Clinical trial results:
An Exploratory Study of the Biologic Effects of Nivolumab and Nivolumab in Combination with Ipilimumab Treatment in Subjects with Advanced Melanoma (Unresectable or Metastatic)

Summary

EudraCT number	2012-001840-23
Trial protocol	Outside EU/EEA
Global end of trial date	25 October 2018

Results information

Result version number	v1 (current)
This version publication date	25 June 2022
First version publication date	25 June 2022

Trial information

Trial identification

Sponsor protocol code	CA209-038

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01621490
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussee de la Hulpe 18, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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	21 March 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the pharmacodynamic activity of nivolumab, and nivolumab in combination with ipilimumab in the tumor environment and the periphery on biomarker measures such as circulating T cell subsets (activated and memory T cell populations by flow cytometry), interferon, interferon inducible factors and T cell (CD4 and CD8) infiltration in tumor biopsy sections from subjects with advanced melanoma.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 September 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 20
Country: Number of subjects enrolled	Spain: 26
Country: Number of subjects enrolled	United States: 124
Worldwide total number of subjects	170
EEA total number of subjects	46

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)	122

From 65 to 84 years	47
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

227 participants were enrolled; 55 did not enter the treatment period: 41 did not meet study criteria; 6 other; 5 withdrew consent; 1 adverse events; 2 deaths. 172 entered the treatment period.2 were not treated;1 received ipilimumab monotherapy prior to the closure of Arm C; 1 received an unplanned treatment;168 were treated

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	N3 60 M Naive

Arm description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg administered intravenously (IV) in 60 minute infusion

Arm title	N3 60M Prog

Arm description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg administered intravenously (IV) in 60 minute infusion

Arm title	N1 60M + I3 90M, W2

Arm description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; W2 = Week 2 Biopsy

Arm type	Experimental
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details: Ipilimumab 3 mg/kg administered intravenously (IV) in 90 minute infusion	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 1 mg/kg administered intravenously (IV) in 60 minute infusion	
Arm title	N1 60M + I3 90M, W4
Arm description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; W4 = Week 4 Biopsy	
Arm type	Experimental
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Ipilimumab 3 mg/kg administered intravenously (IV) in 90 minute infusion	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 1 mg/kg administered intravenously (IV) in 60 minute infusion	
Arm title	N1 60M +I3 90M, WU
Arm description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; WU = Unknown Week Biopsy	
Arm type	Experimental
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Ipilimumab 3 mg/kg administered intravenously (IV) in 90 minute infusion	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 1 mg/kg administered intravenously (IV) in 60 minute infusion	
Arm title	N1 30M + I3 30M non-BM
Arm description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Arm type	Experimental

Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Ipilimumab 3 mg/kg administered intravenously (IV) in 30 minute infusion

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 1 mg/kg administered intravenously (IV) in 30 minute infusion

Arm title	N3 30M non-BM

Arm description:

Treatment Group: N3 = Nivolumab 3mg/kg;30M = 30 minute infusion; BM = Brain metastases

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg administered intravenously (IV) in 30 minute infusion

Arm title	N1 30M +I3 30M BM

Arm description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 1 mg/kg administered intravenously (IV) in 30 minute infusion

Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Ipilimumab 3 mg/kg administered intravenously (IV) in 30 minute infusion

Arm title	N3 30M BM

Arm description:

Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Arm type	Experimental

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg administered intravenously (IV) in 30 minute infusion

Arm title	I3 Monotherapy

Arm description:

Treatment Group: I3 = Ipilimumab 3 mg/kg infusion. Participant was enrolled prior to the closure of this arm via amendment

Arm type	Experimental
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Ipilimumab 3 mg/kg administered intravenously (IV)

Arm title	Unplanned Treatment

Arm description:

Unplanned treatment of nivolumab 1 mg/kg x 4 then nivolumab 3 mg/kg

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 1 mg/kg administered intravenously (IV) for 4 doses followed by Nivolumab 3 mg/kg

Number of subjects in period 1	N3 60 M Naive	N3 60M Prog	N1 60M + I3 90M, W2
Started	41	44	11
Completed	0	0	0
Not completed	41	44	11
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	-	-
Disease progression	27	28	1
Completed	-	-	-
Study drug toxicity	1	4	5
Subject request to discontinue study	1	3	1
Maximum clinical benefit	3	2	-
Adverse event unrelated to study drug	1	1	-
Other reasons	7	6	4

Subject no longer meets study criteria	-	-	-

Number of subjects in period 1	N1 60M + I3 90M, W4	N1 60M +I3 90M, WU	N1 30M + I3 30M non-BM
Started	10	6	25
Completed	0	0	0
Not completed	10	6	25
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	1
Disease progression	5	3	8
Completed	-	-	1
Study drug toxicity	3	1	10
Subject request to discontinue study	1	-	2
Maximum clinical benefit	-	-	-
Adverse event unrelated to study drug	-	-	-
Other reasons	1	1	3
Subject no longer meets study criteria	-	1	-

Number of subjects in period 1	N3 30M non-BM	N1 30M +I3 30M BM	N3 30M BM
Started	11	10	10
Completed	0	0	0
Not completed	11	10	10
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	-	-	-
Disease progression	7	1	4
Completed	-	-	-
Study drug toxicity	1	4	1
Subject request to discontinue study	1	-	1
Maximum clinical benefit	1	2	2
Adverse event unrelated to study drug	-	2	-
Other reasons	1	1	1
Subject no longer meets study criteria	-	-	-

Number of subjects in period 1	I3 Monotherapy	Unplanned Treatment
Started	1	1
Completed	0	0
Not completed	1	1
Adverse event, serious fatal	-	-
Consent withdrawn by subject	-	-
Disease progression	1	1

Completed	-	-
Study drug toxicity	-	-
Subject request to discontinue study	-	-
Maximum clinical benefit	-	-
Adverse event unrelated to study drug	-	-
Other reasons	-	-
Subject no longer meets study criteria	-	-

Baseline characteristics

Reporting groups	
Reporting group title	N3 60 M Naive
Reporting group description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive	
Reporting group title	N3 60M Prog
Reporting group description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed	
Reporting group title	N1 60M + I3 90M, W2
Reporting group description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; W2 = Week 2 Biopsy	
Reporting group title	N1 60M + I3 90M, W4
Reporting group description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; W4 = Week 4 Biopsy	
Reporting group title	N1 60M +I3 90M, WU
Reporting group description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; WU = Unknown Week Biopsy	
Reporting group title	N1 30M + I3 30M non-BM
Reporting group description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Reporting group title	N3 30M non-BM
Reporting group description:	
Treatment Group: N3 = Nivolumab 3mg/kg;30M = 30 minute infusion; BM = Brain metastases	
Reporting group title	N1 30M +I3 30M BM
Reporting group description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Reporting group title	N3 30M BM
Reporting group description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Reporting group title	I3 Monotherapy
Reporting group description:	
Treatment Group: I3 = Ipilimumab 3 mg/kg infusion. Participant was enrolled prior to the closure of this arm via amendment	
Reporting group title	Unplanned Treatment
Reporting group description:	
Unplanned treatment of nivolumab 1 mg/kg x 4 then nivolumab 3 mg/kg	

Reporting group values	N3 60 M Naive	N3 60M Prog	N1 60M + I3 90M, W2
Number of subjects	41	44	11
Age categorical Units: Subjects			
Adults (18-64 years)	34	34	5
From 65-84 years	6	10	6
85 years and over	1	0	0

Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean	55.5	53.7	61.0
standard deviation	± 12.49	± 15.10	± 11.82
Sex: Female, Male			
Units:			
Female	19	18	3
Male	22	26	8
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	41	43	11
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	0	2
Not Hispanic or Latino	34	41	6
Unknown or Not Reported	5	3	3

Reporting group values	N1 60M + I3 90M, W4	N1 60M +I3 90M, WU	N1 30M + I3 30M non-BM
Number of subjects	10	6	25
Age categorical			
Units: Subjects			
Adults (18-64 years)	7	4	16
From 65-84 years	3	2	9
85 years and over	0	0	0
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean	58.5	56.8	56.9
standard deviation	± 13.29	± 9.64	± 13.52
Sex: Female, Male			
Units:			
Female	4	3	8
Male	6	3	17
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	10	6	25
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	10	5	15
Unknown or Not Reported	0	1	10

Reporting group values	N3 30M non-BM	N1 30M +I3 30M BM	N3 30M BM
Number of subjects	11	10	10
Age categorical Units: Subjects			
Adults (18-64 years)	8	8	5
From 65-84 years	3	2	5
85 years and over	0	0	0
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean	51.5	56.9	58.9
standard deviation	± 15.55	± 9.37	± 13.46
Sex: Female, Male Units:			
Female	4	4	5
Male	7	6	5
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	11	10	10
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	1	0
Not Hispanic or Latino	5	3	7
Unknown or Not Reported	5	6	3

Reporting group values	I3 Monotherapy	Unplanned Treatment	Total
Number of subjects	1	1	170
Age categorical Units: Subjects			
Adults (18-64 years)	1	0	122
From 65-84 years	0	1	47
85 years and over	0	0	1
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean	52.0	66.0	
standard deviation	± 999	± 999	-

Sex: Female, Male Units:			
Female	1	0	69
Male	0	1	101
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	1	1	169
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	6
Not Hispanic or Latino	1	1	128
Unknown or Not Reported	0	0	36

Subject analysis sets

Subject analysis set title	N3 60M Naive
Subject analysis set type	Sub-group analysis
Subject analysis set description: Treatment Group: Part 1: Nivolumab 3 mg/kg 60 Minute Infusion Anti-CTLA4 Naive	
Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis
Subject analysis set description: Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed	
Subject analysis set title	N1 60M + I3 90M
Subject analysis set type	Sub-group analysis
Subject analysis set description: Treatment Group: Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute	
Subject analysis set title	N1 30M + I3 30M BM
Subject analysis set type	Sub-group analysis
Subject analysis set description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Subject analysis set title	N1+ I3 Non-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description: Treatment Group: Part 2+3: Nivolumab 1 mg/kg + Ipilimumab 3 mg/kg Non-Brain Metastases	
Subject analysis set title	Naive Nivo Mono
Subject analysis set type	Sub-group analysis
Subject analysis set description: Nivolumab Monotherapy CTLA-4 Naive	
Subject analysis set title	All Nivo
Subject analysis set type	Sub-group analysis
Subject analysis set description: Treatment Group: All Nivolumab Monotherapy	
Subject analysis set title	All Combo

Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: All Combination Therapy	
Subject analysis set title	Total
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All treatments	
Subject analysis set title	N3 60M Naive
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Part 1: Nivolumab 3 mg/kg 60 Minute Infusion Anti-CTLA4 Naive	
Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed	
Subject analysis set title	N1 60M + I3 90M W2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute Infusion Week 2 Biopsy	
Subject analysis set title	N1 60M + I3 90M W4
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute Infusion Week 4 Biopsy	
Subject analysis set title	N3 30M + I3 30M BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Part 4: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Brain Metastases	
Subject analysis set title	Nivo Mono
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Part 1: Regular Infusion Nivolumab Mono	
Subject analysis set title	Nivo Mono Reduced Infusion
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Reduced Infusion Nivolumab Monotherapy	
Subject analysis set title	Week 2 Biopsy Combo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Week 2 Biopsy Combo	
Subject analysis set title	Week 2 Biopsy non-BM Combo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Week 2 Biopsy Non-Brain Metastases Combo	
Subject analysis set title	Naive Nivo Mono non-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: Naive Nivolumab Mono Non-Brain Metastases	
Subject analysis set title	N1 + I3 non-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 2+3: Nivolumab 1 mg/kg + Ipilimumab 3 mg/kg Non-Brain Metastases

Subject analysis set title	N3 60M Naive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N3 = Nivolumab 3mg/kg;60M = 60 minute infusion; NAIVE = Anti-CTLA4 Naive

Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed

Subject analysis set title	N1 60M + I3 90M
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion

Subject analysis set title	N1 30M + I3 30M BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Subject analysis set title	N3 60M Naive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 1: Nivolumab 3 mg/kg 60 Minute Infusion Anti-CTLA4 Naive

Subject analysis set title	N1 60M + I3 90M
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute Infusion

Subject analysis set title	N1 30M + I3 30M Non-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 3: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Non-Brain Metastases

Subject analysis set title	N3 30M Non-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 3: Nivolumab 3 mg/kg 30 Minute Infusion Non-Brain Metastases

Subject analysis set title	N1 30M I3 30M BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 4: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Brain Metastases

Subject analysis set title	N3 60M NAIVE
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive

Subject analysis set title	N1 60M +I3 90M
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion

Subject analysis set title	N3 60M NAIVE
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive

Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed

Subject analysis set title	N1 60M +I3 90M
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion

Subject analysis set title	N1 60M+I3 90M
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion

Subject analysis set title	N1 30M + I3 30M BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N3 = Nivolumab 3mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Subject analysis set title	N1 30M + I3 30M NON-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Subject analysis set title	N3 30M NON-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Subject analysis set title	N3 60M NAIVE
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive

Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed

Subject analysis set title	N1 60M + I3 (Nivo ADA
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute

Subject analysis set title	N1 60M + I3 90M (Ipi ADA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute

Subject analysis set title	N1 30M + I3 30M Non-BM (Nivo ADA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 3: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Non-Brain Metastases

Subject analysis set title	N1 30M + I3 30M Non-BM (Ipi ADA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 3: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Non-Brain

Metastases

Subject analysis set title	N1 30M + I3 30M (Nivo ADA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 4: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Brain Metastases

Subject analysis set title	N1 30M + I3 30M (Ipi ADA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 4: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Brain Metastases

Subject analysis set title	Total (Nivo ADA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Total (All Nivolumab or Nivolumab + Ipilimumab Treated Subjects with Baseline and at Least One Post-Baseline Assessment)

Subject analysis set title	Total (Ipi ADA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Total (All Nivolumab or Nivolumab + Ipilimumab Treated Subjects with Baseline and at Least One Post-Baseline Assessment)

Subject analysis set title	N3 60M NAIVE, W4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; NAIVE = Anti-CTLA4 Naive

Subject analysis set title	N3 60M PROG, W4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed;

Subject analysis set title	N1 60M + I3 90M, WU
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; WU = Unknown Week Biopsy

Subject analysis set title	N1 30M + I3 30M NON-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Subject analysis set title	N3 30M NON-BM, W2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; W2 = Week 2 Biopsy

Subject analysis set title	N1 30M + I3 30M BM, W2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; W2 = Week 2 Biopsy

Subject analysis set title	N3 30M BM, W2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; W2 = Week 2 Biopsy

Subject analysis set title	N3 60M, W4
Subject analysis set type	Sub-group analysis

Subject analysis set description:
N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; W4 = Week 4 Biopsy

Subject analysis set title	N3 30M, W2
Subject analysis set type	Sub-group analysis

Subject analysis set description:
Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; W2 = Week 2 Biopsy

Subject analysis set title	N1 + I3, W2
Subject analysis set type	Sub-group analysis

Subject analysis set description:
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; W2 = Week 2 Biopsy

Subject analysis set title	N1 + I3 W2, NON-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; W2 = Week 2 Biopsy; BM = Brain metastases

Subject analysis set title	N3 NAIVE, NON-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:
N3 = Nivolumab 3mg/kg; NAIVE = Anti-CTLA4 Naive; BM = Brain metastases

Subject analysis set title	N1 + I3 NON-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; BM = Brain metastases

Subject analysis set title	Total
Subject analysis set type	Sub-group analysis

Subject analysis set description:
All treatments

Subject analysis set title	N1 + I3 NON-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; BM = Brain metastases

Subject analysis set title	N3 NAIVE
Subject analysis set type	Sub-group analysis

Subject analysis set description:
N3 = Nivolumab 3mg/kg; NAIVE = Anti-CTLA4 Naive

Subject analysis set title	All N3
Subject analysis set type	Sub-group analysis

Subject analysis set description:
N3 = Nivolumab 3mg/kg

Subject analysis set title	N1 + I3
Subject analysis set type	Sub-group analysis

Subject analysis set description:
All combination

Subject analysis set title	Total
Subject analysis set type	Sub-group analysis

Subject analysis set description:
All treatments

Reporting group values	N3 60M Naive	N3 60M PROG	N1 60M + I3 90M
Number of subjects	40	40	27

Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N1 30M + I3 30M BM	N1+ I3 Non-BM	Naive Nivo Mono
Number of subjects	8	50	58
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian			

Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	All Nivo	All Combo	Total
Number of subjects	98	58	156
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N3 60M Naive	N3 60M PROG	N1 60M + I3 90M W2
Number of subjects	25	23	11
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			

Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N1 60M + I3 90M W4	N3 30M + I3 30M BM	Nivo Mono
Number of subjects	10	3	48
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	Nivo Mono Reduced Infusion	Week 2 Biopsy Combo	Week 2 Biopsy non-BM Combo
Number of subjects	12	29	26
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	Naive Nivo Mono non-BM	N1 + I3 non-BM	N3 60M Naive
Number of subjects	35	40	41
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±

Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N3 60M PROG	N1 60M + I3 90M	N1 30M + I3 30M BM
Number of subjects	44	27	10
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N3 60M Naive	N1 60M + I3 90M	N1 30M + I3 30M Non-BM
Number of subjects	41	27	25
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N3 30M Non-BM	N1 30M I3 30M BM	N3 60M NAIVE
Number of subjects	11	10	41
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native			

Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N1 60M +I3 90M	N3 60M NAIVE	N3 60M PROG
Number of subjects	27	29	33
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N1 60M +I3 90M	N1 60M+I3 90M	N1 30M + I3 30M BM
Number of subjects	21	27	10
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			

85 years and over			

Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean		44.4	70.0
standard deviation	±	±	±
Sex: Female, Male			
Units:			
Female			
Male			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			

Reporting group values	N1 30M + I3 30M NON-BM	N3 30M NON-BM	N3 60M NAIVE
Number of subjects	25	11	38
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean	26.25		
standard deviation	±	±	±
Sex: Female, Male			
Units:			
Female			
Male			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			

White			
More than one race			
Unknown or Not Reported			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			

Reporting group values	N3 60M PROG	N1 60M + I3 (Nivo ADA	N1 60M + I3 90M (Ipi ADA)
Number of subjects	42	22	22
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Sex: Female, Male			
Units:			
Female			
Male			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			

Reporting group values	N1 30M + I3 30M Non-BM (Nivo ADA)	N1 30M + I3 30M Non-BM (Ipi ADA)	N1 30M + I3 30M (Nivo ADA)
Number of subjects	24	23	10
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N1 30M + I3 30M (Ipi ADA)	Total (Nivo ADA)	Total (Ipi ADA)
Number of subjects	9	154	54
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			

Reporting group values	N3 60M NAIVE, W4	N3 60M PROG, W4	N1 60M + I3 90M, WU
Number of subjects	39	36	6
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Sex: Female, Male			
Units:			
Female			
Male			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			

Reporting group values	N1 30M + I3 30M NON-BM	N3 30M NON-BM, W2	N1 30M + I3 30M BM, W2
Number of subjects	22	9	4
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean			
standard deviation	±	±	±

Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N3 30M BM, W2	N3 60M, W4	N3 30M, W2
Number of subjects	3	75	12
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N1 + I3, W2	N1 + I3 W2, NON-BM	N3 NAIVE, NON-BM
Number of subjects	37	33	48
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N1 + I3 NON-BM	Total	N1 + I3 NON-BM
Number of subjects	49	140	52
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native			

Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	N3 NAIVE	All N3	N1 + I3
Number of subjects	62	106	62
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	Total		
Number of subjects	168		
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			

Age Continuous			
"999"=N/A			
Units: years arithmetic mean standard deviation	 ±		
Sex: Female, Male Units:			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

End points reporting groups

Reporting group title	N3 60 M Naive
Reporting group description: Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive	
Reporting group title	N3 60M Prog
Reporting group description: Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed	
Reporting group title	N1 60M + I3 90M, W2
Reporting group description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; W2 = Week 2 Biopsy	
Reporting group title	N1 60M + I3 90M, W4
Reporting group description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; W4 = Week 4 Biopsy	
Reporting group title	N1 60M +I3 90M, WU
Reporting group description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; WU = Unknown Week Biopsy	
Reporting group title	N1 30M + I3 30M non-BM
Reporting group description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Reporting group title	N3 30M non-BM
Reporting group description: Treatment Group: N3 = Nivolumab 3mg/kg;30M = 30 minute infusion; BM = Brain metastases	
Reporting group title	N1 30M +I3 30M BM
Reporting group description: Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Reporting group title	N3 30M BM
Reporting group description: Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Reporting group title	I3 Monotherapy
Reporting group description: Treatment Group: I3 = Ipilimumab 3 mg/kg infusion. Participant was enrolled prior to the closure of this arm via amendment	
Reporting group title	Unplanned Treatment
Reporting group description: Unplanned treatment of nivolumab 1 mg/kg x 4 then nivolumab 3 mg/kg	
Subject analysis set title	N3 60M Naive
Subject analysis set type	Sub-group analysis
Subject analysis set description: Treatment Group: Part 1: Nivolumab 3 mg/kg 60 Minute Infusion Anti-CTLA4 Naive	
Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis
Subject analysis set description: Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed	
Subject analysis set title	N1 60M + I3 90M
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute

Subject analysis set title	N1 30M + I3 30M BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Subject analysis set title	N1+ I3 Non-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 2+3: Nivolumab 1 mg/kg + Ipilimumab 3 mg/kg Non-Brain Metastases

Subject analysis set title	Naive Nivo Mono
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Nivolumab Monotherapy CTLA-4 Naive

Subject analysis set title	All Nivo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: All Nivolumab Monotherapy

Subject analysis set title	All Combo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: All Combination Therapy

Subject analysis set title	Total
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All treatments

Subject analysis set title	N3 60M Naive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 1: Nivolumab 3 mg/kg 60 Minute Infusion Anti-CTLA4 Naive

Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed

Subject analysis set title	N1 60M + I3 90M W2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute Infusion Week 2 Biopsy

Subject analysis set title	N1 60M + I3 90M W4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute Infusion Week 4 Biopsy

Subject analysis set title	N3 30M + I3 30M BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 4: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Brain Metastases

Subject analysis set title	Nivo Mono
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 1: Regular Infusion Nivolumab Mono

Subject analysis set title	Nivo Mono Reduced Infusion
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Reduced Infusion Nivolumab Monotherapy

Subject analysis set title	Week 2 Biopsy Combo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Week 2 Biopsy Combo

Subject analysis set title	Week 2 Biopsy non-BM Combo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Week 2 Biopsy Non-Brain Metastases Combo

Subject analysis set title	Naive Nivo Mono non-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Naive Nivolumab Mono Non-Brain Metastases

Subject analysis set title	N1 + I3 non-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: Part 2+3: Nivolumab 1 mg/kg + Ipilimumab 3 mg/kg Non-Brain Metastases

Subject analysis set title	N3 60M Naive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N3 = Nivolumab 3mg/kg;60M = 60 minute infusion; NAIVE = Anti-CTLA4 Naive

Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed

Subject analysis set title	N1 60M + I3 90M
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion

Subject analysis set title	N1 30M + I3 30M BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Subject analysis set title	N3 60M Naive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 1: Nivolumab 3 mg/kg 60 Minute Infusion Anti-CTLA4 Naive

Subject analysis set title	N1 60M + I3 90M
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute Infusion

Subject analysis set title	N1 30M + I3 30M Non-BM
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part 3: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Non-Brain Metastases

Subject analysis set title	N3 30M Non-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Part 3: Nivolumab 3 mg/kg 30 Minute Infusion Non-Brain Metastases	
Subject analysis set title	N1 30M I3 30M BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Part 4: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Brain Metastases	
Subject analysis set title	N3 60M NAIVE
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive	
Subject analysis set title	N1 60M +I3 90M
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion	
Subject analysis set title	N3 60M NAIVE
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive	
Subject analysis set title	N3 60M PROG
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed	
Subject analysis set title	N1 60M +I3 90M
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion	
Subject analysis set title	N1 60M+I3 90M
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion	
Subject analysis set title	N1 30M + I3 30M BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N3 = Nivolumab 3mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Subject analysis set title	N1 30M + I3 30M NON-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Subject analysis set title	N3 30M NON-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Subject analysis set title	N3 60M NAIVE
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive	
Subject analysis set title	N3 60M PROG

Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed	
Subject analysis set title	N1 60M + I3 (Nivo ADA
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute	
Subject analysis set title	N1 60M + I3 90M (Ipi ADA)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Part 2: Nivolumab 1 mg/kg 60 Minute Infusion + Ipilimumab 3 mg/kg 90 Minute	
Subject analysis set title	N1 30M + I3 30M Non-BM (Nivo ADA)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Part 3: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Non-Brain Metastases	
Subject analysis set title	N1 30M + I3 30M Non-BM (Ipi ADA)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Part 3: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Non-Brain Metastases	
Subject analysis set title	N1 30M + I3 30M (Nivo ADA)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Part 4: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Brain Metastases	
Subject analysis set title	N1 30M + I3 30M (Ipi ADA)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Part 4: Nivolumab 1 mg/kg 30 Minute Infusion + Ipilimumab 3 mg/kg 30 Minute Infusion Brain Metastases	
Subject analysis set title	Total (Nivo ADA)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Total (All Nivolumab or Nivolumab + Ipilimumab Treated Subjects with Baseline and at Least One Post-Baseline Assessment)	
Subject analysis set title	Total (Ipi ADA)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Total (All Nivolumab or Nivolumab + Ipilimumab Treated Subjects with Baseline and at Least One Post-Baseline Assessment)	
Subject analysis set title	N3 60M NAIVE, W4
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; NAIVE = Anti-CTLA4 Naive	
Subject analysis set title	N3 60M PROG, W4
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed;	
Subject analysis set title	N1 60M + I3 90M, WU
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; WU = Unknown Week Biopsy	

Subject analysis set title	N1 30M + I3 30M NON-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases	
Subject analysis set title	N3 30M NON-BM, W2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; W2 = Week 2 Biopsy	
Subject analysis set title	N1 30M + I3 30M BM, W2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; W2 = Week 2 Biopsy	
Subject analysis set title	N3 30M BM, W2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; W2 = Week 2 Biopsy	
Subject analysis set title	N3 60M, W4
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; W4 = Week 4 Biopsy	
Subject analysis set title	N3 30M, W2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; W2 = Week 2 Biopsy	
Subject analysis set title	N1 + I3, W2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; W2 = Week 2 Biopsy	
Subject analysis set title	N1 + I3 W2, NON-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; W2 = Week 2 Biopsy; BM = Brain metastases	
Subject analysis set title	N3 NAIVE, NON-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N3 = Nivolumab 3mg/kg; NAIVE = Anti-CTLA4 Naive; BM = Brain metastases	
Subject analysis set title	N1 + I3 NON-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; BM = Brain metastases	
Subject analysis set title	Total
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All treatments	
Subject analysis set title	N1 + I3 NON-BM
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; BM = Brain metastases	
Subject analysis set title	N3 NAIVE
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N3 = Nivolumab 3mg/kg; NAIVE = Anti-CTLA4 Naive

Subject analysis set title	All N3
Subject analysis set type	Sub-group analysis

Subject analysis set description:

N3 = Nivolumab 3mg/kg

Subject analysis set title	N1 + I3
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All combination

Subject analysis set title	Total
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All treatments

Primary: Median change from baseline to week 7, of Interferon (IFN) and interferon gamma (IFN-gamma) inducible factors

End point title	Median change from baseline to week 7, of Interferon (IFN) and interferon gamma (IFN-gamma) inducible factors[1][2]

End point description:

Baseline and post-treatment modulation of serum levels of chemokines, cytokines and other immune mediators were assessed by techniques that included ELISA or other multiplex-based assay methods. Primary analysis included IFN-gamma and IFN-gamma inducible factors, including chemokine [C-X-C motif] ligand 9 (CXCL9) and CXCL10

End point type	Primary

End point timeframe:

From last non-missing value prior to first dose to week 7 day 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: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N1 30M + I3 30M non-BM	N3 30M non-BM	N3 30M BM	N3 60M Naive
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	23	11	7	40
Units: pg/mL				
median (standard deviation)				
IFN-gamma Simoa	0.1600 (± 1.2047)	0.0520 (± 0.1207)	0.0375 (± 0.1868)	0.0130 (± 0.1740)
CXL9 (aka MIG)	3542.0 (± 12133.1)	-29.0 (± 1684.2)	3610.0 (± 2197.4)	1105.0 (± 10467.4)
CXL10 (aka IP10)	934.5 (± 2842.0)	26.0 (± 172.7)	318.0 (± 354.0)	184.0 (± 514.1)

End point values	N3 60M PROG	N1 60M + I3 90M	N1 30M + I3 30M BM	N1+ I3 Non-BM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	27	8	50

Units: pg/mL				
median (standard deviation)				
IFN-gamma Simoa	0.0320 (± 0.0817)	0.2310 (± 0.4528)	0.0950 (± 1.5082)	0.2200 (± 0.8198)
CXL9 (aka MIG)	1890.0 (± 8706.0)	4680.0 (± 18096.9)	5692.0 (± 6796.0)	458.5 (± 1651.0)
CXL10 (aka IP10)	160.0 (± 539.9)	684.0 (± 2563.1)	514.0 (± 612.3)	695.0 (± 2627.7)

End point values	Naive Nivo Mono	All Nivo	All Combo	Total
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	98	58	156
Units: pg/mL				
median (standard deviation)				
IFN-gamma Simoa	0.0130 (± 0.1674)	0.0240 (± 0.1373)	0.1520 (± 1.0023)	0.0515 (± 0.5944)
CXL9 (aka MIG)	1056.5 (± 9167.8)	1235.0 (± 8984.2)	4680.0 (± 14792.5)	2027.0 (± 11491.9)
CXL10 (aka IP10)	185.0 (± 474.6)	184.0 (± 500.7)	684.0 (± 2450.6)	234.5 (± 1566.3)

Statistical analyses

No statistical analyses for this end point

Primary: Tumor infiltrating lymphocytes (TILs) as measured by medians in percent positive CD8 and positive CD4 at baseline and on-treatment biopsy, both using the Mosaic Singleplex IHC assay

End point title	Tumor infiltrating lymphocytes (TILs) as measured by medians in percent positive CD8 and positive CD4 at baseline and on-treatment biopsy, both using the Mosaic Singleplex IHC assay[3][4]

End point description:

Biomarkers examined were percent positive CD8 and percent positive CD4, both using the Mosaic Singleplex IHC assay. Analyses are presented with the medians at baseline and on-treatment, rather than the median change because the baseline values differed across groups. Baseline was defined as the last non-missing value on or prior to the first dose of study therapy. Biopsies were also collected on treatment.

"999"=N/A

End point type	Primary

End point timeframe:

From last non-missing value prior to first dose to week 4 day 1

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: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.
[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: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N1 30M + I3 30M non-BM	N3 30M non-BM	N3 30M BM	N3 60M Naive
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	15	10	2	25
Units: Percentage of positive cells				
median (standard deviation)				
Percent CD8 Baseline	4.700 (± 9.810)	5.615 (± 12.475)	6.135 (± 5.664)	3.73 (± 10.994)
Percent positive CD8 Week 2	7.970 (± 15.132)	10.100 (± 10.909)	29.735 (± 5.254)	999 (± 999)
Percent positive CD8 Week 4	37.465 (± 5.706)	999 (± 999)	999 (± 999)	18.435 (± 17.108)
Percent CD4 Baseline	4.155 (± 6.624)	4.950 (± 4.992)	2.780 (± 999)	0.360 (± 1.844)
Percent positive CD4 Week 2	6.260 (± 8.518)	4.210 (± 5.029)	20.830 (± 999)	999 (± 999)
Percent positive CD4 Week 4	24.520 (± 2.659)	999 (± 999)	999 (± 999)	1.585 (± 3.071)

End point values	N3 60M PROG	N1 60M + I3 90M W2	N1 60M + I3 90M W4	N3 30M + I3 30M BM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	23	11	10	3
Units: Percentage of positive cells				
median (standard deviation)				
Percent CD8 Baseline	7.230 (± 10.712)	3.260 (± 9.259)	11.105 (± 9.524)	18.590 (± 8.132)
Percent positive CD8 Week 2	999 (± 999)	11.345 (± 21.316)	999 (± 999)	8.470 (± 7.740)
Percent positive CD8 Week 4	7.140 (± 25.204)	999 (± 999)	32.455 (± 15.967)	999 (± 999)
Percent CD4 Baseline	0.600 (± 2.268)	0.840 (± 1.852)	0.470 (± 3.833)	6.500 (± 8.108)
Percent positive CD4 Week 2	999 (± 999)	4.500 (± 10.741)	999 (± 999)	6.420 (± 14.778)
Percent positive CD4 Week 4	1.260 (± 4.641)	999 (± 999)	9.005 (± 13.324)	999 (± 999)

End point values	Nivo Mono	Nivo Mono Reduced Infusion	Week 2 Biopsy Combo	Week 2 Biopsy non-BM Combo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	12	29	26
Units: Percentage of positive cells				
median (standard deviation)				
Percent CD8 Baseline	6.360 (± 10.727)	5.615 (± 11.472)	4.700 (± 9.292)	4.230 (± 9.401)
Percent positive CD8 Week 2	999 (± 999)	10.910 (± 12.387)	9.080 (± 17.510)	9.125 (± 18.654)
Percent positive CD8 Week 4	15.150 (± 21.475)	999 (± 999)	37.465 (± 5.706)	37.465 (± 5.706)
Percent CD4 Baseline	0.375 (± 2.057)	4.600 (± 4.807)	2.750 (± 5.833)	2.610 (± 5.607)

Percent positive CD4 Week 2	999 (± 999)	6.155 (± 6.585)	6.125 (± 10.222)	5.990 (± 9.602)
Percent positive CD4 Week 4	1.275 (± 3.921)	999 (± 999)	24.520 (± 2.659)	24.520 (± 2.659)

End point values	Naive Nivo Mono non-BM	N1 + I3 non-BM		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	40		
Units: Percentage of positive cells				
median (standard deviation)				
Percent CD8 Baseline	5.210 (± 11.288)	4.230 (± 9.844)		
Percent positive CD8 Week 2	10.100 (± 10.909)	9.125 (± 18.654)		
Percent positive CD8 Week 4	18.435 (± 17.108)	34.785 (± 13.856)		
Percent CD4 Baseline	0.870 (± 3.727)	1.510 (± 6.023)		
Percent positive CD4 Week 2	4.210 (± 5.029)	5.990 (± 9.602)		
Percent positive CD4 Week 4	1.585 (± 3.071)	10.155 (± 12.707)		

Statistical analyses

No statistical analyses for this end point

Secondary: Safety and tolerability of Nivolumab, Ipilimumab and Nivolumab in combination with Ipilimumab as measured by the number of deaths and AEs

End point title	Safety and tolerability of Nivolumab, Ipilimumab and Nivolumab in combination with Ipilimumab as measured by the number of deaths and AEs[5]

End point description:

The assessment of safety was based on frequency of deaths and adverse events (AEs). AEs were graded for severity according to the NCI CTCAE version 4.0.

End point type	Secondary

End point timeframe:

Includes events reported between first dose and up to 100 days after last dose of study medication (up to approximately 2 years).

Notes:

[5] - 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: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N1 30M + I3 30M non-BM	N3 30M non-BM	N3 30M BM	N1 60M + I3 90M
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	25	11	10	27
Units: Events				
Participants who died	14	4	4	11
Participants who died within 30 days of last dose	0	0	0	4
Participants who died within 100 days of last dose	0	1	2	5
Participants with an AE	25	11	10	27

End point values	N3 60M Naive	N3 60M PROG	N1 30M + I3 30M BM	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	41	44	10	
Units: Events				
Participants who died	26	25	2	
Participants who died within 30 days of last dose	3	2	1	
Participants who died within 100 days of last dose	5	8	2	
Participants with an AE	41	44	10	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Laboratory Abnormalities in Specific Liver Tests

End point title	Number of Laboratory Abnormalities in Specific Liver Tests[6]

End point description:

Abnormalities in hepatic parameters measured included those in aspartate aminotransferase (AST), alanine aminotransferase (ALT)and total bilirubin, with respect to upper limit of normal (ULN)

End point type	Secondary

End point timeframe:

101-120 days after last dose.

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N1 30M + I3 30M non-BM	N3 30M non-BM	N3 30M BM	N3 60M PROG
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	25	11	10	44
Units: Events				
ALT OR AST > 3XULN	5	0	0	4
ALT OR AST> 5XULN	4	0	0	2
ALT OR AST> 10XULN	2	0	0	0

ALT OR AST > 20XULN	0	0	0	0
TOTAL BILIRUBIN > 2XULN	1	0	0	0
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	1	0	0	0
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 30 DAY	1	0	0	0

End point values	N1 30M + I3 30M BM	N3 60M NAIVE	N1 60M +I3 90M	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	41	27	
Units: Events				
ALT OR AST > 3XULN	3	2	8	
ALT OR AST> 5XULN	1	1	6	
ALT OR AST> 10XULN	1	1	3	
ALT OR AST > 20XULN	1	0	1	
TOTAL BILIRUBIN > 2XULN	2	0	2	
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	1	0	2	
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 30 DAY	1	0	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Laboratory Abnormalities in Specific Thyroid Tests

End point title	Number of Laboratory Abnormalities in Specific Thyroid Tests[7]

End point description:

Abnormalities in thyroid parameters measured included those in thyroid stimulating hormone (TSH) levels with respect to upper limit of normal (ULN) and lower limit of normal (LLN)

End point type	Secondary

End point timeframe:

101-120 days after last dose.

Notes:

[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: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N1 30M + I3 30M non-BM	N3 30M non-BM	N3 30M BM	N1 30M + I3 30M BM
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	25	11	8	10
Units: Events				
TSH > ULN	7	1	4	3
TSH > ULN WITH TSH <= ULN AT BASELINE	4	1	2	3
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	3	0	2	2

TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	0	0	0	0
TSH > ULN WITH FT3/FT4 TEST MISSING	4	1	2	1
TSH < LLN	12	2	5	6
TSH <LLN WITH TSH >= LLN AT BASELINE	12	2	5	6
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	4	0	2	2
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	1	0	1	0
TSH < LLN WITH FT3/FT4 TEST MISSING	7	2	2	4

End point values	N3 60M NAIVE	N3 60M PROG	N1 60M +I3 90M	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	29	33	21	
Units: Events				
TSH > ULN	9	16	7	
TSH > ULN WITH TSH <= ULN AT BASELINE	4	9	7	
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	0	0	3	
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	0	0	0	
TSH > ULN WITH FT3/FT4 TEST MISSING	9	16	4	
TSH < LLN	3	4	11	
TSH <LLN WITH TSH >= LLN AT BASELINE	3	4	11	
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0	0	5	
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	0	0	3	
TSH < LLN WITH FT3/FT4 TEST MISSING	3	4	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the objective response rate (ORR)

End point title	Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the objective response rate (ORR)[8]

End point description:

The objective response rate (ORR) was defined as the number of subjects with a best overall response (BOR) of a complete response (CR) or partial response (PR) divided by the number of randomized subjects in the population of interest (eg, all treated subjects or response-evaluable subjects). The BOR was defined as the subject's best response designation, over the study as a whole, recorded between the date of first study drug administration and the date of objectively documented progression per RECIST 1.1, with subsequent confirmation, or date of subsequent anti-cancer therapy, whichever

occurred first in the study.

End point type	Secondary

End point timeframe:

Approximately every 8 weeks until disease progression and in follow-up if no progression (up to approximately 2 years)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N3 60M Prog	N1 30M + I3 30M non-BM	N3 30M non-BM	N3 30M BM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	25	11	10
Units: Percentage of participants				
number (confidence interval 95%)	22.7 (11.5 to 37.8)	40.0 (21.1 to 61.3)	27.3 (6.0 to 61.0)	60.0 (26.2 to 87.8)

End point values	N3 60M Naive	N1 30M + I3 30M BM	N1 60M+I3 90M	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	41	10	27	
Units: Percentage of participants				
number (confidence interval 95%)	31.7 (18.1 to 48.1)	70.0 (34.8 to 93.3)	44.4 (25.5 to 64.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the median duration of response (mDOR)

End point title	Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the median duration of response (mDOR)[9]

End point description:

Median duration of response (mDOR) was calculated for subjects with BOR of CR or PR only, and is defined as time between the date of first documented objective response and the date of the first subsequent disease progression or death, whichever occurred first, if death occurred within 100 days after last dose of study medication.

"999"=N/A

End point type	Secondary

End point timeframe:

2 years from the first dose of treatment

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N3 30M BM	N1 60M + I3 90M	N3 60M Naive	N3 60M PROG
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	27	41	44
Units: Months				
median (confidence interval 95%)	20.27 (13.57 to 999)	999 (5.85 to 999)	16.59 (7.29 to 999)	999 (5.55 to 999)

End point values	N1 30M + I3 30M BM	N1 30M + I3 30M NON-BM	N3 30M NON-BM	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	25	11	
Units: Months				
median (confidence interval 95%)	999 (22.01 to 999)	26.25 (7.85 to 999)	999 (3.71 to 999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the median time to response (mTTR)

End point title	Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the median time to response (mTTR)[10]

End point description:

Median time to response (mTTR) for a participant with a BOR of CR or PR is defined as the time from the first dosing date to the date of the first documented objective response (CR or PR).

End point type	Secondary

End point timeframe:

2 years from the first dose of treatment

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N3 30M BM	N1 60M + I3 90M	N3 60M Naive	N3 60M PROG
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	27	41	44
Units: Months				
median (confidence interval 95%)	2.14 (1.25 to 4.99)	1.41 (1.28 to 1.87)	1.87 (1.77 to 3.71)	2.78 (1.84 to 14.59)

End point values	N1 30M + I3 30M BM	N1 30M + I3 30M NON-BM	N3 30M NON-BM	

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	25	11	
Units: Months				
median (confidence interval 95%)	1.71 (1.38 to 7.43)	2.51 (1.28 to 2.86)	1.41 (1.41 to 6.90)	

Statistical analyses

No statistical analyses for this end point

Secondary: Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the progression free survival rate (PFSR)

End point title	Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the progression free survival rate (PFSR)[11]

End point description:

The progression free survival rate (PFSR) for a subject was defined as the time from the date of first dose of study medication to the date of the first documented disease progression, or death due to any cause, whichever occurred first, if death occurred within 100 days after last dose of study medication.

"999"=N/A

End point type	Secondary

End point timeframe:

2 years from the first dose of treatment

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N3 30M BM	N1 60M + I3 90M	N3 60M Naive	N3 60M PROG
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	27	41	44
Units: Percentage				
median (confidence interval 95%)	23.00 (0.85 to 999)	7.00 (1.41 to 999)	3.68 (1.84 to 7.36)	5.62 (1.87 to 9.66)

End point values	N1 30M + I3 30M BM	N1 30M + I3 30M NON-BM	N3 30M NON-BM	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	25	11	
Units: Percentage				
median (confidence interval 95%)	999 (1.18 to 999)	9.69 (1.94 to 29.01)	4.93 (1.41 to 999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the number of serum anti-drug antibody (ADA) positive participants and the number of neutralizing ADA positive participants

End point title	Immunogenicity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the number of serum anti-drug antibody (ADA) positive participants and the number of neutralizing ADA positive participants[12]

End point description:

Time Frame: Part 1: Day 1, Day 15, Day 43 of cycle 1, Day 1 of cycle 2, Day 15 of cycle 3, every 16 weeks after cycle 3 up to 2 years, follow-up visit 1 (40-60 days after last treatment), and follow-up visit 2 (101-120 days since last treatment) Part 2, 3 and 4: Weeks 1, 3, 4, 7, 9, 10, 13, 25, 53, 79, 95 follow-up visit 1 (40-60 days after last treatment), and follow-up visit 2 (101-120 days since last treatment).

"999"=N/A

End point type	Secondary

End point timeframe:

Up to follow-up visit 2 (101-120 days since last treatment)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N3 30M non-BM	N3 30M BM	N3 60M NAIVE	N3 60M PROG
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	7	38	42
Units: Participants				
ADA positive	1	1	2	5
Neutralizing ADA positive	0	0	0	0

End point values	N1 60M + I3 (Nivo ADA	N1 60M + I3 90M (Ipi ADA)	N1 30M + I3 30M Non-BM (Nivo ADA)	N1 30M + I3 30M Non-BM (Ipi ADA)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	22	24	23
Units: Participants				
ADA positive	10	1	16	4
Neutralizing ADA positive	0	0	1	0

End point values	N1 30M + I3 30M (Nivo ADA)	N1 30M + I3 30M (Ipi ADA)	Total (Nivo ADA)	Total (Ipi ADA)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	9	154	54
Units: Participants				
ADA positive	7	0	42	5

Neutralizing ADA positive	2	999	3	0

Statistical analyses

No statistical analyses for this end point

Secondary: Association between Programmed cell death ligand 1 (PD-L1) and clinical efficacy measures such as Objective Response Rate (PD-L1 ORR)

End point title	Association between Programmed cell death ligand 1 (PD-L1) and clinical efficacy measures such as Objective Response Rate (PD-L1 ORR)[13]

End point description:

For immunohistochemistry (IHC) measurements, to explore the PD-L1 expression as a potential predictive marker of clinical activity, PD-L1 expression status were derived from percent of tumor cells exhibiting cell surface staining for PD-L1 at baseline and/or in archived biopsy samples using verified and/or validated assays. In the case of multiple specimens, a subject would be identified as PD-L1 expression levels >= x%, where x% can be 10%, 5%, and/or 1% in any of the baseline and/or archived specimens. The association between PD-L1 expression status and/or level and clinical efficacy measures was assessed. The objective response rate (ORR) was defined as the number of subjects with a best overall response (BOR) of a complete response (CR) or partial response (PR) divided by the number of randomized subjects in the population of interest (all response-evaluable participants).

End point type	Secondary

End point timeframe:

2 years from first dose of treatment; Assessed up to September 2017

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N1 60M + I3 90M, W2	N1 60M + I3 90M, W4	N3 60M NAIVE, W4	N3 60M PROG, W4
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	10	39	36
Units: Percentage				
number (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	85.7 (42.1 to 99.6)	50.0 (11.8 to 88.2)	40.0 (19.1 to 63.9)	35.3 (14.2 to 61.7)
STTU 1 - 5% Level PD-L1 Status: Met criteria	80.0 (28.4 to 99.5)	60.0 (14.7 to 94.7)	40.0 (12.2 to 73.8)	33.3 (7.5 to 70.1)
STTU 1 - 10% Level PD-L1 Status: Met criteria	100.0 (29.2 to 100.0)	75.0 (19.4 to 99.4)	42.9 (9.9 to 81.6)	20.0 (0.5 to 71.6)

End point values	N1 60M + I3 90M, WU	N1 30M + I3 30M NON-BM	N3 30M NON-BM, W2	N1 30M + I3 30M BM, W2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	22	9	4
Units: Percentage				
number (confidence interval 95%)				

STTU 1 - 1% Level PD-L1 Status: Met criteria	50.0 (1.3 to 98.7)	63.6 (30.8 to 89.1)	40.0 (5.3 to 85.3)	100.0 (15.8 to 100.0)
STTU 1 - 5% Level PD-L1 Status: Met criteria	100.0 (2.5 to 100.0)	71.4 (29.0 to 96.3)	50.0 (1.3 to 98.7)	100.0 (15.8 to 100.0)
STTU 1 - 10% Level PD-L1 Status: Met criteria	100.0 (2.5 to 100.0)	66.7 (9.4 to 99.2)	100.0 (2.5 to 100.0)	100.0 (15.8 to 100.0)

End point values	N3 30M BM, W2	N3 60M, W4	N3 30M, W2	N1 + I3, W2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	75	12	37
Units: Percentage				
number (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	100.0 (2.5 to 100.0)	37.8 (22.5 to 55.2)	50.0 (11.8 to 88.2)	75.0 (50.9 to 91.3)
STTU 1 - 5% Level PD-L1 Status: Met criteria	100.0 (2.5 to 100.0)	36.8 (16.3 to 61.6)	66.7 (9.4 to 99.2)	78.6 (49.2 to 95.3)
STTU 1 - 10% Level PD-L1 Status: Met criteria	100.0 (2.5 to 100.0)	33.3 (9.9 to 65.1)	100.0 (15.8 to 100.0)	87.5 (47.3 to 99.7)

End point values	N1 + I3 W2, NON-BM	N3 NAIVE, NON-BM	N1 + I3 NON-BM	Total
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	48	49	140
Units: Percentage				
number (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	72.2 (46.5 to 90.3)	40.0 (21.1 to 61.3)	65.4 (44.3 to 82.8)	50.7 (38.6 to 62.8)
STTU 1 - 5% Level PD-L1 Status: Met criteria	75.0 (42.8 to 94.5)	41.7 (15.2 to 72.3)	72.2 (46.5 to 90.3)	57.1 (41.0 to 72.3)
STTU 1 - 10% Level PD-L1 Status: Met criteria	83.3 (35.9 to 99.6)	50.0 (15.7 to 84.3)	81.8 (48.2 to 97.7)	63.0 (42.4 to 80.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Association between Programmed cell death ligand 1 (PD-L1) and clinical efficacy measures such as the Duration of Response (PD-L1 DOR)

End point title	Association between Programmed cell death ligand 1 (PD-L1) and clinical efficacy measures such as the Duration of Response (PD-L1 DOR)[14]

End point description:

For immunohistochemistry (IHC) measurements, to explore the PD-L1 expression as a potential predictive marker of clinical activity, PD-L1 expression status were derived from percent of tumor cells exhibiting cell surface staining for PD-L1 at baseline and/or in archived biopsy samples using verified and/or validated assays. In the case of multiple specimens, a subject would be identified as PD-L1 expression levels >= x%, where x% can be 10%, 5%, and/or 1% in any of the baseline and/or archived specimens. Median duration of response (mDOR) was calculated for all response-evaluable participants with best overall response of CR or PR only, and is defined as time between the date of first documented

objective response and the date of the first subsequent disease progression or death, whichever occurred first, if death occurred within 100 days after last dose of study medication.

"999"=N/A

End point type	Secondary

End point timeframe:

2 years from first dose of treatment; Assessed up to September 2017

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N1 60M + I3 90M, W2	N1 60M + I3 90M, W4	N3 60M NAIVE, W4	N3 60M PROG, W4
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	10	39	36
Units: Months				
median (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	999 (2.96 to 999)	999 (999 to 999)	15.21 (4.60 to 18.20)	999 (15.57 to 999)
STTU 1 - 5% Level PD-L1 Status: Met criteria	999 (2.96 to 999)	999 (999 to 999)	15.21 (11.50 to 16.59)	999 (15.57 to 999)
STTU 1 - 10% Level PD-L1 Status: Met criteria	999 (2.96 to 999)	999 (999 to 999)	15.90 (15.21 to 16.59)	15.57 (-999 to 999)

End point values	N1 60M + I3 90M, WU	N1 30M + I3 30M NON-BM	N3 30M NON-BM, W2	N1 30M + I3 30M BM, W2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	22	9	4
Units: Months				
median (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	999 (999 to 999)	26.25 (8.31 to 999)	999 (3.71 to 999)	22.01 (-999 to 999)
STTU 1 - 5% Level PD-L1 Status: Met criteria	999 (999 to 999)	26.25 (8.31 to 999)	999 (3.71 to 999)	22.01 (-999 to 999)
STTU 1 - 10% Level PD-L1 Status: Met criteria	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)	22.01 (-999 to 999)

End point values	N3 30M BM, W2	N3 60M, W4	N3 30M, W2	N1 + I3, W2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	75	12	37
Units: Months				
median (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	999 (999 to 999)	16.59 (11.50 to 999)	999 (3.71 to 999)	26.25 (22.01 to 999)
STTU 1 - 5% Level PD-L1 Status: Met criteria	999 (999 to 999)	16.59 (11.50 to 999)	999 (999 to 999)	26.25 (8.31 to 999)
STTU 1 - 10% Level PD-L1 Status: Met criteria	999 (999 to 999)	15.57 (15.21 to 16.59)	999 (999 to 999)	999 (2.96 to 999)

End point values	N1 + I3 W2, NON-BM	N3 NAIVE, NON-BM	N1 + I3 NON-BM	Total
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	48	49	140
Units: Months				
median (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	999 (8.31 to 999)	15.21 (3.71 to 999)	999 (26.25 to 999)	26.25 (16.59 to 999)
STTU 1 - 5% Level PD-L1 Status: Met criteria	999 (2.96 to 999)	16.59 (11.50 to 999)	999 (8.31 to 999)	26.25 (15.57 to 999)
STTU 1 - 10% Level PD-L1 Status: Met criteria	999 (2.96 to 999)	16.59 (15.21 to 999)	999 (2.96 to 999)	999 (15.57 to 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Association between Programmed cell death ligand 1 (PD-L1) and clinical efficacy measures such as Progression Free Survival (PD-L1 PFS)

End point title	Association between Programmed cell death ligand 1 (PD-L1) and clinical efficacy measures such as Progression Free Survival (PD-L1 PFS)[15]

End point description:

For immunohistochemistry (IHC) measurements, to explore the PD-L1 expression as a potential predictive marker of clinical activity, PD-L1 expression status were derived from percent of tumor cells exhibiting cell surface staining for PD-L1 at baseline and/or in archived biopsy samples using verified and/or validated assays. In the case of multiple specimens, a subject would be identified as PD-L1 expression levels >= x%, where x% can be 10%, 5%, and/or 1% in any of the baseline and/or archived specimens. The association between PD-L1 expression status and/or level and clinical efficacy measures was assessed. The progression free survival rate (PFSR) for a subject was defined as the time from the date of first dose of study medication to the date of the first documented disease progression, or death due to any cause, whichever occurred first, if death occurred within 100 days after last dose of study medication.

"999"=N/A

End point type	Secondary

End point timeframe:

2 years from first dose of treatment; Assessed up to September 2017

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N1 60M + I3 90M, W2	N1 60M + I3 90M, W4	N3 60M NAIVE, W4	N3 60M PROG, W4
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	10	39	36
Units: Months				
median (confidence interval 95%)				

STTU 1 - 1% Level PD-L1 Status: Met criteria	999 (1.22 to 999)	999 (0.85 to 999)	4.50 (1.84 to 15.18)	9.66 (3.71 to 999)
STTU 1 - 5% Level PD-L1 Status: Met criteria	999 (1.22 to 999)	999 (0.85 to 999)	6.28 (0.33 to 17.05)	19.29 (1.77 to 999)
STTU 1 - 10% Level PD-L1 Status: Met criteria	999 (4.17 to 999)	999 (1.64 to 999)	5.36 (0.33 to 18.40)	19.29 (1.77 to 19.29)

End point values	N1 60M + I3 90M, WU	N1 30M + I3 30M NON-BM	N3 30M NON-BM, W2	N1 30M + I3 30M BM, W2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	22	9	4
Units: Months				
median (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	999 (0.76 to 999)	29.01 (1.94 to 29.01)	8.77 (1.22 to 999)	999 (23.95 to 999)
STTU 1 - 5% Level PD-L1 Status: Met criteria	999 (999 to 999)	29.01 (1.94 to 29.01)	999 (1.22 to 999)	999 (23.95 to 999)
STTU 1 - 10% Level PD-L1 Status: Met criteria	999 (999 to 999)	999 (1.94 to 999)	999 (999 to 999)	999 (23.95 to 999)

End point values	N3 30M BM, W2	N3 60M, W4	N3 30M, W2	N1 + I3, W2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	75	12	37
Units: Months				
median (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	999 (999 to 999)	6.24 (3.65 to 17.05)	8.77 (1.22 to 999)	29.01 (4.17 to 999)
STTU 1 - 5% Level PD-L1 Status: Met criteria	999 (999 to 999)	7.20 (1.87 to 18.40)	999 (1.22 to 999)	29.01 (3.02 to 999)
STTU 1 - 10% Level PD-L1 Status: Met criteria	999 (999 to 999)	6.24 (1.71 to 18.40)	999 (999 to 999)	999 (1.94 to 999)

End point values	N1 + I3 W2, NON-BM	N3 NAIVE, NON-BM	N1 + I3 NON-BM	Total
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	48	49	140
Units: Months				
median (confidence interval 95%)				
STTU 1 - 1% Level PD-L1 Status: Met criteria	29.01 (3.02 to 999)	5.36 (1.94 to 10.94)	29.01 (3.02 to 999)	10.58 (5.62 to 19.81)
STTU 1 - 5% Level PD-L1 Status: Met criteria	29.01 (1.94 to 999)	6.28 (1.22 to 17.05)	29.01 (3.02 to 999)	17.05 (5.36 to 29.01)
STTU 1 - 10% Level PD-L1 Status: Met criteria	999 (1.94 to 999)	11.20 (0.33 to 999)	999 (1.94 to 999)	19.29 (5.36 to 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the Overall Survival Rate (OSR)

End point title	Antitumor Activity of Nivolumab and Nivolumab in combination with Ipilimumab as measured by the Overall Survival Rate (OSR)[16]

End point description:

The proportion of subjects surviving to time t, where t is a specific length of time, eg, 12 months, which was determined by the available data for final analysis and was documented in the DPP. The proportion was calculated by the product-limit method (Kaplan-Meier estimate), which takes into account censored data. The overall survival rate (OSR) for a subject was defined as the time from the date of first dose of study medication to the date of death for any cause. A subject who had not died was censored at last known date alive

End point type	Secondary

End point timeframe:

2 years from first dose of treatment; Assessed up to September 2017

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N3 30M BM	N1 60M + I3 90M	N3 60M Naive	N3 60M PROG
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	27	41	44
Units: Percentage of participants				
median (confidence interval 95%)				
3 months	80.0 (40.9 to 94.6)	85.2 (65.2 to 94.2)	92.7 (79.0 to 97.6)	90.8 (77.3 to 96.4)
6 months	80.0 (40.9 to 94.6)	81.5 (61.1 to 91.8)	85.3 (70.2 to 93.1)	78.9 (63.3 to 88.4)
9 months	68.6 (30.5 to 88.7)	81.5 (61.1 to 91.8)	75.0 (58.5 to 85.7)	71.7 (55.5 to 82.8)
12 months	68.6 (30.5 to 88.7)	77.6 (56.8 to 89.3)	72.4 (55.7 to 83.7)	64.5 (48.2 to 76.9)
24 months	57.1 (21.7 to 81.5)	69.6 (48.3 to 83.5)	51.0 (34.3 to 65.4)	46.8 (31.1 to 61.1)

End point values	N1 30M + I3 30M BM	N1 30M + I3 30M NON-BM	N3 30M NON-BM	N1 + I3 NON-BM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	25	11	52
Units: Percentage of participants				
median (confidence interval 95%)				
3 months	90.0 (47.3 to 98.5)	100.0 (100.0 to 100.0)	90.0 (47.3 to 98.5)	92.3 (80.8 to 97.0)
6 months	90.0 (47.3 to 98.5)	100.0 (100.0 to 100.0)	90.0 (47.3 to 98.5)	90.4 (78.4 to 95.9)
9 months	90.0 (47.3 to 98.5)	88.0 (67.3 to 96.0)	90.0 (47.3 to 98.5)	84.6 (71.6 to 92.0)

12 months	90.0 (47.3 to 98.5)	88.0 (67.3 to 96.0)	80.0 (40.9 to 94.6)	82.6 (69.3 to 90.6)
24 months	80.0 (40.9 to 94.6)	58.1 (36.0 to 75.0)	58.3 (23.0 to 82.1)	64.3 (49.3 to 75.8)

End point values	N3 NAIVE	All N3	N1 + I3	Total
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	106	62	168
Units: Percentage of participants				
median (confidence interval 95%)				
3 months	90.2 (79.6 to 95.5)	90.5 (83.0 to 94.8)	91.9 (81.7 to 96.6)	91.0 (85.5 to 94.5)
6 months	85.3 (73.6 to 92.0)	82.6 (73.8 to 88.6)	90.3 (79.7 to 95.5)	85.5 (79.2 to 90.1)
9 months	76.6 (63.7 to 85.4)	74.6 (64.9 to 81.9)	85.5 (74.0 to 92.2)	78.7 (71.6 to 84.2)
12 months	73.1 (59.8 to 82.6)	69.5 (59.5 to 77.5)	83.8 (72.0 to 91.0)	74.9 (67.5 to 80.9)
24 months	53.3 (39.6 to 65.2)	50.6 (40.3 to 60.0)	66.8 (53.3 to 77.2)	56.8 (48.7 to 64.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Safety and tolerability of Nivolumab, Ipilimumab and Nivolumab in combination with Ipilimumab as measured by SAEs and AEs leading to discontinuation of study drug

End point title	Safety and tolerability of Nivolumab, Ipilimumab and Nivolumab in combination with Ipilimumab as measured by SAEs and AEs leading to discontinuation of study drug[17]

End point description:

The assessment of safety was based on frequency of serious adverse events (SAEs) and AEs leading to discontinuation of study drug. AEs were graded for severity according to the NCI CTCAE version 4.0.

End point type	Secondary

End point timeframe:

From enrollment to 100 days after the last dose date (up to approximately 2 years)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants listed in the baseline period who received treatment per the protocol are reported in the subject analysis sets which are subsets of the full population.

End point values	N3 60M Prog	N3 30M BM	N1 60M + I3 90M	N3 60M Naive
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	44	10	27	41
Units: Events				
SAEs	22	4	20	20
AEs Leading to Discontinuation	6	2	12	2

End point values	N1 30M + I3 30M Non-BM	N3 30M Non-BM	N1 30M I3 30M BM	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	25	11	10	
Units: Events				
SAEs	14	2	7	
AEs Leading to Discontinuation	9	1	4	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From first dose up to 100 days after last dose of study drug, approximately 75 months

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	MedDRA21.1

Reporting groups

Reporting group title	N3 60M NAIVE

Reporting group description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; Naive = Anti-CTLA4 Naive

Reporting group title	N1 60M + I3 90M, W2

Reporting group description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; W2 = Week 2 Biopsy

Reporting group title	N1 60M + I3 90M, W4

Reporting group description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; W4 = Week 4 Biopsy

Reporting group title	N1 60M + I3 90M, WU

Reporting group description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 90M = 90 minute infusion; 60M = 60 minute infusion; WU = Unknown Week Biopsy

Reporting group title	N3 60M PROG

Reporting group description:

Treatment Group: N3 = Nivolumab 3mg/kg; 60M = 60 minute infusion; PROG = Anti-CTLA4 Progressed

Reporting group title	N1 30M + I3 30M non-BM

Reporting group description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Reporting group title	N1 30M + I3 30M BM

Reporting group description:

Treatment Group: N1 = Nivolumab 1mg/kg; I3 = Ipilimumab 3 mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Reporting group title	N3 30M non-BM

Reporting group description:

Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Reporting group title	I3 Monotherapy

Reporting group description:

Treatment Group: I3 = Ipilimumab 3 mg/kg infusion. Participant was enrolled prior to the closure of this arm via amendment

Reporting group title	N3 30M BM

Reporting group description:

Treatment Group: N3 = Nivolumab 3mg/kg; 30M = 30 minute infusion; BM = Brain metastases

Reporting group title	Unplanned Treatment

Reporting group description:

Treatment Group: Unplanned treatment of Nivolumab 1 mg/kg x 4 then Nivolumab 3 mg/kg

Serious adverse events	N3 60M NAIVE	N1 60M + I3 90M, W2	N1 60M + I3 90M, W4
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 41 (48.78%)	8 / 11 (72.73%)	6 / 10 (60.00%)
number of deaths (all causes)	26	4	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 neoplasm progression			
subjects affected / exposed	3 / 41 (7.32%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Metastases to central nervous system			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Hypotension			

subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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	1 / 41 (2.44%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			

subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (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
Respiratory failure			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Hypoxia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	0 / 10 (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
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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 alkaline phosphatase increased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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 bilirubin increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Aphasia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arachnoiditis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysaesthesia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Hemiparesis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nystagmus			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Eye disorders			
Iridocyclitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	3 / 41 (7.32%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 41 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising oesophagitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Volvulus			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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	1 / 41 (2.44%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Autoimmune hepatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct obstruction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Immune-mediated hepatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Rash			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Haematuria			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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

Renal failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Arthritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Bone disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Pain in extremity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Clostridium difficile infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Urinary tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Failure to thrive			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (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
Hypokalaemia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	N1 60M + I3 90M, WU	N3 60M PROG	N1 30M + I3 30M non-BM
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	22 / 44 (50.00%)	14 / 25 (56.00%)
number of deaths (all causes)	4	25	14
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	3 / 6 (50.00%)	8 / 44 (18.18%)	4 / 25 (16.00%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 7	0 / 1
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			

subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	3 / 25 (12.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (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
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatic enzyme increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain herniation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arachnoiditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nystagmus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Iridocyclitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 6 (33.33%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	2 / 6 (33.33%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (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
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bone disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Clostridium difficile infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	0 / 25 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 6 (33.33%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	N1 30M + I3 30M BM	N3 30M non-BM	I3 Monotherapy
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 10 (70.00%)	2 / 11 (18.18%)	1 / 1 (100.00%)
number of deaths (all causes)	2	4	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Malignant neoplasm progression			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Metastatic neoplasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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			
Fatigue			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Malaise			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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

Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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	0 / 10 (0.00%)	0 / 11 (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
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Pneumonitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Pneumothorax			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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 embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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 / 10 (0.00%)	0 / 11 (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
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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 / 10 (0.00%)	0 / 11 (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 / 10 (0.00%)	0 / 11 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Blood bilirubin increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Lipase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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			
Brain herniation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Lower limb fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Fall			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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

Atrial fibrillation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Cardiac failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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			
Aphasia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Arachnoiditis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Guillain-Barre syndrome			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Hemiparesis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Monoplegia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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 disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	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
Nystagmus			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Seizure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Autoimmune haemolytic anaemia			

subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Immune thrombocytopenic purpura			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Thrombocytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Eye disorders			
Iridocyclitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Autoimmune colitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Diarrhoea			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Enterocolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Intestinal ischaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	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
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Necrotising oesophagitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Pancreatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Volvulus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Vomiting			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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			
Autoimmune hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Bile duct obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Hepatotoxicity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Immune-mediated hepatitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Liver disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Skin and subcutaneous tissue disorders			

Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Renal failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Hyperthyroidism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (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
Hypophysitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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			
Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Bone disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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 chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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			
Clostridium difficile infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Encephalitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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

Liver abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Meningitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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	1 / 10 (10.00%)	0 / 11 (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
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Staphylococcal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Failure to thrive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Hyperglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Hypokalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (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

Serious adverse events	N3 30M BM	Unplanned Treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 10 (40.00%)	1 / 1 (100.00%)	
number of deaths (all causes)	4	1	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm progression			
subjects affected / exposed	2 / 10 (20.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Metastases to central nervous system			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Brain herniation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Fall			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arachnoiditis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysaesthesia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoplegia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nystagmus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			

subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Iridocyclitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising oesophagitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatotoxicity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hyperthyroidism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophysitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Clostridium difficile infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	N3 60M NAIVE	N1 60M + I3 90M, W2	N1 60M + I3 90M, W4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 41 (100.00%)	11 / 11 (100.00%)	10 / 10 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	3 / 41 (7.32%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	3	1	2
Tumour embolism			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Oncologic complication			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Flushing			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	6 / 41 (14.63%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	8	0	1
Hypotension			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Lymphoedema			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	1	1
Hot flush			

subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 41 (7.32%)	3 / 11 (27.27%)	2 / 10 (20.00%)
occurrences (all)	3	3	2
Chest pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Chills			
subjects affected / exposed	3 / 41 (7.32%)	3 / 11 (27.27%)	4 / 10 (40.00%)
occurrences (all)	3	3	5
Fatigue			
subjects affected / exposed	21 / 41 (51.22%)	7 / 11 (63.64%)	4 / 10 (40.00%)
occurrences (all)	32	7	5
Hernia pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	4 / 41 (9.76%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	6	3	1
Localised oedema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	3 / 41 (7.32%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Non-cardiac chest pain			

subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	3	0	1
Oedema peripheral			
subjects affected / exposed	9 / 41 (21.95%)	1 / 11 (9.09%)	3 / 10 (30.00%)
occurrences (all)	10	1	4
Pain			
subjects affected / exposed	3 / 41 (7.32%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	5	0	0
Peripheral swelling			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Pyrexia			
subjects affected / exposed	11 / 41 (26.83%)	6 / 11 (54.55%)	6 / 10 (60.00%)
occurrences (all)	12	7	7
Temperature intolerance			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Decreased activity			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Feeling cold			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Feeling of body temperature change			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Inflammation			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Physical deconditioning			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Axillary pain			

subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	1 / 41 (2.44%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	1	2	0
Reproductive system and breast disorders			
Nipple pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Spermatic cord haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Genital rash			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Scrotal swelling			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	10 / 41 (24.39%)	4 / 11 (36.36%)	3 / 10 (30.00%)
occurrences (all)	12	4	3
Dyspnoea			
subjects affected / exposed	3 / 41 (7.32%)	3 / 11 (27.27%)	3 / 10 (30.00%)
occurrences (all)	3	3	3
Hypoxia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Oropharyngeal pain			

subjects affected / exposed	4 / 41 (9.76%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	4	0	0
Nasal congestion			
subjects affected / exposed	6 / 41 (14.63%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	7	0	1
Pleural effusion			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	3 / 10 (30.00%)
occurrences (all)	1	0	3
Pneumonitis			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Productive cough			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
Upper-airway cough syndrome			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Dysphonia			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hiccups			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Respiratory failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	3	0	1
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Anxiety			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	2	0	2
Depression			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Insomnia			
subjects affected / exposed	6 / 41 (14.63%)	1 / 11 (9.09%)	3 / 10 (30.00%)
occurrences (all)	6	1	3
Sleep disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Disorientation			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Hallucination			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Mental status changes			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	6 / 41 (14.63%)	5 / 11 (45.45%)	3 / 10 (30.00%)
occurrences (all)	8	7	3
Amylase increased			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 41 (14.63%)	6 / 11 (54.55%)	3 / 10 (30.00%)
occurrences (all)	11	9	3
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 41 (12.20%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	10	0	1
Blood bilirubin increased			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	4	3	2
Blood creatinine increased			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	1	1
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1

Cortisol increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	8 / 41 (19.51%)	2 / 11 (18.18%)	2 / 10 (20.00%)
occurrences (all)	15	3	4
Lymphocyte count decreased			
subjects affected / exposed	4 / 41 (9.76%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	8	1	0
Platelet count decreased			
subjects affected / exposed	1 / 41 (2.44%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Norovirus test positive			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	8 / 41 (19.51%)	2 / 11 (18.18%)	2 / 10 (20.00%)
occurrences (all)	8	2	2
Weight increased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Blood urea increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Heart rate increased			

subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	5 / 41 (12.20%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	5	0	0
Infusion related reaction			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Limb injury			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Bone fissure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Radiation pneumonitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Tachycardia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
Cardiac failure congestive			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Atrioventricular block second degree			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	5 / 41 (12.20%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	5	1	1
Dysaesthesia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Dysgeusia			
subjects affected / exposed	0 / 41 (0.00%)	2 / 11 (18.18%)	2 / 10 (20.00%)
occurrences (all)	0	2	2
Headache			
subjects affected / exposed	10 / 41 (24.39%)	0 / 11 (0.00%)	3 / 10 (30.00%)
occurrences (all)	13	0	3
Hemiparesis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	1	2
Presyncope			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Amnesia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Fine motor delay			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Encephalopathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hypersomnia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			

subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Mental impairment			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Muscle spasticity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Neurotoxicity			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Syncope			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Spinal cord compression			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Balance disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	9 / 41 (21.95%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	10	0	3
Haemolytic anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	2	0	4

Coagulopathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Microcytic anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cerumen impaction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Eye disorders			
Dry eye			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Eye disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Uveitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Visual impairment			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			

subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Eye swelling			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Iridocyclitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Conjunctival oedema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	1	1
Abdominal pain			
subjects affected / exposed	11 / 41 (26.83%)	3 / 11 (27.27%)	1 / 10 (10.00%)
occurrences (all)	14	3	1
Abdominal pain upper			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Anal pruritus			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Constipation			
subjects affected / exposed	11 / 41 (26.83%)	4 / 11 (36.36%)	2 / 10 (20.00%)
occurrences (all)	13	4	3
Diarrhoea			
subjects affected / exposed	15 / 41 (36.59%)	5 / 11 (45.45%)	5 / 10 (50.00%)
occurrences (all)	23	5	6
Dry mouth			
subjects affected / exposed	3 / 41 (7.32%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Dyspepsia			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Dysphagia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	9 / 41 (21.95%)	3 / 11 (27.27%)	2 / 10 (20.00%)
occurrences (all)	16	4	2
Oral pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	4 / 41 (9.76%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	4	0	0

Vomiting			
subjects affected / exposed	6 / 41 (14.63%)	2 / 11 (18.18%)	2 / 10 (20.00%)
occurrences (all)	10	3	2
Abdominal tenderness			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Aphthous ulcer			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Autoimmune colitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Chronic gastritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Faecaloma			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Bile duct obstruction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Cholelithiasis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Actinic keratosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	7 / 41 (17.07%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	7	1	0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	3 / 41 (7.32%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Eczema nummular			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Livedo reticularis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	11 / 41 (26.83%)	8 / 11 (72.73%)	3 / 10 (30.00%)
occurrences (all)	16	8	3
Rash			
subjects affected / exposed	11 / 41 (26.83%)	5 / 11 (45.45%)	3 / 10 (30.00%)
occurrences (all)	11	6	6

Rash erythematous			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	5 / 41 (12.20%)	2 / 11 (18.18%)	4 / 10 (40.00%)
occurrences (all)	6	2	5
Rash papular			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	3	1
Scab			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Vitiligo			
subjects affected / exposed	4 / 41 (9.76%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	4	2	1
Erythema			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Night sweats			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Scar pain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Facial wasting			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Acute kidney injury			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	3 / 41 (7.32%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	4	1	2
Pollakiuria			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	3	1	0
Nocturia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Polyuria			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Urinary hesitation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 41 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Endocrine disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			

subjects affected / exposed	1 / 41 (2.44%)	3 / 11 (27.27%)	3 / 10 (30.00%)
occurrences (all)	1	3	3
Hypophysitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	5 / 41 (12.20%)	1 / 11 (9.09%)	3 / 10 (30.00%)
occurrences (all)	6	1	3
Thyroiditis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 41 (19.51%)	2 / 11 (18.18%)	3 / 10 (30.00%)
occurrences (all)	13	2	4
Arthritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	11 / 41 (26.83%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	13	1	1
Bone pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	4 / 41 (9.76%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	4	0	1
Muscular weakness			
subjects affected / exposed	3 / 41 (7.32%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	3	1	1
Neck pain			
subjects affected / exposed	1 / 41 (2.44%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	2 / 41 (4.88%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	2	2	1
Pain in extremity			
subjects affected / exposed	7 / 41 (17.07%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	8	0	1
Pain in jaw			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Candida infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	1	0	2
Cellulitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Influenza			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Cytomegalovirus infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Nasopharyngitis			
subjects affected / exposed	3 / 41 (7.32%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	4	1	3
Rash pustular			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	5	0	2
Skin infection			
subjects affected / exposed	3 / 41 (7.32%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 41 (9.76%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	4	1	2
Urinary tract infection			
subjects affected / exposed	2 / 41 (4.88%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	3	1	1
Fungal skin infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0

Infected skin ulcer			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Pyuria			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Staphylococcal infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	10 / 41 (24.39%)	5 / 11 (45.45%)	3 / 10 (30.00%)
occurrences (all)	11	6	3
Dehydration			
subjects affected / exposed	2 / 41 (4.88%)	3 / 11 (27.27%)	1 / 10 (10.00%)
occurrences (all)	2	3	2
Hypercalcaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hyperglycaemia			

subjects affected / exposed	4 / 41 (9.76%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	7	2	0
Hyperuricaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 41 (2.44%)	2 / 11 (18.18%)	2 / 10 (20.00%)
occurrences (all)	1	2	3
Hypomagnesaemia			
subjects affected / exposed	2 / 41 (4.88%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	3	0	1
Hyponatraemia			
subjects affected / exposed	3 / 41 (7.32%)	2 / 11 (18.18%)	2 / 10 (20.00%)
occurrences (all)	3	2	2
Hypophosphataemia			
subjects affected / exposed	3 / 41 (7.32%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	4	0	2
Lactic acidosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Diabetes mellitus			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Fluid retention			
subjects affected / exposed	0 / 41 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Hyperkalaemia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hypophagia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	N1 60M + I3 90M, WU	N3 60M PROG	N1 30M + I3 30M non-BM
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	44 / 44 (100.00%)	25 / 25 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	2 / 25 (8.00%)
occurrences (all)	0	2	2
Tumour embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oncologic complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Flushing			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Hypotension			

subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences (all)	2	0	2
Lymphoedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Orthostatic hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	3 / 25 (12.00%)
occurrences (all)	1	1	3
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Chills			
subjects affected / exposed	1 / 6 (16.67%)	4 / 44 (9.09%)	3 / 25 (12.00%)
occurrences (all)	2	5	4
Fatigue			
subjects affected / exposed	4 / 6 (66.67%)	29 / 44 (65.91%)	13 / 25 (52.00%)
occurrences (all)	5	38	19
Hernia pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 6 (16.67%)	3 / 44 (6.82%)	3 / 25 (12.00%)
occurrences (all)	1	3	3
Localised oedema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Malaise			

subjects affected / exposed	2 / 6 (33.33%)	1 / 44 (2.27%)	2 / 25 (8.00%)
occurrences (all)	2	1	2
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 6 (33.33%)	6 / 44 (13.64%)	6 / 25 (24.00%)
occurrences (all)	2	6	8
Pain			
subjects affected / exposed	1 / 6 (16.67%)	11 / 44 (25.00%)	1 / 25 (4.00%)
occurrences (all)	1	11	1
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 6 (50.00%)	9 / 44 (20.45%)	9 / 25 (36.00%)
occurrences (all)	6	17	10
Temperature intolerance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Decreased activity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Feeling of body temperature change			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Inflammation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Physical deconditioning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Nipple pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Spermatic cord haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Genital rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Scrotal swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 6 (33.33%)	13 / 44 (29.55%)	4 / 25 (16.00%)
occurrences (all)	2	20	6
Dyspnoea			

subjects affected / exposed	3 / 6 (50.00%)	7 / 44 (15.91%)	5 / 25 (20.00%)
occurrences (all)	3	9	6
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 6 (16.67%)	2 / 44 (4.55%)	1 / 25 (4.00%)
occurrences (all)	1	2	1
Nasal congestion			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	2 / 25 (8.00%)
occurrences (all)	1	1	2
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	3 / 25 (12.00%)
occurrences (all)	0	0	3
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 6 (0.00%)	4 / 44 (9.09%)	0 / 25 (0.00%)
occurrences (all)	0	4	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Epistaxis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Hiccups			
subjects affected / exposed	1 / 6 (16.67%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	1	2	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Respiratory failure			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	4 / 44 (9.09%)	0 / 25 (0.00%)
occurrences (all)	0	5	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 6 (33.33%)	5 / 44 (11.36%)	2 / 25 (8.00%)
occurrences (all)	2	6	2
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Disorientation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 6 (33.33%)	2 / 44 (4.55%)	5 / 25 (20.00%)
occurrences (all)	2	2	6
Amylase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 6 (33.33%)	2 / 44 (4.55%)	6 / 25 (24.00%)
occurrences (all)	2	2	7
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 6 (33.33%)	4 / 44 (9.09%)	3 / 25 (12.00%)
occurrences (all)	2	5	3
Blood bilirubin increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)	2 / 44 (4.55%)	1 / 25 (4.00%)
occurrences (all)	1	2	1
Blood thyroid stimulating hormone decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Cortisol increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	2 / 6 (33.33%)	8 / 44 (18.18%)	3 / 25 (12.00%)
occurrences (all)	2	13	4
Lymphocyte count decreased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	1	2	1
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Norovirus test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Weight decreased			
subjects affected / exposed	2 / 6 (33.33%)	5 / 44 (11.36%)	3 / 25 (12.00%)
occurrences (all)	3	6	4
Weight increased			

subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Blood urea increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Limb injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Bone fissure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Radiation pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
Tachycardia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	3	0	1
Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	2 / 6 (33.33%)	8 / 44 (18.18%)	1 / 25 (4.00%)
occurrences (all)	5	9	1
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	3 / 6 (50.00%)	9 / 44 (20.45%)	9 / 25 (36.00%)
occurrences (all)	6	11	10
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	3 / 44 (6.82%)	1 / 25 (4.00%)
occurrences (all)	0	3	1
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Seizure			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Fine motor delay			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hypersomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	1 / 25 (4.00%)
occurrences (all)	0	3	1
Mental impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 6 (33.33%)	8 / 44 (18.18%)	5 / 25 (20.00%)
occurrences (all)	2	9	7

Haemolytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	0	3	2
Coagulopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Microcytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Cerumen impaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Eye disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	2 / 25 (8.00%)
occurrences (all)	1	1	2
Uveitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vision blurred			

subjects affected / exposed	0 / 6 (0.00%)	3 / 44 (6.82%)	3 / 25 (12.00%)
occurrences (all)	0	3	3
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Eye pruritus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Eye swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	3 / 44 (6.82%)	1 / 25 (4.00%)
occurrences (all)	0	3	1
Abdominal pain			
subjects affected / exposed	3 / 6 (50.00%)	5 / 44 (11.36%)	4 / 25 (16.00%)
occurrences (all)	4	5	4
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	3 / 25 (12.00%)
occurrences (all)	0	2	4

Anal pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	2 / 6 (33.33%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Constipation			
subjects affected / exposed	1 / 6 (16.67%)	14 / 44 (31.82%)	1 / 25 (4.00%)
occurrences (all)	2	18	1
Diarrhoea			
subjects affected / exposed	2 / 6 (33.33%)	14 / 44 (31.82%)	9 / 25 (36.00%)
occurrences (all)	7	30	15
Dry mouth			
subjects affected / exposed	1 / 6 (16.67%)	6 / 44 (13.64%)	2 / 25 (8.00%)
occurrences (all)	1	6	2
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	4 / 44 (9.09%)	2 / 25 (8.00%)
occurrences (all)	0	5	5
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	1 / 6 (16.67%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	1	2	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	3 / 6 (50.00%)	12 / 44 (27.27%)	13 / 25 (52.00%)
occurrences (all)	4	14	22

Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 6 (16.67%)	2 / 44 (4.55%)	2 / 25 (8.00%)
occurrences (all)	1	2	2
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)	4 / 44 (9.09%)	9 / 25 (36.00%)
occurrences (all)	2	5	19
Abdominal tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Autoimmune colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Chronic gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	1 / 25 (4.00%)
occurrences (all)	0	3	1
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	1 / 6 (16.67%)	3 / 44 (6.82%)	0 / 25 (0.00%)
occurrences (all)	1	5	0
Hypertransaminasaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Actinic keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	4 / 44 (9.09%)	0 / 25 (0.00%)
occurrences (all)	0	6	0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Eczema nummular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Livedo reticularis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	2 / 6 (33.33%)	12 / 44 (27.27%)	8 / 25 (32.00%)
occurrences (all)	2	17	8
Rash			
subjects affected / exposed	1 / 6 (16.67%)	11 / 44 (25.00%)	6 / 25 (24.00%)
occurrences (all)	1	13	8
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	5 / 44 (11.36%)	4 / 25 (16.00%)
occurrences (all)	0	9	4
Rash papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	3 / 25 (12.00%)
occurrences (all)	0	2	3
Scab			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Vitiligo			
subjects affected / exposed	0 / 6 (0.00%)	6 / 44 (13.64%)	0 / 25 (0.00%)
occurrences (all)	0	6	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Scar pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Skin ulcer			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Facial wasting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Adrenal insufficiency			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	4 / 25 (16.00%)
occurrences (all)	1	0	4
Endocrine disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	4 / 25 (16.00%)
occurrences (all)	0	2	4
Hypophysitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Hypothyroidism			
subjects affected / exposed	2 / 6 (33.33%)	5 / 44 (11.36%)	5 / 25 (20.00%)
occurrences (all)	2	7	6
Thyroiditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 6 (33.33%)	13 / 44 (29.55%)	5 / 25 (20.00%)
occurrences (all)	2	18	5
Arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	8 / 44 (18.18%)	1 / 25 (4.00%)
occurrences (all)	1	9	1
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	3 / 44 (6.82%)	0 / 25 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	6 / 44 (13.64%)	1 / 25 (4.00%)
occurrences (all)	0	6	1
Muscular weakness			
subjects affected / exposed	1 / 6 (16.67%)	3 / 44 (6.82%)	1 / 25 (4.00%)
occurrences (all)	1	3	1
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	5 / 44 (11.36%)	2 / 25 (8.00%)
occurrences (all)	0	5	2
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	7 / 44 (15.91%)	3 / 25 (12.00%)
occurrences (all)	2	7	3
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	5 / 44 (11.36%)	1 / 25 (4.00%)
occurrences (all)	0	6	1
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Conjunctivitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	3

Influenza			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Sepsis			
subjects affected / exposed	2 / 6 (33.33%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	1 / 6 (16.67%)	3 / 44 (6.82%)	1 / 25 (4.00%)
occurrences (all)	1	3	1
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 6 (33.33%)	4 / 44 (9.09%)	2 / 25 (8.00%)
occurrences (all)	2	4	2
Urinary tract infection			
subjects affected / exposed	2 / 6 (33.33%)	3 / 44 (6.82%)	0 / 25 (0.00%)
occurrences (all)	2	3	0

Fungal skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Pyuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	15 / 44 (34.09%)	4 / 25 (16.00%)
occurrences (all)	2	16	5
Dehydration			

subjects affected / exposed	3 / 6 (50.00%)	0 / 44 (0.00%)	2 / 25 (8.00%)
occurrences (all)	3	0	2
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 6 (16.67%)	4 / 44 (9.09%)	2 / 25 (8.00%)
occurrences (all)	1	7	2
Hyperuricaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 6 (33.33%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 44 (2.27%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	3 / 6 (50.00%)	1 / 44 (2.27%)	2 / 25 (8.00%)
occurrences (all)	4	1	3
Hypomagnesaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 44 (2.27%)	2 / 25 (8.00%)
occurrences (all)	1	1	2
Hyponatraemia			
subjects affected / exposed	4 / 6 (66.67%)	3 / 44 (6.82%)	2 / 25 (8.00%)
occurrences (all)	4	3	3
Hypophosphataemia			
subjects affected / exposed	2 / 6 (33.33%)	2 / 44 (4.55%)	0 / 25 (0.00%)
occurrences (all)	3	3	0
Lactic acidosis			
subjects affected / exposed	2 / 6 (33.33%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Malnutrition			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Diabetes mellitus			

subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 44 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hypophagia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 44 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	N1 30M + I3 30M BM	N3 30M non-BM	I3 Monotherapy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	10 / 11 (90.91%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Tumour embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oncologic complication			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Flushing			

subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	6 / 10 (60.00%)	5 / 11 (45.45%)	1 / 1 (100.00%)
occurrences (all)	8	5	1
Hernia pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	3 / 10 (30.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	4	1	0
Localised oedema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	4 / 10 (40.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	5 / 10 (50.00%)	3 / 11 (27.27%)	0 / 1 (0.00%)
occurrences (all)	8	3	0
Temperature intolerance			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Decreased activity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Feeling of body temperature change			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Physical deconditioning			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Nipple pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spermatic cord haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Genital rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Scrotal swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Bronchial obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 10 (30.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Dyspnoea			
subjects affected / exposed	2 / 10 (20.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Insomnia			

subjects affected / exposed	3 / 10 (30.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Sleep disorder			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Amylase increased			
subjects affected / exposed	3 / 10 (30.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	3 / 10 (30.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	1 / 1 (100.00%)
occurrences (all)	0	1	1
Platelet count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Norovirus test positive			

subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Transaminases increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Blood urea increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bone fissure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Radiation pneumonitis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Angina pectoris			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Autonomic nervous system imbalance			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cerebrovascular accident			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Disturbance in attention			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	2 / 10 (20.00%)	3 / 11 (27.27%)	0 / 1 (0.00%)
occurrences (all)	2	3	0
Dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	5 / 10 (50.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Hemiparesis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Aphasia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fine motor delay			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mental impairment			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tremor			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	1 / 1 (100.00%)
occurrences (all)	4	0	1
Haemolytic anaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Coagulopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Microcytic anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Cerumen impaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Eye disorder			

subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Eye pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Uveitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Abdominal distension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	3 / 11 (27.27%)	1 / 1 (100.00%)
occurrences (all)	0	3	1
Abdominal pain upper			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Anal pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Diarrhoea			
subjects affected / exposed	6 / 10 (60.00%)	4 / 11 (36.36%)	0 / 1 (0.00%)
occurrences (all)	8	4	0
Dry mouth			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Dyspepsia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	7 / 10 (70.00%)	4 / 11 (36.36%)	0 / 1 (0.00%)
occurrences (all)	8	5	0
Oral pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 10 (30.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Autoimmune colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Actinic keratosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Dry skin			
subjects affected / exposed	1 / 10 (10.00%)	2 / 11 (18.18%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Dermatitis exfoliative generalised			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eczema nummular			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Livedo reticularis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	4 / 10 (40.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	4	1	0
Rash			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Rash erythematous			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Rash pruritic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Skin hypopigmentation			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Vitiligo			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Erythema			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Facial wasting			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Urinary hesitation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	3 / 10 (30.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Endocrine disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypophysitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	3 / 10 (30.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Thyroiditis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 10 (30.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Arthritis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Bone pain			

subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Joint range of motion decreased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Muscular weakness			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	2 / 10 (20.00%)	3 / 11 (27.27%)	0 / 1 (0.00%)
occurrences (all)	3	3	0
Pain in jaw			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Influenza			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cytomegalovirus infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 10 (40.00%)	1 / 11 (9.09%)	1 / 1 (100.00%)
occurrences (all)	4	1	1
Dehydration			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Hyperuricaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	N3 30M BM	Unplanned Treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 10 (90.00%)	1 / 1 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tumour embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oncologic complication			

subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Lymphoedema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Hot flush			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Orthostatic hypotension			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	2 / 10 (20.00%)	1 / 1 (100.00%)	
occurrences (all)	2	1	
Chills			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Fatigue			

subjects affected / exposed	6 / 10 (60.00%)	1 / 1 (100.00%)		
occurrences (all)	6	2		
Hernia pain				
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)		
occurrences (all)	1	0		
Influenza like illness				
subjects affected / exposed	3 / 10 (30.00%)	0 / 1 (0.00%)		
occurrences (all)	3	0		
Localised oedema				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Malaise				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Mucosal inflammation				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Non-cardiac chest pain				
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)		
occurrences (all)	1	0		
Oedema peripheral				
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)		
occurrences (all)	2	0		
Pain				
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)		
occurrences (all)	1	0		
Peripheral swelling				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Pyrexia				
subjects affected / exposed	3 / 10 (30.00%)	0 / 1 (0.00%)		
occurrences (all)	3	0		
Temperature intolerance				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Decreased activity				

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Feeling cold			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Feeling of body temperature change			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Physical deconditioning			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Axillary pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypersensitivity			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Nipple pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Spermatic cord haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Genital rash			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Scrotal swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	3 / 10 (30.00%)	1 / 1 (100.00%)	
occurrences (all)	4	1	
Dyspnoea			
subjects affected / exposed	2 / 10 (20.00%)	1 / 1 (100.00%)	
occurrences (all)	2	1	
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Upper-airway cough syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hiccups			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pulmonary embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Respiratory tract congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Anxiety			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Depression			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Insomnia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Sleep disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Depressed mood			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Disorientation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hallucination			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Mental status changes			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Amylase increased			

subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	4	0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	4	0	
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Cortisol increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
International normalised ratio increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	8	0	
Lymphocyte count decreased			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Norovirus test positive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Transaminases increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Weight increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Blood urea increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Heart rate increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Limb injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Procedural pain			

subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Bone fissure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Radiation pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	2	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Angina pectoris			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Palpitations			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cardiac failure congestive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Atrioventricular block second degree			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cerebrovascular accident			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Disturbance in attention			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Dizziness			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Dysaesthesia			
subjects affected / exposed	4 / 10 (40.00%)	0 / 1 (0.00%)	
occurrences (all)	4	0	
Dysarthria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Hemiparesis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Lethargy			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Neuropathy peripheral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Presyncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Restless legs syndrome			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Seizure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Aphasia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Amnesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fine motor delay			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Encephalopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypersomnia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Mental impairment			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Muscle spasticity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Neurotoxicity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Syncope			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Spinal cord compression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Balance disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Haemolytic anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Coagulopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Lymphadenopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Microcytic anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cerumen impaction			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Eye disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eye pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Uveitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Vision blurred			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Visual impairment			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Eye pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eye swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Iridocyclitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Lacrimation increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Ocular hyperaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Conjunctival oedema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Abdominal pain upper			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Anal pruritus			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	2 / 10 (20.00%)	1 / 1 (100.00%)	
occurrences (all)	3	2	
Diarrhoea			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Dry mouth			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysphagia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Haemorrhoids			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	2 / 10 (20.00%)	1 / 1 (100.00%)	
occurrences (all)	2	2	
Oral pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	1	2	
Abdominal tenderness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Aphthous ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Autoimmune colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Ascites			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Chronic gastritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Faecaloma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Bile duct obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cholelithiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Actinic keratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dermatitis acneiform			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dry skin			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Eczema nummular			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Lichenoid keratosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Livedo reticularis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	6 / 10 (60.00%)	1 / 1 (100.00%)	
occurrences (all)	6	1	
Rash			
subjects affected / exposed	3 / 10 (30.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Rash erythematous			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Rash papular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Rash pruritic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Scab			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Skin hypopigmentation			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Vitiligo			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Scar pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Skin ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Facial wasting			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	

Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nocturia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Polyuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Urinary hesitation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Urinary incontinence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Endocrine disorder			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Hyperthyroidism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypophysitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Thyroiditis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Bone pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Joint range of motion decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Muscular weakness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Myalgia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	

Pain in jaw			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal stiffness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Rash pustular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Rhinitis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Sepsis				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Sinusitis				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Skin infection				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Upper respiratory tract infection				
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)		
occurrences (all)	1	0		
Urinary tract infection				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Fungal skin infection				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Hordeolum				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Infected skin ulcer				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Laryngitis				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Onychomycosis				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Oral candidiasis				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Oral herpes				

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pyuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Staphylococcal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	2	1	
Dehydration			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	2	3	
Hypercalcaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hyperglycaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	8	0	
Hyperuricaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypoalbuminaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypoglycaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Hypokalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Hypomagnesaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hyponatraemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypophosphataemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Lactic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Malnutrition			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Diabetes mellitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fluid retention			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypophagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported