new lesion or increase by >=50% of previously involved sites from nadir. For nodal masses: appearance of a new lesion(s) > 1.5 cm in any axis, >= 50% increase in SPD of more than one node, or >= 50% increase in longest diameter of a previously identified node > 1 cm in short axis lesions PET positive if FDG-avid lymphoma or PET positive prior to therapy. For spleen: > 50% increase from nadir in the SPD of any previous lesions. For bone marrow: New or recurrent involvement. Kaplan-Meier method was used to evaluate DOR. Evaluable population for efficacy was analysed for this endpoint. The DOR were calculated for participants with objective response. Here, the arbitrary numbers "38.9999 and 1.9999" signifies that median was not estimable because insufficient number of participants had events.

End point type	Primary

End point timeframe:

Cycle 1 Day 1, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[30] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	0[32]	2
Units: Months				
median (full range (min-max))	38.9999 (38.9 to 47.2)	27.5 (27.5 to 27.5)	(to)	3.7 (2.4 to 3.7)

Notes:

[32] - No participant was analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	3		
Units: Months				
median (full range (min-max))	1.9999 (1.0 to 44.7)	3.7 (1.9 to 27.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Disease Control Rate for Part B, Part C, and Part D

End point title	Percentage of Participants With Disease Control Rate for Part B, Part C, and Part D[33][34]

End point description:

Disease control includes CR, PR, or stable disease (SD) for at least 8 weeks according to IWG criteria. The CR is disappearance of all evidence of disease. Nodal masses; FDG-avid or PET positive prior to therapy; mass of any size permitted if PET negative. FDG-avid or PET negative; regression to normal size on CT. Spleen; not palpable, nodules disappeared. Bone marrow; infiltrate cleared on repeat biopsy; if indeterminate by morphology, IHC was negative. PR is regression of measurable disease and no new sites. Nodal masses: >= 50% decrease in SPD of up to 6 largest dominant masses; no increase in size of other nodes (a) FDG-avid or PET positive prior to therapy; one or more PET positive at previously involved site (b) Variably FDG-avid or PET negative; regression on CT. Spleen and liver: >= 50% decrease in SPD of nodules. Bone marrow: irrelevant if positive prior to therapy. SD is failure to attain CR/PR or PD. Evaluable population for efficacy was analysed for this endpoint.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[33] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0[35]	3
Units: Percentage of participants				
number (confidence interval 95%)	100 (29.2 to 100)	100 (29.2 to 100)	(to)	100 (29.2 to 100)

Notes:

[35] - No participant was analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	6		
Units: Percentage of participants				
number (confidence interval 95%)	68.8 (41.3 to 89.0)	46.2 (19.2 to 74.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Duration of Disease Control for Part B, Part C, and Part D

End point title	Duration of Disease Control for Part B, Part C, and Part D[36][37]

End point description:

Duration of disease control is defined as the time period from start of MEDI-551 administration to the event of PD/relapse. PD is defined as any new lesion or increase by >=50% of previously involved sites from nadir. For nodal masses: appearance of a new lesion > 1.5 cm in any axis, >= 50% increase in SPD of more than one node, or >= 50% increase in longest diameter of a previously identified node > 1 cm in short axis lesions PET positive if FDG-avid lymphoma or PET positive prior to therapy. For spleen: > 50% increase from nadir in the SPD of any previous lesions. For bone marrow: New or recurrent involvement. Kaplan-Meier method was used to evaluate duration of disease control. Evaluable population for efficacy was analysed for this endpoint. Duration of disease control is calculated for the participants with objective response or stable disease response. The arbitrary number "9.9999" signifies that median was not estimable because insufficient number of participants had events.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[36] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0[38]	3
Units: Months				
median (full range (min-max))	9.9999 (9.7 to 50.9)	29.8 (22.6 to 39.5)	(to)	5.5 (4.2 to 5.5)

Notes:

[38] - No participant was analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	6		
Units: Months				
median (full range (min-max))	14.6 (1.7 to 46.5)	3.8 (3.5 to 29.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Time to Response for Part B, Part C, and Part D

End point title	Time to Response for Part B, Part C, and Part D[39][40]

End point description:

Time to response (TTR) is measured from the start of MEDI-551 administration to the first documentation of response (CR or PR) and assessed in participants who have achieved objective response. Kaplan-Meier method was used to evaluate TTR. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment. TTR were calculated for the participants with objective response.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[39] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[40] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	0[41]	2
Units: Months				
median (full range (min-max))	6.5 (3.7 to 9.2)	12.0 (12.0 to 12.0)	(to)	1.8 (1.7 to 1.8)

Notes:

[41] - No participant was analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	3		
Units: Months				
median (full range (min-max))	2.0 (1.7 to 17.3)	1.8 (1.6 to 1.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Progression Free Survival for Part B, Part C, and Part D

End point title	Progression Free Survival for Part B, Part C, and Part D[42][43]

End point description:

Progression-free survival (PFS) is measured from the start of MEDI-551 treatment until the first documentation of disease progression, relapse or death, whichever occurs first. The PFS was censored on the date of last disease assessment for participants who have no documented PD/relapse or death prior to data cutoff, dropout, or the initiation of alternative anticancer therapy. Kaplan-Meier method was used to evaluate PFS. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment. Here, the arbitrary number "9.9999" signifies that median was not estimable because insufficient number of participants had events.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[42] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

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

Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0[44]	3
Units: Months				
median (full range (min-max))	9.9999 (9.7 to 50.9)	29.8 (22.6 to 39.5)	(to)	5.5 (4.2 to 5.5)

Notes:

[44] - No participant was analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13		
Units: Months				
median (full range (min-max))	3.5 (0.7 to 46.5)	2.0 (0.7 to 29.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Overall Survival for Part B, Part C, and Part D

End point title	Overall Survival for Part B, Part C, and Part D[45][46]

End point description:

Overall survival (OS) is measured from the start of MEDI-551 treatment until death. For participants who are alive at the end of study or lost to follow-up, OS will be censored on the last date when participants were known to be alive. Kaplan-Meier method was used to evaluate OS. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment. Here, the arbitrary number "19.9999 and 37.9999" signifies that median was not estimable because insufficient number of participants had events.

End point type	Primary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[45] - 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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[46] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0[47]	3
Units: Months				
median (full range (min-max))	19.9999 (19.4 to 53.8)	37.9999 (37.6 to 41.9)	(to)	25.0 (18.3 to 45.4)

Notes:

[47] - No participant was analysed for the specified arm.

End point values	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13		
Units: Months				
median (full range (min-max))	33.4 (0.9 to 51.3)	17.9 (1.2 to 38.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-emergent Adverse Events (TEAEs) and Treatment-emergent Serious Adverse Events (TESAEs) for Part D

End point title	Number of Participants With Treatment-emergent Adverse Events (TEAEs) and Treatment-emergent Serious Adverse Events (TESAEs) for Part D[48]

End point description:

An AE is any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. A SAE is an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. TEAEs are defined as events present at baseline that worsened in intensity after administration of study drug or events absent at baseline that emerged after administration of study drug. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.

End point type	Secondary

End point timeframe:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

Notes:

[48] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part D-MEDI-551 12 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: Participants				
TEAEs	14			
TESAEs	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Clinical Laboratory Abnormalities Reported as TEAEs in Part D

End point title	Number of Participants With Clinical Laboratory Abnormalities Reported as TEAEs in Part D[49]

End point description:

Number of participants with clinical laboratory abnormalities reported as TEAEs are reported. Clinical laboratory abnormalities are defined as any abnormal findings in analysis of serum chemistry, hematology, and urine. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.

End point type	Secondary

End point timeframe:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

Notes:

[49] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part D-MEDI-551 12 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: Participants				
Anemia	2			
Febrile neutropenia	1			
Lymphocyte count decreased	3			
Neutropenia	1			
Neutrophil count decreased	4			
Platelet count decreased	1			
Polycythemia	1			
Thrombocytopenia	2			
White blood cell count decreased	3			
Blood ALP increased	1			
Blood bilirubin increased	1			
Blood LDH increased	1			
Blood potassium decreased	1			
Hypercalcemia	1			
Hyperglycemia	2			
Hyperuricemia	2			

Hypocalcemia	1			
Hypokalemia	2			
Pollakiuria	1			
Urinary incontinence	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Abnormal Vital Signs Reported as TEAEs in Part D

End point title	Number of Participants With Abnormal Vital Signs Reported as TEAEs in Part D[50]

End point description:

Number of participants with abnormal vital signs reported as TEAEs are reported. Abnormal vital signs are defined as any abnormal findings in the vital signs parameters (temperature, blood pressure, pulse rate, respiratory rate, and pulse oximetry). The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.

End point type	Secondary

End point timeframe:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

Notes:

[50] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part D-MEDI-551 12 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: Participants				
Chills	2			
Dyspnea	1			
Hypertension	1			
Hypotension	1			
Palpitations	1			
Pyrexia	2			
Tachycardia	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Abnormal Electrocardiograms Reported as TEAEs in Part D

End point title	Number of Participants With Abnormal Electrocardiograms Reported as TEAEs in Part D[51]

End point description:

Number of participants with abnormal ECGs reported as TEAEs are reported. Abnormal ECGs are defined as any abnormal findings in heart rate, RR interval, PR interval, QRS, axis, and QT intervals from the primary lead of the digital 12-lead ECG. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.

End point type	Secondary

End point timeframe:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

Notes:

[51] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part D-MEDI-551 12 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: Participants				
ECG QT prolonged	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Complete Response for Part A

End point title	Percentage of Participants With Complete Response for Part

End point description:

The CR is defined as disappearance of all evidence of disease according to IWG criteria. For nodal masses; FDG-avid or PET positive prior to therapy; mass of any size permitted if PET negative .Variably FDG-avid or PET negative; regression to normal size on CT. For spleen; not palpable, nodules disappeared. For bone marrow; infiltrate cleared on repeat biopsy; if indeterminate by morphology, IHC was negative. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[52] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	5
Units: Percentage of Participants				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	0 (0.0 to 60.2)	0 (0.0 to 70.8)	20.0 (0.5 to 71.6)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	72		
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 70.8)	12.5 (5.9 to 22.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Partial Response for Part A

End point title	Percentage of Participants With Partial Response for Part A[53]

End point description:

The PR is defined as regression of measurable disease and no new sites according to IWG criteria. Nodal masses: >= 50% decrease in sum of the product diameters (SPD) of up to 6 largest dominant masses; no increase in size of other nodes (a) FDG-avid or PET positive prior to therapy; one or more PET positive at previously involved site (b) FDG-avid or PET negative; regression on CT. Spleen and liver: >= 50% decrease in SPD of nodules (for single nodule in greatest transverse diameter); no increase in size of liver or spleen. Bone marrow: irrelevant if positive prior to therapy. Evaluable population for efficacy included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[53] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	5
Units: Percentage of Participants				
number (not applicable)	33.3	0	0	0

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	72		
Units: Percentage of Participants				
number (not applicable)	33.3	15.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Complete Response for Part A

End point title	Duration of Complete Response for Part A[54]

End point description:

Duration of CR is from the first documentation of a CR to the time of progressive disease/relapse according to IWG criteria. The CR is disappearance of all evidence of disease. For nodal masses; FDG-avid or PET positive prior to therapy; mass of any size permitted if PET negative. Variably FDG-avid or PET negative; regression to normal size on CT. For spleen; not palpable, nodules disappeared. For bone marrow; infiltrate cleared on repeat biopsy; if indeterminate by morphology, IHC was negative. Kaplan-Meier method was used to evaluate duration of CR. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment. Duration of CR is calculated for participants with CR.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[54] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[55]	0[56]	1
Units: Months				
median (full range (min-max))	7.1 (7.1 to 7.1)	(to)	(to)	14.9 (14.9 to 14.9)

Notes:

[55] - No participants were analysed, as no response was observed in this specified arm.

[56] - No participants were analysed, as no response was observed in this specified arm.

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[57]	9		
Units: Months				
median (full range (min-max))	(to)	14.3 (1.9 to 31.8)		

Notes:

[57] - No participants were analysed, as no response was observed in this specified arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Objective Response Rate for Part A

End point title	Percentage of Participants With Objective Response Rate for Part A[58]

End point description:

The ORR is defined as proportion of participants with CR or PR according to IWG criteria. CR is disappearance of all evidence of disease. For nodal masses; FDG-avid or PET positive prior to therapy; mass of any size permitted if PET negative. FDG-avid or PET negative; regression to normal size on CT. For spleen; not palpable, nodules disappeared. For bone marrow; infiltrate cleared on repeat biopsy; if unknown by morphology, IHC was negative. PR is regression of measurable disease and no new sites. For nodal masses: >= 50% decrease in SPD of up to 6 largest dominant masses; no increase in size of other nodes a) FDG-avid or PET positive prior to therapy; one or more PET positive at previously involved site b) FDG-avid or PET negative; regression on CT. For spleen and liver: >= 50% decrease in SPD of nodules; no increase in size of liver or spleen. For bone marrow: irrelevant if positive prior to therapy. Evaluable population for efficacy was analysed for this endpoint.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[58] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	5
Units: Percentage of participants				
number (confidence interval 95%)	66.7 (9.4 to 99.2)	0 (0.0 to 60.2)	0 (0.0 to 70.8)	20.0 (0.5 to 71.6)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	72		
Units: Percentage of participants				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	27.8 (17.9 to 39.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Objective Response for Part A

End point title	Duration of Objective Response for Part A[59]

End point description:

The DOR is the first documentation of objective response to the first documented PD or relapse

according to IWG criteria. PD is defined as any new lesion or increase by >=50% of previously involved sites from nadir. For nodal masses: appearance of a new lesion(s) > 1.5 cm in any axis, >= 50% increase in SPD of more than one node, or >= 50% increase in longest diameter of a previously identified node > 1 cm in short axis lesions PET positive if FDG-avid lymphoma or PET positive prior to therapy. For spleen: > 50% increase from nadir in the SPD of any previous lesions. For bone marrow: New or recurrent involvement. Kaplan-Meier method was used to evaluate DOR. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment. The DOR were calculated for participants with objective response.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[59] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	0[60]	0[61]	1
Units: Months				
median (full range (min-max))	8.8 (7.4 to 8.8)	(to)	(to)	15.0 (15.0 to 15.0)

Notes:

[60] - No participants were analysed, as no response was observed in this specified arm.

[61] - No participants were analysed, as no response was observed in this specified arm.

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	20		
Units: Months				
median (full range (min-max))	3.0 (3.0 to 3.0)	19.8 (0.0 to 41.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Disease Control Rate for Part A

End point title	Percentage of Participants With Disease Control Rate for Part

End point description:

Disease control includes CR, PR, or SD for at least 8 weeks according to IWG criteria. The CR is disappearance of all evidence of disease. For nodal masses; FDG -avid or PET positive prior to therapy; mass of any size permitted if PET negative. FDG-avid or PET negative; regression to normal size on CT. For spleen; not palpable, nodules disappeared. For bone marrow; infiltrate cleared on repeat biopsy; if indeterminate by morphology, IHC was negative. PR is regression of measurable disease and no new sites. For nodal masses: >= 50% decrease in SPD of up to 6 largest dominant masses; no increase in size of other nodes a) FDG-avid or PET positive prior to therapy; one or more PET positive at previously involved site b) Variably FDG-avid or PET negative; regression on CT. For spleen and liver: >= 50% decrease in SPD of nodules. For bone marrow: irrelevant if positive prior to therapy. SD is failure to

attain CR/PR or PD. Evaluable population for efficacy was analysed for this endpoint.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[62] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	4
Units: Percentage of participants				
number (confidence interval 95%)	66.7 (9.4 to 99.2)	50.0 (6.8 to 93.2)	66.7 (9.4 to 99.2)	80.0 (28.4 to 99.5)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	53		
Units: Percentage of participants				
number (confidence interval 95%)	66.7 (9.4 to 99.2)	73.6 (61.9 to 83.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Disease Control for Part A

End point title	Duration of Disease Control for Part A[63]

End point description:

Duration of disease control is defined as time period from start of MEDI-551 administration to event of PD/relapse according to IWG criteria. PD is defined as new lesion or increase by >=50% of previously involved sites from nadir. Nodal masses:appearance of a new lesion >1.5 cm in any axis, >= 50% increase in SPD of more than one node, or >= 50% increase in longest diameter of a previously identified node >1 cm in short axis lesions PET positive if FDG-avid lymphoma or PET positive prior to therapy. Spleen: >50% increase from nadir in the SPD of any previous lesions. Bone marrow:New or recurrent involvement. Kaplan-Meier method was used to evaluate duration of disease control. Evaluable population for efficacy was analysed for this endpoint. Duration of disease control is calculated for the participants with objective response or stable disease response. Arbitrary numbers "9.9999 and 3.9999" signifies median was not estimable because insufficient number of participants had events.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[63] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	4
Units: Months				
median (full range (min-max))	12.6 (1.4 to 12.6)	9.9999 (9.4 to 21.0)	3.9999 (3.5 to 7.4)	10.9 (3.9 to 94.9)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	53		
Units: Months				
median (full range (min-max))	6.6 (2.8 to 6.6)	18.0 (0.9 to 49.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response for Part A

End point title	Time to Response for Part A[64]

End point description:

The TTR is measured from the start of MEDI-551 administration to the first documentation of response (CR or PR) and assessed in participants who have achieved objective response. Kaplan-Meier method was used to evaluate TTR. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment. TTR were calculated for the participants with objective response.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[64] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	0[65]	0[66]	1
Units: Months				
median (full range (min-max))	3.7 (3.5 to 3.9)	(to)	(to)	1.9 (1.9 to 1.9)

Notes:

[65] - No participants were analysed, as no response was observed in this specified arm.

[66] - No participants were analysed, as no response was observed in this specified arm.

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	20		
Units: Months				
median (full range (min-max))	3.6 (3.6 to 3.6)	3.2 (0.3 to 22.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival for Part A

End point title	Progression Free Survival for Part A[67]

End point description:

The PFS is measured from the start of MEDI-551 treatment until the first documentation of disease progression, relapse or death, whichever occurs first. Kaplan-Meier method was used to evaluate PFS. The PFS was censored on the date of last disease assessment for participants who have no documented PD/relapse or death prior to data cutoff, dropout, or the initiation of alternative anticancer therapy. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[67] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	5
Units: Months				
median (full range (min-max))	12.6 (1.4 to 12.6)	5.9 (0.6 to 21.0)	3.5 (1.6 to 9.9)	4.9 (1.1 to 94.9)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	72		
Units: Months				
median (full range (min-max))	6.6 (2.1 to 6.6)	11.3 (0.0 to 49.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival for Part A

End point title	Overall Survival for Part A[68]

End point description:

The OS is measured from the start of MEDI-551 treatment until death. For participants who are alive at the end of study or lost to follow-up, OS will be censored on the last date when participants were known to be alive. Kaplan-Meier method was used to evaluate OS. Evaluable population for efficacy was analysed for this endpoint, which included all participants who received any treatment of MEDI-551 and completed at least one post-baseline disease assessment. Here, the arbitrary number "1.9999" signifies that median was not estimable because insufficient number of participants had events.

End point type	Secondary

End point timeframe:

Day 1 of all Cycles, then every 2 months during the first year of treatment and then every 6 months until end of treatment (unacceptable toxicity, disease progression, withdraws consent, whichever occurred first) (approximately 9 years)

Notes:

[68] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	5
Units: Months				
median (full range (min-max))	1.9999 (1.4 to 21.5)	44.6 (0.8 to 91.5)	9.9 (2.8 to 9.9)	1.9999 (1.7 to 94.9)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	72		
Units: Months				
median (full range (min-max))	8.1 (2.8 to 12.5)	45.3 (0.7 to 83.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Serum Concentration of MEDI-551 by Treatment Cycle

End point title	Trough Serum Concentration of MEDI-551 by Treatment Cycle

End point description:

Trough serum concentration (Ctrough) is defined as lowest concentration reached by a drug before the next dose is administered. The PK population was analysed for this endpoint, which included all participants who received at least one dose of MEDI-551 and had at least one measurable serum concentration of MEDI-551. Here, the arbitrary numbers "999", "9999", "99999", and "999999" signifies that the sample was below limit of quantification, analysis is not applicable, standard deviation is not reported as only one participant was evaluable, and no participants were analysed for the specified arms respectively.

End point type	Secondary

End point timeframe:

For Part A: C1D1 of each cycles; For Part B: C1D1 of each cycle + C1D8, C1D15, and C1D22; For Part C: C1D2, C1D8, then Day 1 of each cycle until Cycle 10;For Part D: C1D1, C1D8, then Day 1 of each cycle until Cycle 10

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: µg/mL				
arithmetic mean (standard deviation)				
C1D1(n= 3, 4, 3, 6, 3, 6, 3, 3, 1, 3, 17, 14, 66)	999 (± 999)	0.333 (± 0.665)	999 (± 999)	999 (± 999)
C1D2(n= 3, 4, 3, 6, 3, 6, 3, 3, 1, 3, 17, 14, 67)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8(n= 3, 4, 3,6,3,6,3,3,1,3,16,14,67)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D15(n= 3,4,3, 6, 3, 6,3, 3, 1,3 17,14,67)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D22(n= 3,4,3,6,3,6,3,3,0,3,17,14,67)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1(n= 3,3,3,4,3,6,3,3,0,3,12,11,56)	15.6 (± 0.823)	25.9 (± 10.9)	12.9 (± 4.55)	59.4 (± 11.0)
C3D1(n= 2,3,2, 4,2,6,3,3,0,3,11,6,46)	19.3 (± 3.33)	26.9 (± 12.2)	6.78 (± 2.01)	43.0 (± 8.40)
C4D1(n=2,2,2,4,1,5,3,3,0,3,10,6,43)	20.9 (± 6.69)	36.5 (± 0.550)	5.59 (± 0.146)	37.9 (± 13.8)
C5D1(n= 2,2,0,3,1,3,3,3,0,2,7, 2, 34)	26.6 (± 7.17)	46.8 (± 8.03)	999999 (± 999999)	56.9 (± 19.6)
C6D1 (n= 2,2,1,1,1,3,3,3,0,1,7,2, 35)	29.1 (± 6.17)	29.1 (± 17.3)	11.7 (± 99999)	32.0 (± 99999)
C7D1(n= 2,2,1,1,1,3,3,3,0,1 5,1, 28)	31.4 (± 7.08)	25.1 (± 27.8)	9.93 (± 99999)	38.2 (± 99999)
C8D1 (n= 2,2,1,1,0,1,3,3,0,0,5,1, 27)	27.1 (± 14.9)	28.0 (± 1.86)	8.80 (± 99999)	33.3 (± 99999)
C9D1(n= 1,2, 1, 1, 0, 2, 3, 3, 0, 0, 5, 2, 22)	21.6 (± 99999)	31.6 (± 1.23)	10.7 (± 99999)	33.6 (± 99999)
C10D1(n= 1, 1, 1, 1, 0, 2, 3, 3, 0, 0, 4, 1, 23)	17.6 (± 99999)	25.1 (± 99999)	10.6 (± 99999)	32.9 (± 99999)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	3
Units: µg/mL				
arithmetic mean (standard deviation)				
C1D1(n= 3, 4, 3, 6, 3, 6, 3, 3, 1, 3, 17, 14, 66)	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)
C1D2(n= 3, 4, 3, 6, 3, 6, 3, 3, 1, 3, 17, 14, 67)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8(n= 3, 4, 3,6,3,6,3,3,1,3,16,14,67)	9999 (± 9999)	9999 (± 9999)	46.5 (± 20.9)	102 (± 25.0)
C1D15(n= 3,4,3, 6, 3, 6,3, 3, 1,3 17,14,67)	9999 (± 9999)	9999 (± 9999)	81.8 (± 38.3)	197 (± 51.2)
C1D22(n= 3,4,3,6,3,6,3,3,0,3,17,14,67)	9999 (± 9999)	9999 (± 9999)	116 (± 47.4)	281 (± 29.5)
C2D1(n= 3,3,3,4,3,6,3,3,0,3,12,11,56)	89.8 (± 64.9)	166 (± 54.0)	122 (± 37.2)	326 (± 68.0)
C3D1(n= 2,3,2, 4,2,6,3,3,0,3,11,6,46)	97.0 (± 94.5)	149 (± 46.2)	57.6 (± 43.1)	187 (± 80.6)
C4D1(n=2,2,2,4,1,5,3,3,0,3,10,6,43)	33.4 (± 99999)	146 (± 55.5)	36.0 (± 31.6)	134 (± 67.7)
C5D1(n= 2,2,0,3,1,3,3,3,0,2,7, 2, 34)	31.8 (± 99999)	136 (± 19.3)	35.7 (± 32.0)	121 (± 78.1)
C6D1 (n= 2,2,1,1,1,3,3,3,0,1,7,2, 35)	33.7 (± 99999)	138 (± 27.2)	37.3 (± 33.5)	106 (± 54.6)
C7D1(n= 2,2,1,1,1,3,3,3,0,1 5,1, 28)	27.9 (± 99999)	144 (± 42.4)	28.1 (± 21.2)	95.1 (± 54.4)
C8D1 (n= 2,2,1,1,0,1,3,3,0,0,5,1, 27)	999999 (± 999999)	109 (± 99999)	30.8 (± 30.4)	86.8 (± 54.4)
C9D1(n= 1,2, 1, 1, 0, 2, 3, 3, 0, 0, 5, 2, 22)	999999 (± 999999)	124 (± 23.2)	27.3 (± 27.1)	94.8 (± 69.4)
C10D1(n= 1, 1, 1, 1, 0, 2, 3, 3, 0, 0, 4, 1, 23)	999999 (± 999999)	98.3 (± 5.05)	33.4 (± 34.8)	84.2 (± 57.4)

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	17	14
Units: µg/mL				
arithmetic mean (standard deviation)				
C1D1(n= 3, 4, 3, 6, 3, 6, 3, 3, 1, 3, 17, 14, 66)	999 (± 999)	9999 (± 9999)	9999 (± 9999)	999 (± 999)
C1D2(n= 3, 4, 3, 6, 3, 6, 3, 3, 1, 3, 17, 14, 67)	9999 (± 9999)	999 (± 999)	999 (± 999)	9999 (± 9999)
C1D8(n= 3, 4, 3,6,3,6,3,3,1,3,16,14,67)	125 (± 99999)	58.0 (± 14.3)	115 (± 38.0)	109 (± 58.5)
C1D15(n= 3,4,3, 6, 3, 6,3, 3, 1,3 17,14,67)	329 (± 99999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D22(n= 3,4,3,6,3,6,3,3,0,3,17,14,67)	999999 (± 999999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1(n= 3,3,3,4,3,6,3,3,0,3,12,11,56)	999999 (± 999999)	52.4 (± 17.7)	106 (± 28.8)	114 (± 40.1)
C3D1(n= 2,3,2, 4,2,6,3,3,0,3,11,6,46)	999999 (± 999999)	44.7 (± 14.2)	92.1 (± 30.7)	93.9 (± 35.6)
C4D1(n=2,2,2,4,1,5,3,3,0,3,10,6,43)	999999 (± 999999)	48.2 (± 20.8)	113 (± 70.0)	102 (± 61.5)
C5D1(n= 2,2,0,3,1,3,3,3,0,2,7, 2, 34)	999999 (± 999999)	51.6 (± 2.64)	102 (± 26.3)	147 (± 105)
C6D1 (n= 2,2,1,1,1,3,3,3,0,1,7,2, 35)	999999 (± 999999)	45.9 (± 99999)	100 (± 22.9)	150 (± 116)
C7D1(n= 2,2,1,1,1,3,3,3,0,1 5,1, 28)	999999 (± 999999)	45.3 (± 99999)	108 (± 20.2)	248 (± 99999)

C8D1 (n= 2,2,1,1,0,1,3,3,0,0,5,1, 27)	999999 (± 999999)	999999 (± 999999)	147 (± 82.2)	177 (± 99999)
C9D1(n= 1,2, 1, 1, 0, 2, 3, 3, 0, 0, 5, 2, 22)	999999 (± 999999)	999999 (± 999999)	95.0 (± 7.59)	192 (± 25.9)
C10D1(n= 1, 1, 1, 1, 0, 2, 3, 3, 0, 0, 4, 1, 23)	999999 (± 999999)	999999 (± 999999)	113 (± 27.6)	215 (± 99999)

End point values	Part A-MEDI-551 12 mg/kg (expansion)			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: µg/mL				
arithmetic mean (standard deviation)				
C1D1(n= 3, 4, 3, 6, 3, 6, 3, 3, 1, 3, 17, 14, 66)	2.97 (± 24.1)			
C1D2(n= 3, 4, 3, 6, 3, 6, 3, 3, 1, 3, 17, 14, 67)	9999 (± 9999)			
C1D8(n= 3, 4, 3,6,3,6,3,3,1,3,16,14,67)	9999 (± 9999)			
C1D15(n= 3,4,3, 6, 3, 6,3, 3, 1,3 17,14,67)	9999 (± 9999)			
C1D22(n= 3,4,3,6,3,6,3,3,0,3,17,14,67)	9999 (± 9999)			
C2D1(n= 3,3,3,4,3,6,3,3,0,3,12,11,56)	124 (± 64.8)			
C3D1(n= 2,3,2, 4,2,6,3,3,0,3,11,6,46)	113 (± 70.3)			
C4D1(n=2,2,2,4,1,5,3,3,0,3,10,6,43)	113 (± 57.1)			
C5D1(n= 2,2,0,3,1,3,3,3,0,2,7, 2, 34)	117 (± 60.9)			
C6D1 (n= 2,2,1,1,1,3,3,3,0,1,7,2, 35)	123 (± 67.9)			
C7D1(n= 2,2,1,1,1,3,3,3,0,1 5,1, 28)	109 (± 64.2)			
C8D1 (n= 2,2,1,1,0,1,3,3,0,0,5,1, 27)	114 (± 63.8)			
C9D1(n= 1,2, 1, 1, 0, 2, 3, 3, 0, 0, 5, 2, 22)	121 (± 77.5)			
C10D1(n= 1, 1, 1, 1, 0, 2, 3, 3, 0, 0, 4, 1, 23)	139 (± 80.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Peak Serum Concentration of MEDI-551 by Treatment Cycle

End point title	Peak Serum Concentration of MEDI-551 by Treatment Cycle

End point description:

Peak serum concentration is concentration that a drug achieves in a specified compartment or test area of the body after the drug has been administrated and before the administration of a second dose. The PK population was analysed for this endpoint, which included all participants who received at least one dose of MEDI-551 and had at least one measurable serum concentration of MEDI-551. Here, the arbitrary numbers "999", "9999", and "99999", signifies that no participants were analysed, standard deviation is not reported as only one participant was evaluable, and analysis is not applicable, for the specified arms respectively.

End point type	Secondary

End point timeframe:

For Part A: C1D1 of each cycles; For Part B: C1D1 of each cycle + C1D8, C1D15, and C1D22; For Part C: C1D2, C1D8, then Day 1 of each cycle until Cycle 10;For Part D: C1D1, C1D8, then Day 1 of each cycle until Cycle 10

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: µg/mL				
arithmetic mean (standard deviation)				
C1 D1 (n= 3,4,3,4,3,6,3,3,1,3,17, 13, 62)	12.3 (± 1.20)	22.8 (± 1.24)	46.0 (± 22.2)	100 (± 11.0)
C1D2 (n= 3,4,3,6,3,6,3,3,1,3 17, 14, 67)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D8 (n= 3,4,3,6,3,6,3,3,1,3,16, 13, 67)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D15(n= 3,4 3,6 3,6,3,3,1,3 17, 14, 67)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D22(n= 3,4,3,6,3,6,3,3 0,3 17, 14, 67)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1(n= 3,3,3,4 3,6 3,3 0,3,12, 10, 53)	27.5 (± 0.752)	43.9 (± 13.2)	48.8 (± 21.7)	149 (± 29.7)
C3D1(n= 2,3,2,4,2,6,3,3 0,3,11,6, 46)	26.3 (± 2.20)	46.4 (± 16.6)	58.7 (± 0.783)	145 (± 31.2)
C4D1 (n= 2,2,2,4 1,5 3,3 0,3 10, 6, 41)	30.3 (± 5.46)	48.3 (± 12.7)	63.7 (± 35.1)	161 (± 85.6)
C5D1(n= 2,2 0,2 1,3 3,3 0,2 7,2, 32)	39.4 (± 6.85)	70.8 (± 5.43)	999 (± 999)	151 (± 58.1)
C6D1 (n= 2,2 1,1,1,3, 3, 3, 0, 1, 6, 2, 35)	40.4 (± 3.87)	34.4 (± 4.21)	43.2 (± 9999)	123 (± 9999)
C7D1(n= 2,2 1,1, 1, 3,3 3,0,1,5, 1, 27)	41.3 (± 4.72)	39.5 (± 30.8)	41.0 (± 9999)	123 (± 9999)
C8D1 (n= 2,2 1,1 0,1, 3, 3, 0, 0, 5, 1, 26)	29.9 (± 12.3)	58.2 (± 16.9)	32.2 (± 9999)	130 (± 9999)
C9D1 (n= 1,2 1,1 0,2, 3, 3, 0, 0, 5, 2, 22)	32.2 (± 9999)	46.8 (± 5.58)	37.8 (± 9999)	127 (± 999)
C10D1 (n= 1,1,1,1,0,2, 3, 3, 0, 0, 4, 1, 21)	43.3 (± 9999)	33.5 (± 9999)	42.3 (± 9999)	133 (± 9999)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	3
Units: µg/mL				
arithmetic mean (standard deviation)				
C1 D1 (n= 3,4,3,4,3,6,3,3,1,3,17, 13, 62)	166 (± 59.5)	280 (± 99.1)	122 (± 24.2)	335 (± 79.1)
C1D2 (n= 3,4,3,6,3,6,3,3,1,3 17, 14, 67)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D8 (n= 3,4,3,6,3,6,3,3,1,3,16, 13, 67)	99999 (± 99999)	99999 (± 99999)	162 (± 17.3)	393 (± 80.8)
C1D15(n= 3,4 3,6 3,6,3,3,1,3 17, 14, 67)	99999 (± 99999)	99999 (± 99999)	182 (± 31.1)	517 (± 135)
C1D22(n= 3,4,3,6,3,6,3,3 0,3 17, 14, 67)	99999 (± 99999)	99999 (± 99999)	208 (± 46.7)	533 (± 223)

C2D1(n= 3,3,3,4 3,6 3,3 0,3,12, 10, 53)	238 (± 106)	467 (± 114)	186 (± 116)	749 (± 133)
C3D1(n= 2,3,2,4,2,6,3,3 0,3,11,6, 46)	260 (± 89.6)	374 (± 116)	155 (± 38.2)	374 (± 125)
C4D1 (n= 2,2,2,4 1,5 3,3 0,3 10, 6, 41)	201 (± 9999)	359 (± 115)	156 (± 81.7)	384 (± 169)
C5D1(n= 2,2 0,2 1,3 3,3 0,2 7,2, 32)	203 (± 9999)	372 (± 113)	153 (± 71.6)	363 (± 261)
C6D1 (n= 2,2 1,1,1,3, 3, 3, 0, 1, 6, 2, 35)	198 (± 9999)	345 (± 101)	130 (± 45.7)	349 (± 140)
C7D1(n= 2,2 1,1, 1, 3,3 3,0,1,5, 1, 27)	182 (± 9999)	383 (± 54.6)	174 (± 60.4)	333 (± 133)
C8D1 (n= 2,2 1,1 0,1, 3, 3, 0, 0, 5, 1, 26)	999 (± 999)	409 (± 9999)	164 (± 52.0)	342 (± 173)
C9D1 (n= 1,2 1,1 0,2, 3, 3, 0, 0, 5, 2, 22)	999 (± 999)	391 (± 79.6)	159 (± 64.7)	299 (± 69.8)
C10D1 (n= 1,1,1,1,0,2, 3, 3, 0, 0, 4, 1, 21)	999 (± 999)	307 (± 49.8)	166 (± 64.1)	316 (± 189)

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	17	14
Units: µg/mL				
arithmetic mean (standard deviation)				
C1 D1 (n= 3,4,3,4,3,6,3,3,1,3,17, 13, 62)	199 (± 9999)	99999 (± 99999)	99999 (± 99999)	260 (± 87.3)
C1D2 (n= 3,4,3,6,3,6,3,3,1,3 17, 14, 67)	99999 (± 99999)	160 (± 23.5)	214 (± 79.9)	99999 (± 99999)
C1D8 (n= 3,4,3,6,3,6,3,3,1,3,16, 13, 67)	470 (± 9999)	246 (± 76.1)	115 (± 38.0)	303 (± 97.4)
C1D15(n= 3,4 3,6 3,6,3,3,1,3 17, 14, 67)	619 (± 9999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D22(n= 3,4,3,6,3,6,3,3 0,3 17, 14, 67)	999 (± 999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1(n= 3,3,3,4 3,6 3,3 0,3,12, 10, 53)	999 (± 999)	205 (± 33.5)	304 (± 108)	333 (± 72.7)
C3D1(n= 2,3,2,4,2,6,3,3 0,3,11,6, 46)	999 (± 999)	192 (± 78.1)	311 (± 74.0)	277 (± 95.7)
C4D1 (n= 2,2,2,4 1,5 3,3 0,3 10, 6, 41)	999 (± 999)	212 (± 84.1)	261 (± 99.4)	295 (± 116)
C5D1(n= 2,2 0,2 1,3 3,3 0,2 7,2, 32)	999 (± 999)	250 (± 82.3)	290 (± 66.0)	338 (± 245)
C6D1 (n= 2,2 1,1,1,3, 3, 3, 0, 1, 6, 2, 35)	999 (± 999)	209 (± 9999)	332 (± 102)	303 (± 237)
C7D1(n= 2,2 1,1, 1, 3,3 3,0,1,5, 1, 27)	999 (± 999)	235 (± 9999)	392 (± 93.0)	502 (± 9999)
C8D1 (n= 2,2 1,1 0,1, 3, 3, 0, 0, 5, 1, 26)	999 (± 999)	999 (± 999)	317 (± 150)	511 (± 9999)
C9D1 (n= 1,2 1,1 0,2, 3, 3, 0, 0, 5, 2, 22)	999 (± 999)	999 (± 999)	363 (± 90.3)	593 (± 200)
C10D1 (n= 1,1,1,1,0,2, 3, 3, 0, 0, 4, 1, 21)	999 (± 999)	999 (± 999)	349 (± 70.4)	484 (± 9999)

End point values	Part A-MEDI-551 12 mg/kg (expansion)			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: µg/mL				

arithmetic mean (standard deviation)				
C1 D1 (n= 3,4,3,4,3,6,3,3,1,3,17, 13, 62)	240 (± 90.0)			
C1D2 (n= 3,4,3,6,3,6,3,3,1,3 17, 14, 67)	99999 (± 99999)			
C1D8 (n= 3,4,3,6,3,6,3,3,1,3,16, 13, 67)	99999 (± 99999)			
C1D15(n= 3,4 3,6 3,6,3,3,1,3 17, 14, 67)	99999 (± 99999)			
C1D22(n= 3,4,3,6,3,6,3,3 0,3 17, 14, 67)	99999 (± 99999)			
C2D1(n= 3,3,3,4 3,6 3,3 0,3,12, 10, 53)	350 (± 130)			
C3D1(n= 2,3,2,4,2,6,3,3 0,3,11,6, 46)	326 (± 110)			
C4D1 (n= 2,2,2,4 1,5 3,3 0,3 10, 6, 41)	342 (± 119)			
C5D1(n= 2,2 0,2 1,3 3,3 0,2 7,2, 32)	347 (± 98.1)			
C6D1 (n= 2,2 1,1,1,3, 3, 3, 0, 1, 6, 2, 35)	337 (± 82.1)			
C7D1(n= 2,2 1,1, 1, 3,3 3,0,1,5, 1, 27)	355 (± 95.7)			
C8D1 (n= 2,2 1,1 0,1, 3, 3, 0, 0, 5, 1, 26)	367 (± 102)			
C9D1 (n= 1,2 1,1 0,2, 3, 3, 0, 0, 5, 2, 22)	394 (± 125)			
C10D1 (n= 1,1,1,1,0,2, 3, 3, 0, 0, 4, 1, 21)	394 (± 157)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration Curve at Steady State (AUCss) of MEDI-551

End point title	Area Under the Concentration Curve at Steady State (AUCss) of MEDI-551

End point description:

Area under the concentration-time curve at steady state (Css, AUC) of MEDI-551 is reported. Pharmacokinetic (PK) population was analysed for this endpoint, which included all participants who received at least one dose of MEDI-551 and had at least one measurable serum concentration of MEDI-551. Here, the arbitrary number "999" signifies that data not reported due to limited PK data up to Cycle 1 Day 15.

End point type	Secondary

End point timeframe:

Part A:Cycle(C)1 Day(D)1 (Pre & post dose [PPD] 2,6,24,48 hrs PD); PPD once a week in 4 weeks C till C71; Part B:C1 (D1,D8,D15,D22),PPD of D1 of each C till C28; Part C & D:PPD of C1 (D2,D8), predose D15 and 22, PPD of D1 of each C till C24

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: µgday/mL				
arithmetic mean (standard deviation)	212 (± 28.1)	287 (± 110)	479 (± 57.7)	1660 (± 778)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	3
Units: µgday/mL				
arithmetic mean (standard deviation)	2880 (± 2190)	5720 (± 1620)	1730 (± 1030)	4920 (± 1440)

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	17	14
Units: µgday/mL				
arithmetic mean (standard deviation)	999 (± 999)	2240 (± 338)	4260 (± 1340)	4250 (± 2000)

End point values	Part A-MEDI-551 12 mg/kg (expansion)			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: µgday/mL				
arithmetic mean (standard deviation)	4850 (± 1720)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Clearance of MEDI-551

End point title	Apparent Clearance of MEDI-551

End point description:

Apparent clearance of MEDI-551 is reported. The PK population was analysed for this endpoint, which included all participants who received at least one dose of MEDI-551 and had at least one measurable serum concentration of MEDI-551. Here, the arbitrary number "999" signifies that standard deviation is not reported as only one participant was evaluable for the specified arm.

End point type	Secondary

End point timeframe:

Part A:Cycle(C)1 Day(D)1 (Pre & post dose [PPD] 2,6,24,48 hrs PD); PPD once a week in 4 weeks C till

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: mL/day				
arithmetic mean (standard deviation)	206 (± 101)	302 (± 173)	373 (± 70.9)	210 (± 28.9)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	3
Units: mL/day				
arithmetic mean (standard deviation)	268 (± 126)	198 (± 44.3)	303 (± 108)	243 (± 81.6)

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	17	14
Units: mL/day				
arithmetic mean (standard deviation)	279 (± 999)	288 (± 43.0)	235 (± 87.5)	237 (± 72.5)

End point values	Part A-MEDI-551 12 mg/kg (expansion)			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: mL/day				
arithmetic mean (standard deviation)	235 (± 110)			

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution of MEDI-551

End point title	Volume of Distribution of MEDI-551

End point description:

Volume of distribution was defined as the theoretical volume in which the total amount of drug would

need to be uniformly distributed to produce the desired serum concentration of a drug. Central volume of distribution (Vd1) is defined as hypothetical volume into which a drug initially distributes upon administration and peripheral volume of distribution (Vd2) is defined as the sum of all tissue spaces outside the central compartment. The PK population was analysed for this endpoint, which included all participants who received at least one dose of MEDI-551 and had at least one measurable serum concentration of MEDI-551. Here, the arbitrary number "999" signifies that standard deviation is not reported as only one participant was evaluable for the specified arm.

End point type	Secondary

End point timeframe:

Part A:Cycle(C)1 Day(D)1 (Pre & post dose [PPD] 2,6,24,48 hrs PD); PPD once a week in 4 weeks C till C71; Part B:C1 (D1,D8,D15,D22),PPD of D1 of each C till C28; Part C & D:PPD of C1 (D2,D8), predose D15 and 22, PPD of D1 of each C till C24

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: mL				
arithmetic mean (standard deviation)				
Vd1	3970 (± 851)	3920 (± 491)	4350 (± 948)	4070 (± 464)
Vd2	2670 (± 351)	2010 (± 1080)	1980 (± 888)	2290 (± 767)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	3
Units: mL				
arithmetic mean (standard deviation)				
Vd1	4210 (± 510)	4230 (± 234)	3560 (± 286)	4490 (± 947)
Vd2	2620 (± 1240)	2920 (± 1070)	3290 (± 1440)	2640 (± 1840)

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	17	14
Units: mL				
arithmetic mean (standard deviation)				
Vd1	5690 (± 999)	4520 (± 126)	4350 (± 851)	4510 (± 647)
Vd2	3670 (± 999)	4590 (± 847)	2640 (± 1200)	3200 (± 1440)

End point values	Part A-MEDI-551 12 mg/kg (expansion)			

Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: mL				
arithmetic mean (standard deviation)				
Vd1 Vd2	4450 (± 889) 3430 (± 2250)			

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Half-life (t1/2) of MEDI-551

End point title	Terminal Half-life (t1/2) of MEDI-551

End point description:

Terminal half-life is the time required for the plasma concentration of MEDI-551 to fall by 50% during the terminal phase. The PK population was analysed for this endpoint, which included all participants who received at least one dose of MEDI-551 and had at least one measurable serum concentration of MEDI-551. Here, the arbitrary number "999" signifies that standard deviation is not reported as only one participant was evaluable for the specified arm.

End point type	Secondary

End point timeframe:

Part A:Cycle(C)1 Day(D)1 (Pre & post dose [PPD] 2,6,24,48 hrs PD); PPD once a week in 4 weeks C till C71; Part B:C1 (D1,D8,D15,D22),PPD of D1 of each C till C28; Part C & D:PPD of C1 (D2,D8), predose D15 and 22, PPD of D1 of each C till C24

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: Days				
arithmetic mean (standard deviation)	26.0 (± 6.88)	17.3 (± 7.65)	13.3 (± 6.41)	22.1 (± 3.26)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	3
Units: Days				
arithmetic mean (standard deviation)	21.7 (± 8.65)	27.9 (± 9.08)	19.9 (± 9.34)	23.8 (± 10.9)

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	17	14

Units: Days				
arithmetic mean (standard deviation)	25.1 (± 999)	25.3 (± 4.40)	23.6 (± 9.38)	25.6 (± 7.96)

End point values	Part A-MEDI-551 12 mg/kg (expansion)			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: Days				
arithmetic mean (standard deviation)	28.9 (± 15.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive Anti-drug Antibodies (ADA) Titer to MEDI-551

End point title	Number of Participants With Positive Anti-drug Antibodies (ADA) Titer to MEDI-551[69]

End point description:

Number of participants with positive Anti-drug antibodies (ADA) titer to MEDI-551 is reported. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551. Participants only with positive ADA is reported.

End point type	Secondary

End point timeframe:

Part A:C1D1; Part B: C1D1; Part C: C1D1; Part D: C1D1; End of treatment (EOT); 90 Days post last dose (approximately 9 years)

Notes:

[69] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: Participants				
C1D1	0	1	0	0
EOT	0	0	0	0
90 Day Post Dose0	0	0	0	0

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	76	3	3
Units: Participants				

C1D1	0	2	0	0
EOT	0	0	0	0
90 Day Post Dose0	0	0	0	0

End point values	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	17	14	
Units: Participants				
C1D1	0	0	2	
EOT	0	0	0	
90 Day Post Dose0	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: B-cell Concentration in Serum

End point title	B-cell Concentration in Serum

End point description:

B-cell concentration in serum is reported. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551.Safety population included all participants who received any treatment of MEDI-551. It was pre-specified that B-cell analysis was not required, due to limited data availability.

End point type	Secondary

End point timeframe:

Part A:C1D1 of each cycles; Part B: C1D1 of each cycle + C1D8, C1D15, and C1D22; Part C: C1D2, C1D8, then Day 1 of each cycle until Cycle 10; Part D: C1D1, C1D8, Day 1 of each cycle until Cycle 10; EOT;90 Days post last dose (approximately 9 years)

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[70]	0[71]	0[72]	0[73]
Units: mg/dL				

Notes:

[70] - It was pre-specified that B-cell analysis was not required, due to limited data availability

[71] - It was pre-specified that B-cell analysis was not required, due to limited data availability

[72] - It was pre-specified that B-cell analysis was not required, due to limited data availability

[73] - It was pre-specified that B-cell analysis was not required, due to limited data availability

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 6 mg/kg	Part B-MEDI-551 12 mg/kg

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[74]	0[75]	0[76]	0[77]
Units: mg/dL				

Notes:

[74] - It was pre-specified that B-cell analysis was not required, due to limited data availability
[75] - It was pre-specified that B-cell analysis was not required, due to limited data availability
[76] - It was pre-specified that B-cell analysis was not required, due to limited data availability
[77] - It was pre-specified that B-cell analysis was not required, due to limited data availability

End point values	Part B-MEDI-551 24 mg/kg	Part C-MEDI-551 8 mg/kg + rituximab	Part C-MEDI-551 12 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[78]	0[79]	0[80]	0[81]
Units: mg/dL				

Notes:

[78] - It was pre-specified that B-cell analysis was not required, due to limited data availability
[79] - It was pre-specified that B-cell analysis was not required, due to limited data availability
[80] - It was pre-specified that B-cell analysis was not required, due to limited data availability
[81] - It was pre-specified that B-cell analysis was not required, due to limited data availability

Statistical analyses

No statistical analyses for this end point

Secondary: Immunoglobulin (Ig) Concentration in Serum

End point title	Immunoglobulin (Ig) Concentration in Serum[82]

End point description:

Immunoglobin (Ig) concentration in serum is reported. The safety population was analysed for this endpoint, which included all participants who received any treatment of MEDI-551. Here, the arbitrary numbers "9999 and 999"signifies that no participants were analysed for the specified arm and standard deviation is not reported as only one participant was evaluable for the specified arm respectively.

End point type	Secondary

End point timeframe:

Part A:C1D1 of each cycles; EOT;90 Days post last dose (approximately 9 years)

Notes:

[82] - 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 those baseline period arms for which analysis was planned were reported in the end point.

End point values	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 4 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: mg/dL				
arithmetic mean (standard deviation)				
C1D1 (n= 3, 4, 3, 6, 3, 68)	120.00 (± 46.36)	110.00 (± 76.25)	81.00 (± 66.36)	61.67 (± 54.52)

C2D1 (n= 2, 33, 4, 2, 59)	67.50 (± 7.78)	113.67 (± 92.81)	67.67 (± 58.05)	57.00 (± 47.05)
C3D1 (n= 2, 3, 2, 4, 2, 50)	62.50 (± 6.36)	106.00 (± 87.93)	31.00 (± 29.70)	57.25 (± 48.29)
C4D1 (n= 2, 2, 2, 3, 1, 50)	64.00 (± 9.90)	152.50 (± 13.44)	31.00 (± 33.94)	63.67 (± 56.52)
C5D1 (2, 2, 1, 3, 1, 38)	69.00 (± 11.31)	145.50 (± 38.89)	50.00 (± 999)	58.67 (± 45.17)
C6D1 (2, 2, 0, 1, 1, 36)	63.50 (± 13.44)	156.00 (± 48.08)	9999 (± 9999)	41.00 (± 999)
C7D1 (n= 2, 1, 1, 1, 1, 31)	56.00 (± 1.41)	127.00 (± 999)	47.00 (± 999)	41.00 (± 999)
C8D1 (n= 2, 2, 1, 1, 0, 29)	47.00 (± 7.07)	147.00 (± 28.28)	45.00 (± 999)	41.00 (± 999)
C9D1 (n= 1, 2, 1, 1, 0, 26)	51.00 (± 999)	137.50 (± 30.41)	46.00 (± 999)	41.00 (± 999)
C10D1 (1, 1, 1, 1, 0, 24)	47.00 (± 999)	155.00 (± 999)	46.00 (± 999)	41.00 (± 999)
EOT (n= 2, 3, 3, 5, 3, 48)	43.50 (± 12.02)	96.00 (± 80.58)	7.00 (± 999)	54.40 (± 46.55)
90 Days Post Dose (n= 1, 2, 0, 3, 0, 15)	49.00 (± 999)	84.50 (± 60.10)	9999 (± 9999)	93.33 (± 42.06)

End point values	Part A-MEDI-551 8 mg/kg	Part A-MEDI-551 12 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	76		
Units: mg/dL				
arithmetic mean (standard deviation)				
C1D1 (n= 3, 4, 3, 6, 3, 68)	93.33 (± 46.11)	93.01 (± 88.56)		
C2D1 (n= 2, 33, 4, 2, 59)	74.50 (± 47.38)	88.90 (± 92.05)		
C3D1 (n= 2, 3, 2, 4, 2, 50)	76.50 (± 50.20)	67.90 (± 66.59)		
C4D1 (n= 2, 2, 2, 3, 1, 50)	98.00 (± 999)	66.84 (± 61.83)		
C5D1 (2, 2, 1, 3, 1, 38)	77.00 (± 999)	69.24 (± 70.45)		
C6D1 (2, 2, 0, 1, 1, 36)	71.00 (± 999)	62.86 (± 65.04)		
C7D1 (n= 2, 1, 1, 1, 1, 31)	61.00 (± 999)	67.26 (± 69.36)		
C8D1 (n= 2, 2, 1, 1, 0, 29)	9999 (± 9999)	73.76 (± 66.87)		
C9D1 (n= 1, 2, 1, 1, 0, 26)	9999 (± 9999)	62.35 (± 61.90)		
C10D1 (1, 1, 1, 1, 0, 24)	9999 (± 9999)	73.17 (± 66.34)		
EOT (n= 2, 3, 3, 5, 3, 48)	65.33 (± 19.76)	217.25 (± 1003.38)		
90 Days Post Dose (n= 1, 2, 0, 3, 0, 15)	9999 (± 9999)	45.20 (± 38.72)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 through 90-Day Post Last Dose (Approximately 9 years)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Part A-MEDI-551 0.5 mg/kg

Reporting group description:

Participants received intravenous (IV) infusion of MEDI 551 0.5 mg/kg once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 1 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 1 mg/kg once every week in 4-week cycles until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 4 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 4 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 2 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 2 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 8 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 8 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part B-MEDI-551 6 mg/kg

Reporting group description:

Participants received IV infusion of MEDI- 551 6 mg/kg weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part A-MEDI-551 12 mg/kg

Reporting group description:

Participants received IV infusion of MEDI 551 12 mg/kg on Days 1 and 8 of Cycle 1 (loading doses) and then once every 28 days at the start of each subsequent cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part B-MEDI-551 12 mg/kg

Reporting group description:

Participants received IV infusion of MEDI- 551 12 mg/kg weekly for 4 weeks during Cycle 1 (Days 1, 8, 15, and 22) and thereafter from Cycle 2 on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part B-MEDI-551 24 mg/kg

Reporting group description:

Participants received IV infusion of MEDI- 551 24 mg/kg weekly for 4 weeks during Cycle 1 (over 2 days on Day 1 and Day 2, and on Days 8, 15, and 22) and thereafter from Cycle 2, on Day 1 of each 28-day cycle until complete response, disease progression, toxicity, or another reason for treatment discontinuation was observed.

Reporting group title	Part C-MEDI-551 8 mg/kg + rituximab

Reporting group description:

Participants received IV infusion of 8 mg/kg on days 2 and 8 during Cycle 1 and day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m2 on days 1, 8, 15, and 22. From Cycle 3 only MEDI-551 8 mg/kg was administered on day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdraws consent.

Reporting group title	Part D-MEDI-551 12 mg/kg

Reporting group description:

Participants received IV infusion of MEDI-551 12 mg/kg on Days 1 and 8 of Cycle 1 and thereafter Day 1 of 28- day cycles from Cycle 2 onwards. Treatment was continued until the participants experiences unacceptable toxicity, disease progression, reached CR or consent withdrawal.

Reporting group title	Part C-MEDI-551 12 mg/kg + rituximab

Reporting group description:

Participants received IV infusion of MEDI- 551 12 mg/kg on Days 2 and 8 during Cycle 1 and on Day 1 during Cycle 2 (28-day cycle) in combination with rituximab 375 mg/m^2 on Days 1, 8, 15, and 22. From Cycle 3 onwards, only MEDI- 551 8 mg/kg was administered on Day 1 of each 28-day cycle. The treatment was continued until the participants experienced unacceptable toxicity, disease progression, reached complete response or withdraws consent.

Serious adverse events	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 4 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 6 (16.67%)
number of deaths (all causes)	0	2	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Adenocarcinoma of colon			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
B-cell lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Diffuse large b-cell lymphoma			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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-hodgkin's lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Polycythaemia vera			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Shock haemorrhagic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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			
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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	0 / 3 (0.00%)	0 / 4 (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
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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			
Bronchiectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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 haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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
Procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	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
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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			
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	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
Nervous system disorders			
Cauda equina syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	1 / 4 (25.00%)	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
Toxic encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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	0 / 3 (0.00%)	0 / 4 (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
Febrile neutropenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Faecaloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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
Hepatobiliary disorders			

Acute hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Skin and subcutaneous tissue disorders			
Pemphigoid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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			
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Lumbar spinal stenosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (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
Osteolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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	0 / 3 (0.00%)	0 / 4 (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 / 1
Sepsis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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	0 / 3 (0.00%)	0 / 4 (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			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 4 (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	Part A-MEDI-551 2	Part A-MEDI-551 8	Part B-MEDI-551 6

	mg/kg	mg/kg	mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	1 / 3 (33.33%)
number of deaths (all causes)	2	2	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Adenocarcinoma of colon			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
B-cell lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	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
Diffuse large b-cell lymphoma			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Malignant melanoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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-hodgkin's lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Polycythaemia vera			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Shock haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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			
Bronchiectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Cauda equina syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Toxic encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Faecaloma			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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			
Acute hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Skin and subcutaneous tissue disorders			
Pemphigoid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	0 / 3 (0.00%)	0 / 3 (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

Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 disc protrusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Lumbar spinal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Osteolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	0 / 3 (0.00%)	0 / 3 (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	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 76 (30.26%)	2 / 3 (66.67%)	1 / 1 (100.00%)
number of deaths (all causes)	30	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Adenocarcinoma of colon			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
B-cell lymphoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large b-cell lymphoma			

subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Malignant melanoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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-hodgkin's lymphoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia vera			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Squamous cell carcinoma			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Shock haemorrhagic			

subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
General physical health deterioration			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchiectasis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (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	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (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
Pneumothorax			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Pulmonary embolism			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 failure			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	6 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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

Spinal compression fracture			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Cauda equina syndrome			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Syncope			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (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
Neutropenia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Abdominal pain upper			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Nausea			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Vomiting			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			

Acute hepatic failure			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Cholecystitis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Skin and subcutaneous tissue disorders			
Pemphigoid			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Dysuria			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Back pain			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Intervertebral disc protrusion			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Lumbar spinal stenosis			

subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Abscess limb			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Bacteraemia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Bronchitis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Gastroenteritis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Lung infection			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sepsis syndrome			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Septic shock			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Staphylococcal sepsis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (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
Varicella			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (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
Hypercalcaemia			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0

Serious adverse events	Part C-MEDI-551 8	Part D-MEDI-551 12	Part C-MEDI-551 12

	mg/kg + rituximab	mg/kg	mg/kg + rituximab
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	5 / 14 (35.71%)	9 / 17 (52.94%)
number of deaths (all causes)	2	8	9
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large b-cell lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Malignant melanoma			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (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
Non-hodgkin's lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Polycythaemia vera			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
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, thoracic and mediastinal disorders			
Bronchiectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
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 haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Cauda equina syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pemphigoid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
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 and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 disc protrusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Part A-MEDI-551 0.5 mg/kg	Part A-MEDI-551 1 mg/kg	Part A-MEDI-551 4 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemangioma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Metastatic lymphoma			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	3 / 4 (75.00%)	0 / 6 (0.00%)
occurrences (all)	1	3	0

Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Systolic hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breakthrough pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	1	5	2
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ill-defined disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infusion site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Medical device site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Medical device site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Immune system disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Ex-tobacco user			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Breast swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematospermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nipple disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	1	3	0
Dry throat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Increased bronchial secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nasal polyps			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sneezing			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hallucinations, mixed			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Blood cholesterol increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood fibrinogen increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood immunoglobulin m decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood iron decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram qt prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glucose urine present			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Karnofsky scale worsened			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
Mean cell volume increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Neutrophil count abnormal			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	2	5	4
Occult blood positive			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Protein total decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Red blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Serum ferritin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin d decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Fall			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Procedural complication			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wrong drug administered			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atrial tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac failure chronic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seizure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypergammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Polycythaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	3 / 6 (50.00%)
occurrences (all)	0	1	7
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Exophthalmos			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	5	0
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	3 / 3 (100.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	10	4	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Intestinal ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oesophageal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Tongue coated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema annulare			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperhidrosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Miliaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoglobinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bursitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Inguinal mass			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sarcopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	6	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	6	2
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin d deficiency			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A-MEDI-551 2 mg/kg	Part A-MEDI-551 8 mg/kg	Part B-MEDI-551 6 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Haemangioma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastatic lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breakthrough pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	3 / 3 (100.00%)	2 / 3 (66.67%)
occurrences (all)	1	3	2
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ill-defined disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical device site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical device site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Immune system disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Social circumstances			
Ex-tobacco user			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Haematospermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nipple disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			

disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dry throat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Increased bronchial secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal polyps			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pleural effusion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Wheezing			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucinations, mixed			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Product issues			
Device dislocation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood immunoglobulin m decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram qt prolonged			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glucose urine present			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Karnofsky scale worsened			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mean cell volume increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Occult blood positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin d decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	6
Laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wrong drug administered			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Cardiac failure chronic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypersomnia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tremor			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypergammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Increased tendency to bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Polycythaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Ear swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Exophthalmos			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intestinal ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Oesophageal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oral pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue coated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blister			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema annulare			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Petechiae			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urine flow decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Inguinal mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Muscular weakness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sarcopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Bacterial vaginosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	2
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Furuncle			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1

Laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	3
Pyelonephritis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	6
Tonsillitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	6
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin d deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A-MEDI-551 12 mg/kg	Part B-MEDI-551 12 mg/kg	Part B-MEDI-551 24 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	75 / 76 (98.68%)	3 / 3 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			

subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Haemangioma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metastatic lymphoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Skin papilloma			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Squamous cell carcinoma			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Tumour pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Haematoma			
subjects affected / exposed	4 / 76 (5.26%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0

Hot flush			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	8 / 76 (10.53%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	8	5	0
Hypotension			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	3	0	1
Orthostatic hypotension			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 76 (6.58%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Breakthrough pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	5 / 76 (6.58%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	6	4	0
Cyst			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Early satiety			

subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	28 / 76 (36.84%)	3 / 3 (100.00%)	0 / 1 (0.00%)
occurrences (all)	33	6	0
Gait disturbance			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Gravitational oedema			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ill-defined disorder			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Infusion site pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Mass			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Medical device site bruise			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Medical device site pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			

subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Necrosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Oedema			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	8 / 76 (10.53%)	2 / 3 (66.67%)	1 / 1 (100.00%)
occurrences (all)	9	5	2
Pain			
subjects affected / exposed	4 / 76 (5.26%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Performance status decreased			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Peripheral swelling			
subjects affected / exposed	5 / 76 (6.58%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	9	0	0
Pyrexia			
subjects affected / exposed	13 / 76 (17.11%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	18	4	0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorder			

subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
Ex-tobacco user			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast swelling			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematospermia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Nipple disorder			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	26 / 76 (34.21%)	3 / 3 (100.00%)	0 / 1 (0.00%)
occurrences (all)	31	7	0
Dry throat			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	9 / 76 (11.84%)	2 / 3 (66.67%)	1 / 1 (100.00%)
occurrences (all)	10	6	1
Dyspnoea exertional			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Epistaxis			

subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Increased bronchial secretion			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Nasal polyps			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Obstructive airways disorder			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	3 / 76 (3.95%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	3	4	0
Paranasal sinus hypersecretion			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Pleural effusion			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Pleuritic pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pulmonary hypertension			

subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Sinus congestion			
subjects affected / exposed	4 / 76 (5.26%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Sneezing			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Throat tightness			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	6	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	8 / 76 (10.53%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	8	1	0
Confusional state			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0

Depressed mood			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Hallucination			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hallucinations, mixed			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	8 / 76 (10.53%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Mental status changes			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	3	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 76 (5.26%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	4	0	3
Blood albumin decreased			

subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	1	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	1	1	1
Blood fibrinogen decreased			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood fibrinogen increased			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Blood immunoglobulin m decreased			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood iron decreased			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	3	0	1
Blood phosphorus decreased			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

Blood potassium decreased			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood triglycerides increased			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood urea increased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	5	0
Electrocardiogram qt prolonged			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Glucose urine present			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Karnofsky scale worsened			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	11
Mean cell volume increased			

subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophil count abnormal			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	5 / 76 (6.58%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	7	3	1
Occult blood positive			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	3	1	1
Prostatic specific antigen increased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Red blood cell count decreased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Vitamin d decreased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	3 / 76 (3.95%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Weight increased			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
White blood cell count decreased			

subjects affected / exposed	3 / 76 (3.95%)	2 / 3 (66.67%)	1 / 1 (100.00%)
occurrences (all)	4	4	8
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	2	0	1
Fall			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	2
Infusion related reaction			
subjects affected / exposed	34 / 76 (44.74%)	2 / 3 (66.67%)	1 / 1 (100.00%)
occurrences (all)	108	8	1
Laceration			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Limb injury			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Rib fracture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			

subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Wrong drug administered			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	3 / 76 (3.95%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	2	0
Atrial flutter			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Atrial tachycardia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Bradycardia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac failure chronic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	6 / 76 (7.89%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0

Nervous system disorders			
Amnesia			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Anosmia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cerebrovascular accident			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	10 / 76 (13.16%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	12	0	1
Dysgeusia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	15 / 76 (19.74%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	20	7	0
Hypersomnia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	4 / 76 (5.26%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Memory impairment			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Tremor			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 76 (7.89%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	8	1	2
Febrile neutropenia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypergammaglobulinaemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Leukocytosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	5	0
Lymph node pain			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Lymphopenia			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Neutropenia			
subjects affected / exposed	13 / 76 (17.11%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	19	13	0
Polycythaemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	6 / 76 (7.89%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	7	2	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Ear swelling			

subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Otorrhoea			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dry eye			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Exophthalmos			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	2	0	1

Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Abdominal distension			
subjects affected / exposed	3 / 76 (3.95%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	4	0
Abdominal pain			
subjects affected / exposed	6 / 76 (7.89%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	7	2	0
Abdominal pain lower			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	4 / 76 (5.26%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Anal incontinence			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	10 / 76 (13.16%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	12	3	0
Dental caries			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	18 / 76 (23.68%)	2 / 3 (66.67%)	1 / 1 (100.00%)
occurrences (all)	21	3	2
Dry mouth			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	3	0	1
Dyspepsia			
subjects affected / exposed	3 / 76 (3.95%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Dysphagia			

subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 76 (1.32%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Gingival pain			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Impaired gastric emptying			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Intestinal ischaemia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Lip dry			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	13 / 76 (17.11%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	16	1	0
Oesophageal stenosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Tongue coated			

subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	7 / 76 (9.21%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	8	1	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Alopecia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Dermatitis allergic			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Dry skin			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Eczema			

subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	3 / 76 (3.95%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Erythema annulare			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	5 / 76 (6.58%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Ingrowing nail			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	6 / 76 (7.89%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	7	1	0
Petechiae			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	7 / 76 (9.21%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	11	1	0
Purpura			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	11 / 76 (14.47%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	19	1	0
Rash erythematous			

subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Scab			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Skin irritation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Solar lentigo			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Haemoglobinuria			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Hydronephrosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Urinary incontinence			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 76 (7.89%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	9	5	0
Arthritis			

subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Back pain			
subjects affected / exposed	11 / 76 (14.47%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	12	4	0
Bone pain			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Bursitis			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Groin pain			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Inguinal mass			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	9 / 76 (11.84%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Muscular weakness			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	2	0	1
Musculoskeletal chest pain			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	2	2	1
Musculoskeletal pain			
subjects affected / exposed	3 / 76 (3.95%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	4 / 76 (5.26%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	4	1	0
Osteoarthritis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	6 / 76 (7.89%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	9	2	0
Pain in jaw			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Sarcopenia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	4 / 76 (5.26%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	6	3	0
Candida infection			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Chronic sinusitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Diverticulitis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Ear infection			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Herpes zoster			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Influenza			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Nasopharyngitis			
subjects affected / exposed	4 / 76 (5.26%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	5	2	0
Oral herpes			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pyelonephritis acute			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Rhinitis			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Sinusitis			
subjects affected / exposed	4 / 76 (5.26%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	4	2	0
Tonsillitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	9 / 76 (11.84%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	11	10	0
Urinary tract infection			
subjects affected / exposed	8 / 76 (10.53%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	9	1	0
Viral infection			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	7 / 76 (9.21%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	7	1	1
Dehydration			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	3 / 76 (3.95%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	2
Hypertriglyceridaemia			
subjects affected / exposed	4 / 76 (5.26%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Hyperuricaemia			
subjects affected / exposed	2 / 76 (2.63%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	4	0	2
Hypoalbuminaemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	3
Hypocalcaemia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	0	1	2
Hypoglycaemia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 76 (1.32%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			

subjects affected / exposed	2 / 76 (2.63%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Hyponatraemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vitamin d deficiency			
subjects affected / exposed	0 / 76 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part C-MEDI-551 8 mg/kg + rituximab	Part D-MEDI-551 12 mg/kg	Part C-MEDI-551 12 mg/kg + rituximab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	14 / 14 (100.00%)	17 / 17 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Bowen's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haemangioma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Melanocytic naevus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Metastatic lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic keratosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	0	2	4
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	4
Breakthrough pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	5 / 14 (35.71%)	9 / 17 (52.94%)
occurrences (all)	2	6	20
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	3 / 17 (17.65%)
occurrences (all)	0	1	3
Gravitational oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Ill-defined disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Mass			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Medical device site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Medical device site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			

subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	5 / 17 (29.41%)
occurrences (all)	0	2	9
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	2 / 17 (11.76%)
occurrences (all)	0	2	3
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Immune system disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Ex-tobacco user			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Breast swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Erectile dysfunction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haematospermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nipple disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	3 / 17 (17.65%)
occurrences (all)	0	5	3
Dry throat			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	4 / 17 (23.53%)
occurrences (all)	0	1	5
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Increased bronchial secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	3
Nasal polyps			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	5
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Sputum discoloured			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	2	4
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	1	1	4
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	2 / 17 (11.76%)
occurrences (all)	0	2	2
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 3 (33.33%)	1 / 14 (7.14%)	3 / 17 (17.65%)
occurrences (all)	1	1	3
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hallucinations, mixed			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 14 (28.57%)	2 / 17 (11.76%)
occurrences (all)	0	4	5
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Product issues			
Device dislocation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	0	1	4
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Blood chloride decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Blood fibrinogen decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood immunoglobulin m decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Blood triglycerides increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Electrocardiogram qt prolonged			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Glucose urine present			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Haematocrit decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Karnofsky scale worsened			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 14 (21.43%)	2 / 17 (11.76%)
occurrences (all)	0	3	7
Mean cell volume increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neutrophil count abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	4 / 14 (28.57%)	2 / 17 (11.76%)
occurrences (all)	0	4	2
Occult blood positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Prostatic specific antigen increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vitamin d decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	5
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 14 (21.43%)	2 / 17 (11.76%)
occurrences (all)	0	4	4
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	3
Fall			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Infusion related reaction			

subjects affected / exposed	0 / 3 (0.00%)	4 / 14 (28.57%)	1 / 17 (5.88%)
occurrences (all)	0	12	1
Laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vascular access complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Wrong drug administered			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Atrial tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cardiac failure chronic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Mitral valve incompetence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	3 / 14 (21.43%)	1 / 17 (5.88%)
occurrences (all)	0	4	2
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	3 / 17 (17.65%)
occurrences (all)	0	0	3
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	3
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Sinus headache			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	4 / 17 (23.53%)
occurrences (all)	0	3	18
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypergammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	1	2	7
Polycythaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Splenomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	2 / 17 (11.76%)
occurrences (all)	0	4	19
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Ear swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Otorrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Vertigo			

subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Exophthalmos			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Glaucoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	0	1	3
Abdominal pain lower			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	2 / 14 (14.29%)	6 / 17 (35.29%)
occurrences (all)	1	2	7
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	3 / 14 (21.43%)	5 / 17 (29.41%)
occurrences (all)	1	4	15
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	0	3	2
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Intestinal ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	3 / 14 (21.43%)	5 / 17 (29.41%)
occurrences (all)	2	3	9
Oesophageal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Tongue coated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	4 / 17 (23.53%)
occurrences (all)	1	0	6
Hepatobiliary disorders			

Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Erythema annulare			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Macule			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Miliaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	3 / 17 (17.65%)
occurrences (all)	0	0	4
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Scab			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Skin irritation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Haemoglobinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2

Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Urine flow decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	3 / 17 (17.65%)
occurrences (all)	1	0	6
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 3 (66.67%)	2 / 14 (14.29%)	4 / 17 (23.53%)
occurrences (all)	2	6	5
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Groin pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Inguinal mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	0	2	5
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	3
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Osteonecrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	5 / 17 (29.41%)
occurrences (all)	0	0	6
Pain in jaw			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sarcopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Spondylitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	3
Chronic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 3 (33.33%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	1	1	7

Furuncle			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	4
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	0	2	2
Pyelonephritis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	4 / 17 (23.53%)
occurrences (all)	0	2	8
Tonsillitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	3 / 17 (17.65%)
occurrences (all)	0	2	4
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	3
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	5 / 14 (35.71%)	2 / 17 (11.76%)
occurrences (all)	0	6	2
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	2 / 17 (11.76%)
occurrences (all)	0	2	4
Hyperkalaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	3
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	6
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	1 / 17 (5.88%)
occurrences (all)	0	2	5
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	5
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	6
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	3
Vitamin d deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 May 2009	Inclusion criterion number 11 amended. Exclusion criterion 1 added to exclude participants who were eligible for a life-prolonging or life-saving standard line of therapy.
06 November 2009	Text was added to indicate that an interim safety analysis was to be conducted when the MTD or OBD had been established. Inclusion criterion number 3 was edited to specify that the chronic lymphocytic leukemia (CLL) population was to include participants with SLL. Inclusion criterion number 10 was edited to specify platelet count >= 75,000/mm^3 (except for CLL participants with evidence of bone marrow disease, who must have had a platelet count >= 50,000/mm^3. Inclusion criterion number 12 was edited to clarify the recommended methods of contraception and to state that participants must use adequate contraception methods through 90 days after the last dose of MEDI-551. Inclusion criterion number 13 was edited to specify that for participants with diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL) only, disease was to be evaluable by the International Working Group criteria (formerly RECIST criteria). An additional analysis population, the Per-protocol population (defined as all participants who completed 2 cycles of treatment or who discontinued treatment for toxicity due to MEDI-551, disease progression, or death due to disease) was added.
27 January 2010	Exclusion criterion number 12 was edited to clarify that participants with active hepatitis B or C infection as defined by seropositivity for hepatitis are not eligible to participate in the study.
23 September 2010	The study design and treatment sections of the protocol were updated to specify that dose escalation began in participants with FL or multiple myeloma (MM) per Protocol Version 4.0 through Cohort 2, and that Cohorts 3 to 6 would enroll participants with FL, MM, CLL or DLBCL with a modified dosing schedule. Participants in Cohorts 1 and 2 would continue to follow the Protocol Version 4.0 dose schedule of 0.5 mg/kg (Cohort 1) or 1 mg/kg (Cohort 2) MEDI-551 IV infusion QW in 4-week cycles. Participants enrolled on Cohorts 3 and higher were to receive 2, 4, 8, or 12 mg/kg MEDI-551 (Cohorts 3 to 6, respectively) IV once per week on Days 1 and 8 in the first cycle (loading doses) and then Q4W at the start of each subsequent cycle on Days 1 and 8 in the first cycle (loading doses) and then Q4W at the start of each subsequent cycle.
18 July 2011	The text was updated to specify that all participants (US and non-US) who achieved a CR may receive an additional 2 cycles of MEDI-551 at the same dose level. The FDA were to be consulted concerning the possibility of additional treatment with MEDI-551 for participants within the US who achieved a CR and subsequently relapse; however, non-US participants were not to be re-treated on subsequent relapse. The objective response rate was revised from 12 weeks to 8 weeks.
04 October 2011	Sections throughout the protocol were amended to state that the maximum dose-escalation phase dose of 12 mg/kg was selected for the expansion phase of the study. An additional safety follow-up visit at 60 days after the last dose was added (subsequent Protocol Versions increased doses of MEDI-551 above 12 mg/kg).

02 May 2012	Sections throughout the protocol were modified to note discontinuation of enrollment of MM participants. The expansion phase was to enrol approximately 60 participants: 20 participants each with FL, CLL (including small lymphocytic lymphoma [SLL]), or DLBCL. All eligibility criteria and evaluations pertaining to participants with MM were removed. Inclusion criterion number 3 was modified to state that participants with a diagnosis of CLL (including SLL), DLBCL, or FL are included and that SLL, DLBCL, and FL must be histologically confirmed. Inclusion criterion number 7 was revised to specify that permitted prior radiation therapy must have occurred at least 6 weeks before the first dose of MEDI-551. Inclusion criteria number 10 was changed to provide different hematological criteria for CLL participants with BM involvement. Inclusion criterion number 11 was changed to modify the definition of adequate organ function. IgE testing was removed.
15 July 2013	Text was added to specify that study completion would be after the deaths of 50% of all planned participants or the date the sponsor stops the study. Inclusion criterion number 5 had the term SLL removed.
07 October 2013	Primary, secondary, and exploratory objectives and endpoints were added for Arms B and C. Inclusion criteria numbers 3 to 6, and 10 were revised to reflect the participants to be included in Arms B and C. Exclusion criterion number 10 was modified to indicate that it only applied to Arm A. A sentence was added to indicate that the schedule of study procedures for Arms A, B, and C are presented in separate subsections. The schedule of study procedures and by-visit descriptions of procedures were added for Arm B and Arm C. The Per-protocol population was removed, and the statistical analysis for efficacy, safety and sample size were all updated to include the assessments for Arms A, B and C.
21 March 2014	Primary, secondary, and exploratory objectives and endpoints were added for Arm D. Inclusion criteria numbers 3, 5, 6 and 10 were revised. Inclusion criterion number 4 was revised indicating fresh tumor biopsy was optional and applicable to Arm D. Exclusion criteria numbers 4 and 5 were revised to reflect a washout period of 28 days or 5 half-lives instead of 6 weeks. Exclusion criteria number 7 was revised indicating “live or attenuated” vaccines. Exclusion criterion number 9 was removed. Exclusion criteria numbers 18 and 20 were revised for clarification. Schedule of study procedures and by-visit descriptions of procedures were added for Arm D. In addition, schedule of study procedures and by-visit descriptions of procedures for Arms B and C were updated to include Karnofsky performance status assessment and BM biopsy with minimal residual disease analysis. Statistical analysis for efficacy, safety and sample size were all updated to include assessments for Arm D.
27 January 2015	Language was added where relevant to describe the dosing schedule for participnats in Arm B receiving 24 or 48 mg/kg dose levels of MEDI-551. The initial doses were to be administered over 2 days on Day 1 and Day 2 in Cycle 1. Exclusion criterion number 12 was modified. Exclusion criterion number 22 was added.
01 June 2017	Key safety assessments relevant to MEDI-551 were retained. Vital signs were to be evaluated pre-dose and at end of infusion only. Exploratory evaluations were removed. Disease evaluations were to be performed at regular intervals to determine whether MEDI-551 was continuing to provide clinical benefit. Study completion was updated to be defined as the date of the last protocol-specified visit for the last participants in the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported