



Clinical trial results:

A Phase 1/2 Study of the Safety, Tolerability, and Efficacy of Epacadostat Administered in Combination With Nivolumab in Select Advanced Cancers (ECHO-204)

Summary

EudraCT number	2016-002423-29
Trial protocol	GB
Global end of trial date	16 June 2020

Results information

Result version number	v1 (current)
This version publication date	02 July 2021
First version publication date	02 July 2021

Trial information

Trial identification

Sponsor protocol code	INCB 24360-204 / ECHO-204
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02327078
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cut-Off, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, +44 (0)330 100 3677, globalmedinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, +44 (0)330 100 3677, globalmedinfo@incyte.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	16 June 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	16 June 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a Phase 1/2, open label study. Phase 1 consists of 2 parts. Part 1 is a dose-escalation assessment of the safety and tolerability of epacadostat administered with nivolumab in subjects with select advanced solid tumors and lymphomas. Phase 2 is comprised of 9 tumor specific expansion cohorts in including melanoma, NSCLC, SCCHN, colorectal cancer, ovarian cancer, glioblastoma and diffuse large B-cell lymphoma (DLBCL), and will further characterize the safety, efficacy, pharmacokinetics and pharmacodynamics of the combination of epacadostat and nivolumab.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 December 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 301
Country: Number of subjects enrolled	United Kingdom: 6
Worldwide total number of subjects	307
EEA total number of subjects	0

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)	185
From 65 to 84 years	116
85 years and over	6

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 25 study sites in the United States and 2 study sites in United Kingdom. For each treatment group, results included data contributed by participants from Phase 1 Part 1, Phase 1 Part 2 and Phase 2.

Pre-assignment

Screening details:

A total of 307 participants were enrolled in the study. Study enrollment was permanently discontinued on 25 Oct 2018 as a strategic decision. At the time of data cut-off date of 01Feb 2019, 22 participants were ongoing.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab

Arm description:

Epacadostat 25mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W

Arm type	Experimental
Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule

Arm title	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab
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Arm description:

Epacadostat 50mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.

Arm type	Experimental
Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule

Arm title	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab
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Arm description:

Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.

Arm type	Experimental
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Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use
Dosage and administration details:	
Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule	
Arm title	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab
Arm description:	
Epacadostat 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.	
Arm type	Experimental
Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use
Dosage and administration details:	
Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule	
Arm title	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5-FU/Platinum
Arm description:	
Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360mg Q3W and 5-FU/Platinum(Carboplatin or Cisplatin+5-Fluorouracil) administered intravenously (IV).	
Arm type	Experimental
Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use
Dosage and administration details:	
Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule	
Arm title	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/Platinum
Arm description:	
Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360 mg Q3W and Pemetrexed/Platinum (Carboplatin orCisplatin+Pemetrexed) administered intravenously (IV).	
Arm type	Experimental
Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use
Dosage and administration details:	
Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule	
Arm title	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Platinum
Arm description:	
Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360 mg Q3W and Paclitaxel/Platinum(Carboplatin+Cisplatin+Paclitaxel)administered intravenously (IV).	
Arm type	Experimental

Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule

Arm title	Phase 2 Epacadostat 100mg BID + Nivolumab
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Arm description:

Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W or 480 mg Q4W based on tumor type administered intravenously (IV).

Arm type	Experimental
Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule

Arm title	Phase 2 Epacadostat 300mg BID + Nivolumab
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Arm description:

Epacadostat 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Arm type	Experimental
Investigational medicinal product name	Epacadostat and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Epacadostat : oral twice daily continuous at the protocol-defined dose Nivolumab : specified dose and dosing schedule

Number of subjects in period 1	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab
Started	3	6	14
Completed	0	0	0
Not completed	3	6	14
completed 100 days of safety FU period	-	-	-
Consent withdrawn by subject	-	1	2
Physician decision	-	-	-
Death	2	4	10
Unknown	-	-	-
Study Terminated by Sponsor	1	-	1

Lost to follow-up	-	1	1
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Number of subjects in period 1	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/Platin um
Started	13	6	3
Completed	0	0	0
Not completed	13	6	3
completed 100 days of safety FU period	1	-	-
Consent withdrawn by subject	1	1	-
Physician decision	1	1	-
Death	6	4	3
Unknown	-	-	-
Study Terminated by Sponsor	4	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Platinum	Phase 2 Epacadostat 100mg BID + Nivolumab	Phase 2 Epacadostat 300mg BID + Nivolumab
Started	3	83	176
Completed	0	0	0
Not completed	3	83	176
completed 100 days of safety FU period	1	3	11
Consent withdrawn by subject	-	11	25
Physician decision	-	-	1
Death	2	51	97
Unknown	-	5	12
Study Terminated by Sponsor	-	11	25
Lost to follow-up	-	2	5

Baseline characteristics

Reporting groups

Reporting group title	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab
Reporting group description: Epacadostat 25mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W	
Reporting group title	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab
Reporting group description: Epacadostat 50mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.	
Reporting group title	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.	
Reporting group title	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab
Reporting group description: Epacadostat 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.	
Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5-FU/Platinum
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360mg Q3W and 5-FU/Platinum(Carboplatin or Cisplatin+5-Fluorouracil) administered intravenously (IV).	
Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/Platinum
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360 mg Q3W and Pemetrexed/Platinum (Carboplatin orCisplatin+Pemetrexed) administered intravenously (IV).	
Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Platinum
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360 mg Q3W and Paclitaxel/Platinum(Carboplatin+Cisplatin+Paclitaxel)administered intravenously (IV).	
Reporting group title	Phase 2 Epacadostat 100mg BID + Nivolumab
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W or 480 mg Q4W based on tumor type administered intravenously (IV).	
Reporting group title	Phase 2 Epacadostat 300mg BID + Nivolumab
Reporting group description: Epacadostat 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).	

Reporting group values	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab
Number of subjects	3	6	14
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0

Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	3	9
From 65-84 years	1	3	5
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	50.0	62.5	57.5
standard deviation	± 26.00	± 12.41	± 13.27
Sex: Female, Male Units:			
Female	2	1	11
Male	1	5	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	5	14
Unknown or Not Reported	0	1	0
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	3	6	13
More than one race	0	0	0
Unknown or Not Reported	0	0	1
ECOG Performance Status			
The Eastern Cooperative Oncology Group (ECOG) scale describes a patient's level of functioning in terms of their ability to care for themselves, activity, and ability. The scale is from 0 to 5; 0 - Fully active; 1 - Restricted in physically strenuous activity but ambulatory; 2- Ambulatory and capable of all selfcare but unable to carry out any work activities; 3- Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours; 4 - Completely disabled; 5 - Dead.			
Units: Subjects			
zero	3	5	6
one	0	1	8
two	0	0	0
missing	0	0	0

Reporting group values	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/Platin um
Number of subjects	13	6	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0

Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	9	3	1
From 65-84 years	4	3	2
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	61.6	64.3	67.7
standard deviation	± 10.67	± 6.38	± 6.43
Sex: Female, Male			
Units:			
Female	5	1	1
Male	8	5	2
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	13	6	3
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	13	5	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
ECOG Performance Status			
The Eastern Cooperative Oncology Group (ECOG) scale describes a patient's level of functioning in terms of their ability to care for themselves, activity, and ability. The scale is from 0 to 5; 0 - Fully active; 1 - Restricted in physically strenuous activity but ambulatory; 2- Ambulatory and capable of all selfcare but unable to carry out any work activities; 3- Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours; 4 - Completely disabled; 5 - Dead.			
Units: Subjects			
zero	8	2	1
one	5	4	2
two	0	0	0
missing	0	0	0

Reporting group values	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Platinum	Phase 2 Epacadostat 100mg BID + Nivolumab	Phase 2 Epacadostat 300mg BID + Nivolumab
Number of subjects	3	83	176
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	65	92

From 65-84 years	2	18	78
85 years and over	0	0	6

Age Continuous Units: years arithmetic mean standard deviation	70.3 ± 11.37	56.5 ± 13.45	62.6 ± 12.12
Sex: Female, Male Units:			
Female	1	46	77
Male	2	37	99
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	6	11
Not Hispanic or Latino	3	77	159
Unknown or Not Reported	0	0	6
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	3
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	0	2	4
White	3	76	160
More than one race	0	0	0
Unknown or Not Reported	0	5	8
ECOG Performance Status			
The Eastern Cooperative Oncology Group (ECOG) scale describes a patient's level of functioning in terms of their ability to care for themselves, activity, and ability. The scale is from 0 to 5; 0 - Fully active; 1 - Restricted in physically strenuous activity but ambulatory; 2- Ambulatory and capable of all selfcare but unable to carry out any work activities; 3- Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours; 4 - Completely disabled; 5 - Dead.			
Units: Subjects			
zero	1	40	73
one	2	43	101
two	0	0	1
missing	0	0	1

Reporting group values	Total		
Number of subjects	307		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	185		
From 65-84 years	116		
85 years and over	6		

Age Continuous Units: years arithmetic mean standard deviation	-		
Sex: Female, Male Units:			
Female	145		
Male	162		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	17		
Not Hispanic or Latino	283		
Unknown or Not Reported	7		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	3		
Native Hawaiian or Other Pacific Islander	1		
Black or African American	7		
White	282		
More than one race	0		
Unknown or Not Reported	14		
ECOG Performance Status			
The Eastern Cooperative Oncology Group (ECOG) scale describes a patient's level of functioning in terms of their ability to care for themselves, activity, and ability. The scale is from 0 to 5; 0 - Fully active; 1 - Restricted in physically strenuous activity but ambulatory; 2- Ambulatory and capable of all selfcare but unable to carry out any work activities; 3- Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours; 4 - Completely disabled; 5 - Dead.			
Units: Subjects			
zero	139		
one	166		
two	1		
missing	1		

Subject analysis sets

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Colorectal Cancer
Subject analysis set type	Full analysis
Subject analysis set description:	
Epacadostat 100mg or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).	
Subject analysis set title	Phase 2 Epacadostat + Nivolumab in DLBCL
Subject analysis set type	Full analysis
Subject analysis set description:	
Epacadostat 100mg or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).	
Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Melanoma(I/O Naive)
Subject analysis set type	Full analysis
Subject analysis set description:	
Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).	
Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Relapsed)
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100mg or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 480mg Q4W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Refractory)
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100mg or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 480mg Q4W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in NSCLC
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Ovarian Cancer
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in SCCHN
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Glioblastoma
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Reporting group values	Phase 2 Epacadostat + Nivolumab in Colorectal Cancer	Phase 2 Epacadostat + Nivolumab in DLBCL	Phase 2 Epacadostat + Nivolumab in Melanoma(I/O Naive)
Number of subjects	26	18	50
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	23	11	28
From 65-84 years	3	6	21
85 years and over	0	1	1
Age Continuous Units: years			
arithmetic mean	1	0	31
standard deviation	±	±	±
Sex: Female, Male Units:			
Female			
Male			

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
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			
ECOG Performance Status			
The Eastern Cooperative Oncology Group (ECOG) scale describes a patient's level of functioning in terms of their ability to care for themselves, activity, and ability. The scale is from 0 to 5; 0 - Fully active; 1 - Restricted in physically strenuous activity but ambulatory; 2- Ambulatory and capable of all selfcare but unable to carry out any work activities; 3- Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours; 4 - Completely disabled; 5 - Dead.			
Units: Subjects			
zero			
one			
two			
missing			

Reporting group values	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Relapsed)	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Refractory)	Phase 2 Epacadostat + Nivolumab in NSCLC
Number of subjects	7	7	58
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	4	26
From 65-84 years	2	3	29
85 years and over	0	0	3
Age Continuous			
Units: years			
arithmetic mean	1	2	12
standard deviation	±	±	±
Sex: Female, Male			
Units:			
Female			
Male			

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
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			
ECOG Performance Status			
The Eastern Cooperative Oncology Group (ECOG) scale describes a patient's level of functioning in terms of their ability to care for themselves, activity, and ability. The scale is from 0 to 5; 0 - Fully active; 1 - Restricted in physically strenuous activity but ambulatory; 2- Ambulatory and capable of all selfcare but unable to carry out any work activities; 3- Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours; 4 - Completely disabled; 5 - Dead.			
Units: Subjects			
zero			
one			
two			
missing			

Reporting group values	Phase 2 Epacadostat + Nivolumab in Ovarian Cancer	Phase 2 Epacadostat + Nivolumab in SCCHN	Phase 2 Epacadostat + Nivolumab in Glioblastoma
Number of subjects	29	31	33
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	18	17	25
From 65-84 years	11	13	8
85 years and over	0	1	0
Age Continuous			
Units: years			
arithmetic mean	4	8	0
standard deviation	±	±	±
Sex: Female, Male			
Units:			
Female			
Male			

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
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			
ECOG Performance Status			
<p>The Eastern Cooperative Oncology Group (ECOG) scale describes a patient's level of functioning in terms of their ability to care for themselves, activity, and ability. The scale is from 0 to 5; 0 - Fully active; 1 - Restricted in physically strenuous activity but ambulatory; 2- Ambulatory and capable of all selfcare but unable to carry out any work activities; 3- Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours; 4 - Completely disabled; 5 - Dead.</p>			
Units: Subjects			
zero			
one			
two			
missing			

End points

End points reporting groups

Reporting group title	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab
Reporting group description: Epacadostat 25mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W	
Reporting group title	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab
Reporting group description: Epacadostat 50mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.	
Reporting group title	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.	
Reporting group title	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab
Reporting group description: Epacadostat 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W.	
Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5-FU/Platinum
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360mg Q3W and 5-FU/Platinum(Carboplatin or Cisplatin+5-Fluorouracil) administered intravenously (IV).	
Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/Platinum
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360 mg Q3W and Pemetrexed/Platinum (Carboplatin orCisplatin+Pemetrexed) administered intravenously (IV).	
Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Platinum
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360 mg Q3W and Paclitaxel/Platinum(Carboplatin+Cisplatin+Paclitaxel)administered intravenously (IV).	
Reporting group title	Phase 2 Epacadostat 100mg BID + Nivolumab
Reporting group description: Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W or 480 mg Q4W based on tumor type administered intravenously (IV).	
Reporting group title	Phase 2 Epacadostat 300mg BID + Nivolumab
Reporting group description: Epacadostat 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).	
Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Colorectal Cancer
Subject analysis set type	Full analysis
Subject analysis set description: Epacadostat 100mg or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).	
Subject analysis set title	Phase 2 Epacadostat + Nivolumab in DLBCL
Subject analysis set type	Full analysis
Subject analysis set description: Epacadostat 100mg or300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).	
Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Melanoma(I/O Naive)
Subject analysis set type	Full analysis
Subject analysis set description: Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab	

240mg Q2W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Relapsed)
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100mg or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 480mg Q4W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Refractory)
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100mg or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 480mg Q4W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in NSCLC
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Ovarian Cancer
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in SCCHN
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Subject analysis set title	Phase 2 Epacadostat + Nivolumab in Glioblastoma
Subject analysis set type	Full analysis

Subject analysis set description:

Epacadostat 100 or 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Primary: Phase 1, Part 1: Safety and tolerability of epacadostat and nivolumab assessed by number of subjects with dose limiting toxicities (DLTs)

End point title	Phase 1, Part 1: Safety and tolerability of epacadostat and nivolumab assessed by number of subjects with dose limiting toxicities (DLTs) ^{[1][2]}
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End point description:

A DLT was defined as the occurrence of any of the toxicities occurring up to and including Day 42 in Phase 1 Parts 1 and 2.

End point type	Primary
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End point timeframe:

42 days

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: No statistical analyses for this end point

[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: No statistical analyses for this end point

End point values	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	14	13
Units: participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1, Part 2: Safety and tolerability of epacadostat administered in combination with nivolumab and chemotherapy regimen assessed by number of subjects with DLTs

End point title	Phase 1, Part 2: Safety and tolerability of epacadostat administered in combination with nivolumab and chemotherapy regimen assessed by number of subjects with DLTs ^[3] ^[4]
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End point description:

A DLT was defined as the occurrence of any of the toxicities occurring up to and including Day 42 in Phase 1 Parts 1 and 2.

End point type	Primary
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End point timeframe:

42 days

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: No statistical analyses for this end point

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

Justification: No statistical analyses for this end point

End point values	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/P latinum	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Plat inum	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	3	
Units: participants				
number (not applicable)	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1, Part 1 and 2: Safety assessed by number of Treatment Emergent Adverse Events (TEAEs)

End point title	Phase 1, Part 1 and 2: Safety assessed by number of Treatment Emergent Adverse Events (TEAEs) ^[5] ^[6]
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End point description:

A treatment-emergent adverse event (TEAE) is any AE either reported for the first time or worsening of a pre-existing event after first dose of study drug and up to 100 days after last dose of study drug.

End point type	Primary
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End point timeframe:

up to 27 months

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point

[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: No statistical analyses for this end point

End point values	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	14	13
Units: participants	3	6	14	13

End point values	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/P latinum	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Plat inum	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	3	
Units: participants	6	3	3	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 for subjects with solid tumors and per Cheson criteria for subjects with DLBCL

End point title	Phase 2: Objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 for subjects with solid tumors and per Cheson criteria for subjects with DLBCL ^[7]
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End point description:

ORR was defined as the percentage of participants having a complete response (CR) or partial response (PR) as determined by investigator assessment of radiographic disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, Cheson criteria for DLBCL and RANO criteria for Glioblastoma.

End point type	Primary
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End point timeframe:

Response is assessed every 8 weeks up to 24 months

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point

End point values	Phase 2 Epacadostat + Nivolumab in Colorectal Cancer	Phase 2 Epacadostat + Nivolumab in DLBCL	Phase 2 Epacadostat + Nivolumab in Melanoma(I/O Naive)	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Relapsed)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	26	18	50	7
Units: participants				
number (not applicable)	1	0	31	1

End point values	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Refractory)	Phase 2 Epacadostat + Nivolumab in NSCLC	Phase 2 Epacadostat + Nivolumab in Ovarian Cancer	Phase 2 Epacadostat + Nivolumab in SCCHN
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	58	29	31
Units: participants				
number (not applicable)	2	12	4	8

End point values	Phase 2 Epacadostat + Nivolumab in Glioblastoma			
Subject group type	Subject analysis set			
Number of subjects analysed	33			
Units: participants				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Progression free survival (PFS)

End point title	Phase 2: Progression free survival (PFS) ^[8]
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End point description:

PFS is defined as the time from randomization to the first documented progressive disease per RECIST v1.1 or death due to any cause, whichever occurs first.

End point type	Primary
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End point timeframe:

Response is assessed every 8 weeks up to 24 months

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point

End point values	Phase 2 Epacadostat + Nivolumab in Colorectal Cancer	Phase 2 Epacadostat + Nivolumab in DLBCL	Phase 2 Epacadostat + Nivolumab in Melanoma(I/O Naive)	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Relapsed)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	26	18	50	7
Units: months				
median (confidence interval 95%)	1.78 (1.74 to 1.81)	1.64 (1.35 to 3.52)	9.99999 (9.51 to 99999)	1.76 (0.46 to 999999)

End point values	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Refractory)	Phase 2 Epacadostat + Nivolumab in NSCLC	Phase 2 Epacadostat + Nivolumab in Ovarian Cancer	Phase 2 Epacadostat + Nivolumab in SCCHN
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	58	29	31
Units: months				
median (confidence interval 95%)	2.55 (0.59 to 999999)	1.88 (1.78 to 2.04)	1.88 (1.68 to 3.52)	3.62 (1.78 to 9.08)

End point values	Phase 2 Epacadostat + Nivolumab in Glioblastoma			
Subject group type	Subject analysis set			
Number of subjects analysed	33			
Units: months				
median (confidence interval 95%)	1.84 (1.78 to 2.63)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Overall survival (OS) for subjects with Glioblastoma

End point title	Phase 2: Overall survival (OS) for subjects with Glioblastoma ^[9]
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End point description:

Overall survival (OS) at 9 months defined as the proportion of patients alive 9 months after the start of treatment

End point type	Primary
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End point timeframe:

Subjects will be followed-up for survival every 12 weeks for up to 9 months.

Notes:

[9] - 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: No data is being reported for other tumor types in Phase 2 of the study as the end point applies to only Glioblastoma population in Phase 2 of the study

End point values	Phase 2 Epacadostat + Nivolumab in Glioblastoma			
Subject group type	Subject analysis set			
Number of subjects analysed	33			
Units: Survival Rate				
number (confidence interval 90%)	0.458 (0.297 to 0.605)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1, Part 1: ORR per RECIST v1.1 and mRECIST for subjects with solid tumors; per Cheson and mCheson criteria for subjects with B-cell NHL; and per RANO and mRANO criteria for subjects with GBM

End point title	Phase 1, Part 1: ORR per RECIST v1.1 and mRECIST for subjects with solid tumors; per Cheson and mCheson criteria for subjects with B-cell NHL; and per RANO and mRANO criteria for subjects with GBM ^[10]
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End point description:

End point type	Secondary
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End point timeframe:

Response will be assessed every 8 weeks during study participation which is estimated to be up to 24 months.

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: No statistical analyses for this end point

End point values	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[11]	0 ^[12]	0 ^[13]	0 ^[14]
Units: participants				
number (not applicable)				

Notes:

[11] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[12] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[13] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[14] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1, Part 2: ORR per RECIST v1.1 and modified RECIST for subjects with advanced or metastatic SCCHN and advanced or metastatic NSCLC

End point title	Phase 1, Part 2: ORR per RECIST v1.1 and modified RECIST for subjects with advanced or metastatic SCCHN and advanced or metastatic NSCLC ^[15]
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End point description:

End point type	Secondary
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End point timeframe:

Response will be assessed every 8 weeks during study participation which is estimated to be up to 24 months.

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: No data is being reported for Phase part 1 of the study as the end point applies to only Phase 1 Part 2 of the study

End point values	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/P latinum	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Plat inum	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[16]	0 ^[17]	0 ^[18]	
Units: participants				
number (not applicable)				

Notes:

[16] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[17] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[18] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1, Part 2: Duration of response (DOR) for subjects with advanced or metastatic SCCHN and advanced or metastatic NSCLC

End point title	Phase 1, Part 2: Duration of response (DOR) for subjects with advanced or metastatic SCCHN and advanced or metastatic NSCLC ^[19]
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End point description:

End point type	Secondary
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End point timeframe:

Response will be assessed every 8 weeks during study participation which is estimated to be up to 24 months.

Notes:

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

Justification: No data is being reported for Phase part 1 of the study as the end point applies to only Phase 1 Part 2 of the study

End point values	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/P latinum	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Plat inum	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[20]	0 ^[21]	0 ^[22]	
Units: participants				
number (not applicable)				

Notes:

[20] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[21] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[22] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1, Part 2: PFS for subjects with advanced or metastatic SCCHN and advanced or metastatic NSCLC

End point title	Phase 1, Part 2: PFS for subjects with advanced or metastatic SCCHN and advanced or metastatic NSCLC ^[23]
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End point description:

End point type	Secondary
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End point timeframe:

Response will be assessed every 8 weeks during study participation which is estimated to be up to 24 months.

Notes:

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

Justification: No data is being reported for Phase part 1 of the study as the end point applies to only Phase 1 Part 2 of the study

End point values	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/P latinum	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Plat inum	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[24]	0 ^[25]	0 ^[26]	
Units: participants				
number (not applicable)				

Notes:

[24] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[25] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

[26] - Phase 1 had small sample size & heterogeneous population, hence efficacy was not summarized.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Duration of response (DOR)

End point title	Phase 2: Duration of response (DOR)
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End point description:

End point type	Secondary
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End point timeframe:

Response will be assessed every 8 weeks during study participation which is estimated to be up to 24 months.

End point values	Phase 2 Epacadostat + Nivolumab in Colorectal Cancer	Phase 2 Epacadostat + Nivolumab in DLBCL	Phase 2 Epacadostat + Nivolumab in Melanoma(I/O Naive)	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Relapsed)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	[27]	31	1
Units: months				
median (confidence interval 95%)	0.8888888 (- 9999999 to 9999999)	0.8888888 (- 9999999 to 9999999)	8.888888 (7.37 to 9999999)	0.888888 (- 9999999 to 9999999)

Notes:

[27] - No responders

End point values	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Refractory)	Phase 2 Epacadostat + Nivolumab in NSCLC	Phase 2 Epacadostat + Nivolumab in Ovarian Cancer	Phase 2 Epacadostat + Nivolumab in SCCHN
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	12	4	8
Units: months				
median (confidence interval 95%)	0.8888888 (- 9999999 to 9999999)	8.888888 (1.94 to 9999999)	3.93 (3.13 to 5.53)	8.8888888 (7.37 to 9999999)

End point values	Phase 2 Epacadostat + Nivolumab in Glioblastoma			
Subject group type	Subject analysis set			
Number of subjects analysed	[28]			
Units: months				
median (confidence interval 95%)	0.8888888 (- 9999999 to 9999999)			

Notes:

[28] - No responders

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Duration of disease control, defined as CR, PR, and stable disease (SD)

End point title	Phase 2: Duration of disease control, defined as CR, PR, and stable disease (SD)
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End point description:

End point type	Secondary
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End point timeframe:

Response will be assessed every 8 weeks during study participation which is estimated to be up to 24 months.

End point values	Phase 2 Epacadostat + Nivolumab in Colorectal Cancer	Phase 2 Epacadostat + Nivolumab in DLBCL	Phase 2 Epacadostat + Nivolumab in Melanoma(I/O Naive)	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Relapsed)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed				
Units: months				
median (confidence interval 95%)	3.72 (2.86 to 9999999)	4.57 (3.52 to 10.26)	9999999 (9999999 to 9999999)	9999999 (9999999 to 9999999)

End point values	Phase 2 Epacadostat + Nivolumab in Melanoma (I/O Refractory)	Phase 2 Epacadostat + Nivolumab in NSCLC	Phase 2 Epacadostat + Nivolumab in Ovarian Cancer	Phase 2 Epacadostat + Nivolumab in SCCHN
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed				
Units: months				
median (confidence interval 95%)	9999999 (3.19 to 9999999)	9999999 (9.11 to 9999999)	5.86 (3.52 to 7.47)	10.89 (4.84 to 9999999)

End point values	Phase 2 Epacadostat + Nivolumab in Glioblastoma			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: months				
median (confidence interval 95%)	3.72 (3.49 to 5.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Safety and tolerability measured by the frequency of adverse events (AEs), serious adverse events (SAEs), and deaths

End point title	Phase 2: Safety and tolerability measured by the frequency of adverse events (AEs), serious adverse events (SAEs), and deaths ^[29]
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End point description:

End point type	Secondary
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End point timeframe:

AEs are assessed for the duration of the study participation which is estimated to be up to 27 months (24 months +100 day safety FU).

Notes:

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

Justification: No statistical analyses for this end point

End point values	Phase 2 Epacadostat 100mg BID + Nivolumab	Phase 2 Epacadostat 300mg BID + Nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	176		
Units: participants				
number (not applicable)				
Subjects with Treatment Emergent Adverse Events	82	176		
Subjects with Serious Treatment Emergent AEs	40	89		
Subjects with fatal Treatment Emergent AEs	4	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 27 months

Adverse event reporting additional description:

AE additional description

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22
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Reporting groups

Reporting group title	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab
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Reporting group description:

Epacadostat 25mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W

Reporting group title	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab
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Reporting group description:

Epacadostat 50mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W

Reporting group title	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab
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Reporting group description:

Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W

Reporting group title	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab
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Reporting group description:

Epacadostat 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab administered intravenously (IV) at 3mg/kg Q2W

Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5-FU/Platinum
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Reporting group description:

Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360mg Q3W and 5-FU/Platinum(Carboplatin or Cisplatin+5-Fluorouracil) administered intravenously (IV).

Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Platinum
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Reporting group description:

Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360 mg Q3W and Paclitaxel/Platinum(Carboplatin+Cisplatin+Paclitaxel)administered intravenously (IV).

Reporting group title	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/Platinum
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Reporting group description:

Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 360 mg Q3W and Pemetrexed/Platinum (Carboplatin orCisplatin+Pemetrexed) administered intravenously (IV).

Reporting group title	Phase 2 Epacadostat 100mg BID + Nivolumab
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Reporting group description:

Epacadostat 100mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W or 480 mg Q4W based on tumor type administered intravenously (IV).

Reporting group title	Phase 2 Epacadostat 300mg BID + Nivolumab
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Reporting group description:

Epacadostat 300mg oral twice daily (BID) continuous daily dosing in combination with Nivolumab 240mg Q2W administered intravenously (IV).

Reporting group title	Total
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Reporting group description:

Total

Serious adverse events	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	4 / 14 (28.57%)
number of deaths (all causes)	2	4	11
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm malignant			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Arterial haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exsanguination			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Obstructive airways disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
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 distress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda equina syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemianopia homonymous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
VIIth nerve paralysis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Adrenocortical insufficiency acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Lactic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Platinum
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 13 (30.77%)	4 / 6 (66.67%)	2 / 3 (66.67%)
number of deaths (all causes)	7	4	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm malignant			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arterial haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exsanguination			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation necrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Aphasia	subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain compression	subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema	subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda equina syndrome	subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident	subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion	subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness	subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy	subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemianopia homonymous			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIIth nerve paralysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasogenic cerebral oedema			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal perforation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rash maculo-papular			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenocortical insufficiency acute			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	2 / 3 (66.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 3 (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
Septic shock			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/Platin um	Phase 2 Epacadostat 100mg BID + Nivolumab	Phase 2 Epacadostat 300mg BID + Nivolumab
Serious adverse events			
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	40 / 83 (48.19%)	89 / 176 (50.57%)
number of deaths (all causes)	3	52	97
number of deaths resulting from adverse events	1	4	5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm malignant			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
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			
Arterial haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exsanguination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			

subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	4 / 176 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	6 / 176 (3.41%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	5 / 176 (2.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 3 (33.33%)	1 / 83 (1.20%)	5 / 176 (2.84%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	4 / 176 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
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 / 3 (0.00%)	0 / 83 (0.00%)	4 / 176 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			

subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Head injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
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	1 / 3 (33.33%)	0 / 83 (0.00%)	0 / 176 (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
Atrioventricular block complete			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
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 arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
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 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain compression			

subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda equina syndrome			
subjects affected / exposed	1 / 3 (33.33%)	0 / 83 (0.00%)	0 / 176 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	6 / 176 (3.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Facial paresis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	4 / 176 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemianopia homonymous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIIth nerve paralysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
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 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	4 / 176 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Enterovesical fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			

subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	5 / 176 (2.84%)
occurrences causally related to treatment / all	0 / 0	0 / 2	3 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Rectal perforation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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 / 3 (0.00%)	2 / 83 (2.41%)	6 / 176 (3.41%)
occurrences causally related to treatment / all	0 / 0	0 / 2	3 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenocortical insufficiency acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Central nervous system infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	8 / 176 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
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 bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
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 / 3 (0.00%)	1 / 83 (1.20%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Viral infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	4 / 176 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (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

Serious adverse events	Total		
Total subjects affected by serious adverse events			
subjects affected / exposed	148 / 307 (48.21%)		
number of deaths (all causes)	182		
number of deaths resulting from adverse events	11		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm malignant			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant ascites			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to peritoneum			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Arterial haemorrhage			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Deep vein thrombosis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Embolism			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Exsanguination			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Flushing			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Superior vena cava syndrome			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombosis			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences causally related to treatment / all	1 / 6		
deaths causally related to treatment / all	0 / 0		
Gait disturbance			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Oedema			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences causally related to treatment / all	4 / 5		
deaths causally related to treatment / all	0 / 0		
Systemic inflammatory response syndrome			

subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cough			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	11 / 307 (3.58%)		
occurrences causally related to treatment / all	1 / 12		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Hypoxia				
subjects affected / exposed	6 / 307 (1.95%)			
occurrences causally related to treatment / all	1 / 6			
deaths causally related to treatment / all	0 / 0			
Obstructive airways disorder				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	7 / 307 (2.28%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 1			
Pneumonia aspiration				
subjects affected / exposed	6 / 307 (1.95%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	2 / 307 (0.65%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	5 / 307 (1.63%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				

subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Wheezing			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Delirium			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lipase increased			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Platelet count decreased			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
White blood cell count decreased			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Muscle rupture			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radiation necrosis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block complete			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bradycardia			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Myocardial infarction			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinus tachycardia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Aphasia			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Brain compression			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain oedema			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cauda equina syndrome			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			

subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Convulsion				
subjects affected / exposed	7 / 307 (2.28%)			
occurrences causally related to treatment / all	1 / 7			
deaths causally related to treatment / all	0 / 0			
Depressed level of consciousness				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	2 / 307 (0.65%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	7 / 307 (2.28%)			
occurrences causally related to treatment / all	1 / 8			
deaths causally related to treatment / all	0 / 1			
Facial paresis				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Headache				
subjects affected / exposed	5 / 307 (1.63%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Hemianopia homonymous				

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolic encephalopathy			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myoclonus			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral motor neuropathy			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal cord compression			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Status epilepticus			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Tremor			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
VIIth nerve paralysis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vasogenic cerebral oedema			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Haemolytic anaemia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune thrombocytopenic purpura			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences causally related to treatment / all	1 / 5		
deaths causally related to treatment / all	0 / 0		
Duodenal perforation			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysphagia			

subjects affected / exposed	2 / 307 (0.65%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterovesical fistula				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer perforation				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	3 / 307 (0.98%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				
subjects affected / exposed	2 / 307 (0.65%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	7 / 307 (2.28%)			
occurrences causally related to treatment / all	3 / 9			
deaths causally related to treatment / all	0 / 0			
Obstruction gastric				

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal perforation			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	7 / 307 (2.28%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Stomatitis			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences causally related to treatment / all	3 / 10		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Erythema multiforme			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences causally related to treatment / all	5 / 6		
deaths causally related to treatment / all	0 / 0		
Swelling face			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure acute			
subjects affected / exposed	6 / 307 (1.95%)		
occurrences causally related to treatment / all	1 / 6		
deaths causally related to treatment / all	0 / 1		

Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Adrenocortical insufficiency acute			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Myalgia			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Neck pain			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal infection			

subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Central nervous system infection				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	2 / 307 (0.65%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Influenza				

subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	4 / 307 (1.30%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Ophthalmic herpes zoster				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pelvic abscess				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pelvic infection				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	15 / 307 (4.89%)			
occurrences causally related to treatment / all	1 / 17			
deaths causally related to treatment / all	0 / 0			
Pneumonia klebsiella				
subjects affected / exposed	1 / 307 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	5 / 307 (1.63%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Septic shock				

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Sinusitis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	5 / 307 (1.63%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypomagnesaemia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	9 / 307 (2.93%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Lactic acidosis			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Type 2 diabetes mellitus			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Phase 1 Part 1 Epacadostat 25mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 50mg BID +Nivolumab	Phase 1 Part 1 Epacadostat 100mg BID +Nivolumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	14 / 14 (100.00%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Facial pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	3 / 6 (50.00%)	4 / 14 (28.57%)
occurrences (all)	3	3	4
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	3 / 14 (21.43%)
occurrences (all)	2	0	3
Suprapubic pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Scrotal oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Vaginal odour			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	1	1	2
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hiccups			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Increased upper airway secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Oropharyngeal swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiration abnormal			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Throat tightness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Tracheal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	3

Mental status changes subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Panic attack subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1
Amylase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 14 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 14 (7.14%) 2
Blood albumin decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 14 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 6 (16.67%) 1	2 / 14 (14.29%) 2
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 14 (0.00%) 0
Carcinoembryonic antigen increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin B1 decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	2 / 14 (14.29%)
occurrences (all)	0	2	2
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stoma site haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Stoma site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	3	0	1
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Head discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	2 / 14 (14.29%)
occurrences (all)	4	2	2
Hemiparesis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Post herpetic neuralgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Sinus headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1
Tremor subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	2 / 6 (33.33%) 2	3 / 14 (21.43%) 3
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1
Leukopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Ear and labyrinth disorders			
Ear discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Vestibular disorder			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	4 / 14 (28.57%)
occurrences (all)	0	0	4
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	5 / 14 (35.71%)
occurrences (all)	1	1	5
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Abdominal pain upper			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Anorectal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	2 / 14 (14.29%)
occurrences (all)	3	2	3
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	3 / 14 (21.43%)
occurrences (all)	7	1	5
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Faecal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gingival bleeding			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	6 / 14 (42.86%)
occurrences (all)	3	1	6
Oral mucosal eruption			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pancreatic insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Rectal discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Salivary duct inflammation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	4 / 14 (28.57%)
occurrences (all)	0	0	4
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Night sweats			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	4	1	1
Pruritus generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	5 / 14 (35.71%)
occurrences (all)	0	1	7
Rash generalised			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 6 (16.67%) 1	1 / 14 (7.14%) 1
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypogonadism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	4	0	3
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	3
Costochondritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	4	0	1
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Tendonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Ear infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral herpes			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Subcutaneous abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 3 (100.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	4	0	1
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Decreased appetite subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	2 / 6 (33.33%) 2	7 / 14 (50.00%) 7
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	1 / 14 (7.14%) 1
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 14 (0.00%) 0
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 14 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	2 / 14 (14.29%) 2
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 6 (33.33%) 2	1 / 14 (7.14%) 1
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0

Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0
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Non-serious adverse events	Phase 1 Part 1 Epacadostat 300mg BID +Nivolumab	Phase 1 Part 2 Epacadostat 100mg BID +Nivolumab +5- FU/Platinum	Phase 1 Part 2 Epacadostat 100mg BID +Paclitaxel/Platinum
Total subjects affected by non-serious adverse events subjects affected / exposed	13 / 13 (100.00%)	6 / 6 (100.00%)	3 / 3 (100.00%)
Vascular disorders			
Hot flush subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0
Lymphoedema subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
General disorders and administration site conditions			
Chest pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	1 / 3 (33.33%) 1
Face oedema subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0
Facial pain subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Fatigue			

subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 3	4 / 6 (66.67%) 6	2 / 3 (66.67%) 2
Gait disturbance subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Localised oedema subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0
Oedema subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	1 / 3 (33.33%) 1
Peripheral swelling subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 4	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Suprapubic pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Immune system disorders Contrast media allergy subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Reproductive system and breast disorders Scrotal oedema subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Vaginal odour			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	4 / 13 (30.77%)	2 / 6 (33.33%)	2 / 3 (66.67%)
occurrences (all)	4	2	3
Dysphonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	4 / 13 (30.77%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	5	4	0
Dyspnoea exertional			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoxia			

subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal swelling			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Paranasal sinus hypersecretion			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiration abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tracheal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	0 / 13 (0.00%)	3 / 6 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Insomnia			
subjects affected / exposed	3 / 13 (23.08%)	3 / 6 (50.00%)	0 / 3 (0.00%)
occurrences (all)	3	3	0
Mental status changes			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Panic attack subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 3	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0
Amylase increased subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 4	1 / 6 (16.67%) 2	0 / 3 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	3 / 13 (23.08%) 5	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0
Blood albumin decreased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Carcinoembryonic antigen increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Gamma-glutamyltransferase increased			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	4 / 13 (30.77%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	12	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 6 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Transaminases increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Troponin I increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vitamin B1 decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 13 (7.69%)	2 / 6 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Weight increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 13 (7.69%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Infusion related reaction			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Stoma site haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sunburn			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Convulsion			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 13 (0.00%)	3 / 6 (50.00%)	2 / 3 (66.67%)
occurrences (all)	0	4	2
Head discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 13 (15.38%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Hemiparesis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 6 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Myasthenia gravis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	2 / 3 (66.67%)
occurrences (all)	2	0	2
Post herpetic neuralgia			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sinus headache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 13 (15.38%)	4 / 6 (66.67%)	2 / 3 (66.67%)
occurrences (all)	2	4	2
Increased tendency to bruise			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Leukopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 13 (0.00%)	2 / 6 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Vestibular disorder			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	1 / 3 (33.33%) 1
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Eye pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Photophobia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 13 (0.00%)	2 / 6 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	2
Visual impairment			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	3 / 13 (23.08%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	3 / 13 (23.08%)	2 / 6 (33.33%)	2 / 3 (66.67%)
occurrences (all)	3	2	2
Diarrhoea			
subjects affected / exposed	2 / 13 (15.38%)	4 / 6 (66.67%)	0 / 3 (0.00%)
occurrences (all)	4	6	0
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	4 / 13 (30.77%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	4	1	0
Dysphagia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Faecal incontinence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	3 / 13 (23.08%)	3 / 6 (50.00%)	2 / 3 (66.67%)
occurrences (all)	3	6	2
Oral mucosal eruption			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	1 / 13 (7.69%)	2 / 6 (33.33%)	2 / 3 (66.67%)
occurrences (all)	1	2	2
Pancreatic insufficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pancreatitis acute			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal discharge			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salivary duct inflammation			

subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Salivary hypersecretion			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 13 (7.69%)	5 / 6 (83.33%)	0 / 3 (0.00%)
occurrences (all)	1	9	0
Vomiting			
subjects affected / exposed	4 / 13 (30.77%)	2 / 6 (33.33%)	1 / 3 (33.33%)
occurrences (all)	6	5	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Dermatitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Night sweats			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	4 / 13 (30.77%)	4 / 6 (66.67%)	0 / 3 (0.00%)
occurrences (all)	4	5	0
Pruritus generalised			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	4 / 13 (30.77%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	2
Rash generalised			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	3 / 13 (23.08%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Rash papular			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin hypopigmentation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urticaria			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urinary incontinence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urinary tract obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypogonadism			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	0 / 13 (0.00%)	2 / 6 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Costochondritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Flank pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Muscular weakness			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	2 / 3 (66.67%)
occurrences (all)	0	1	2
Myositis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Neck pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Candida infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Mucosal infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral herpes			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Subcutaneous abscess			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 13 (15.38%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	2	4	0
Viral infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	1 / 13 (7.69%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	2 / 6 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Hypercalcaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 6 (16.67%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Hypomagnesaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Vitamin D deficiency subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0
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Non-serious adverse events	Phase 1 Part 2 Epacadostat 100mg BID +Pemetrexed/Platin um	Phase 2 Epacadostat 100mg BID + Nivolumab	Phase 2 Epacadostat 300mg BID + Nivolumab
Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 3 (100.00%)	81 / 83 (97.59%)	173 / 176 (98.30%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	4 / 176 (2.27%)
occurrences (all)	0	4	4
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	13 / 83 (15.66%)	16 / 176 (9.09%)
occurrences (all)	0	17	32
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	6 / 83 (7.23%)	16 / 176 (9.09%)
occurrences (all)	0	7	18
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	2 / 176 (1.14%)
occurrences (all)	0	2	2
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	10 / 83 (12.05%)	8 / 176 (4.55%)
occurrences (all)	0	11	10
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	3 / 3 (100.00%)	36 / 83 (43.37%)	123 / 176 (69.89%)
occurrences (all)	4	38	131
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	2 / 176 (1.14%)
occurrences (all)	0	4	4
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	15 / 83 (18.07%)	17 / 176 (9.66%)
occurrences (all)	0	18	18
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences (all)	0	0	3
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	12 / 83 (14.46%)	29 / 176 (16.48%)
occurrences (all)	0	16	41
Suprapubic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Scrotal oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Vaginal odour			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 3 (0.00%)	19 / 83 (22.89%)	41 / 176 (23.30%)
occurrences (all)	0	23	50
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	5 / 176 (2.84%)
occurrences (all)	0	1	5
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	21 / 83 (25.30%)	30 / 176 (17.05%)
occurrences (all)	1	22	34
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences (all)	0	0	3
Epistaxis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 83 (0.00%)	5 / 176 (2.84%)
occurrences (all)	1	0	7
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	3 / 176 (1.70%)
occurrences (all)	0	1	3
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Hypoxia			

subjects affected / exposed	1 / 3 (33.33%)	2 / 83 (2.41%)	9 / 176 (5.11%)
occurrences (all)	1	3	10
Increased upper airway secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	5 / 83 (6.02%)	20 / 176 (11.36%)
occurrences (all)	0	5	24
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	13 / 176 (7.39%)
occurrences (all)	0	6	16
Oropharyngeal swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	5 / 83 (6.02%)	3 / 176 (1.70%)
occurrences (all)	0	5	3
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences (all)	0	0	5
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	3 / 176 (1.70%)
occurrences (all)	0	1	3
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	10 / 176 (5.68%)
occurrences (all)	0	2	11
Respiration abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	4 / 176 (2.27%)
occurrences (all)	0	4	5
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	4 / 176 (2.27%)
occurrences (all)	0	0	4
Throat tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Tracheal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	7 / 176 (3.98%)
occurrences (all)	0	3	9
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	2 / 176 (1.14%)
occurrences (all)	0	1	2
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	5 / 83 (6.02%)	12 / 176 (6.82%)
occurrences (all)	1	6	12
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	7 / 176 (3.98%)
occurrences (all)	0	2	10
Depression			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	11 / 176 (6.25%)
occurrences (all)	0	4	11
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	9 / 83 (10.84%)	25 / 176 (14.20%)
occurrences (all)	0	9	25
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences (all)	0	1	0

Panic attack subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 83 (0.00%) 0	0 / 176 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	12 / 83 (14.46%) 17	37 / 176 (21.02%) 51
Amylase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	9 / 83 (10.84%) 15	16 / 176 (9.09%) 21
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	17 / 83 (20.48%) 27	39 / 176 (22.16%) 58
Blood albumin decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	6 / 83 (7.23%) 6	1 / 176 (0.57%) 1
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	15 / 83 (18.07%) 25	23 / 176 (13.07%) 27
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	4 / 83 (4.82%) 7	4 / 176 (2.27%) 4
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 83 (0.00%) 0	2 / 176 (1.14%) 2
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	16 / 83 (19.28%) 26	13 / 176 (7.39%) 21
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 83 (1.20%) 3	2 / 176 (1.14%) 2
Carcinoembryonic antigen increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 83 (0.00%) 0	0 / 176 (0.00%) 0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Hepatic enzyme increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	8 / 83 (9.64%)	20 / 176 (11.36%)
occurrences (all)	0	11	28
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 83 (7.23%)	14 / 176 (7.95%)
occurrences (all)	0	12	18
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	5 / 83 (6.02%)	5 / 176 (2.84%)
occurrences (all)	0	14	5
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Vitamin B1 decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 3 (66.67%)	9 / 83 (10.84%)	26 / 176 (14.77%)
occurrences (all)	2	9	29
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 83 (7.23%)	5 / 176 (2.84%)
occurrences (all)	0	8	5
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	9 / 176 (5.11%)
occurrences (all)	0	4	12
Injury, poisoning and procedural complications			
Animal bite			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 3 (33.33%)	3 / 83 (3.61%)	3 / 176 (1.70%)
occurrences (all)	1	3	3
Fall			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	21 / 176 (11.93%)
occurrences (all)	0	4	24
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	8 / 176 (4.55%)
occurrences (all)	0	6	10
Stoma site haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Sunburn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 83 (6.02%)	10 / 176 (5.68%)
occurrences (all)	0	7	10
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 83 (7.23%)	6 / 176 (3.41%)
occurrences (all)	0	6	8
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	4 / 176 (2.27%)
occurrences (all)	0	0	4
Convulsion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	4
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	12 / 83 (14.46%)	28 / 176 (15.91%)
occurrences (all)	0	13	32
Dysgeusia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 83 (3.61%)	14 / 176 (7.95%)
occurrences (all)	1	3	14
Head discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Headache			
subjects affected / exposed	0 / 3 (0.00%)	15 / 83 (18.07%)	40 / 176 (22.73%)
occurrences (all)	0	17	52
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	9 / 176 (5.11%)
occurrences (all)	0	0	12
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	5 / 176 (2.84%)
occurrences (all)	0	0	5
Myasthenia gravis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences (all)	0	0	3
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	7 / 176 (3.98%)
occurrences (all)	0	1	7
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	11 / 176 (6.25%)
occurrences (all)	0	3	13
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	5 / 176 (2.84%)
occurrences (all)	0	3	5
Post herpetic neuralgia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Sinus headache			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	3 / 176 (1.70%)
occurrences (all)	0	2	3
Tremor			
subjects affected / exposed	1 / 3 (33.33%)	2 / 83 (2.41%)	6 / 176 (3.41%)
occurrences (all)	1	2	6
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	17 / 83 (20.48%)	30 / 176 (17.05%)
occurrences (all)	2	22	42
Increased tendency to bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	2
Leukopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	3 / 176 (1.70%)
occurrences (all)	0	3	3
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	5 / 176 (2.84%)
occurrences (all)	0	1	6
Vestibular disorder			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 83 (0.00%) 0	0 / 176 (0.00%) 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	7 / 176 (3.98%)
occurrences (all)	0	0	7
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 3 (33.33%)	4 / 83 (4.82%)	9 / 176 (5.11%)
occurrences (all)	1	4	10
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	3 / 176 (1.70%)
occurrences (all)	0	5	3
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	6 / 83 (7.23%)	2 / 176 (1.14%)
occurrences (all)	0	6	2
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	14 / 83 (16.87%)	18 / 176 (10.23%)
occurrences (all)	1	19	20
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			

subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	7 / 176 (3.98%)
occurrences (all)	0	3	7
Anorectal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	0 / 176 (0.00%)
occurrences (all)	0	2	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	25 / 83 (30.12%)	51 / 176 (28.98%)
occurrences (all)	1	26	57
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	25 / 83 (30.12%)	58 / 176 (32.95%)
occurrences (all)	3	32	91
Dry mouth			
subjects affected / exposed	1 / 3 (33.33%)	7 / 83 (8.43%)	10 / 176 (5.68%)
occurrences (all)	1	7	11
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	13 / 176 (7.39%)
occurrences (all)	0	4	13
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	8 / 176 (4.55%)
occurrences (all)	0	5	8
Faecal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	4 / 176 (2.27%)
occurrences (all)	0	2	4
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	5 / 83 (6.02%)	9 / 176 (5.11%)
occurrences (all)	0	5	9
Gingival bleeding			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	30 / 83 (36.14%)	75 / 176 (42.61%)
occurrences (all)	0	35	99
Oral mucosal eruption			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Pancreatic insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	0 / 176 (0.00%)
occurrences (all)	0	2	0
Rectal discharge			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Salivary duct inflammation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	5 / 83 (6.02%)	14 / 176 (7.95%)
occurrences (all)	0	5	15
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	17 / 83 (20.48%)	43 / 176 (24.43%)
occurrences (all)	0	21	64
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	2 / 176 (1.14%)
occurrences (all)	0	4	2
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	7 / 176 (3.98%)
occurrences (all)	0	1	9
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	2 / 176 (1.14%)
occurrences (all)	0	1	2
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	8 / 176 (4.55%)
occurrences (all)	0	1	8
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	4 / 176 (2.27%)
occurrences (all)	0	3	4
Night sweats			

subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	9 / 176 (5.11%)
occurrences (all)	0	2	9
Photosensitivity reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	16 / 83 (19.28%)	34 / 176 (19.32%)
occurrences (all)	0	27	44
Pruritus generalised			
subjects affected / exposed	1 / 3 (33.33%)	1 / 83 (1.20%)	4 / 176 (2.27%)
occurrences (all)	1	1	5
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	19 / 83 (22.89%)	39 / 176 (22.16%)
occurrences (all)	0	25	50
Rash generalised			
subjects affected / exposed	1 / 3 (33.33%)	2 / 83 (2.41%)	1 / 176 (0.57%)
occurrences (all)	1	4	1
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	11 / 83 (13.25%)	29 / 176 (16.48%)
occurrences (all)	0	14	32
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	3 / 176 (1.70%)
occurrences (all)	0	7	3
Skin hypopigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Urticaria			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 83 (1.20%) 1	1 / 176 (0.57%) 2
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Haematuria			
subjects affected / exposed	1 / 3 (33.33%)	4 / 83 (4.82%)	0 / 176 (0.00%)
occurrences (all)	1	6	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	3 / 176 (1.70%)
occurrences (all)	0	1	3
Urinary incontinence			
subjects affected / exposed	2 / 3 (66.67%)	2 / 83 (2.41%)	3 / 176 (1.70%)
occurrences (all)	2	2	3
Urinary retention			
subjects affected / exposed	1 / 3 (33.33%)	2 / 83 (2.41%)	1 / 176 (0.57%)
occurrences (all)	1	2	1
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	5 / 176 (2.84%)
occurrences (all)	0	2	5
Hypogonadism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Hypothyroidism			
subjects affected / exposed	1 / 3 (33.33%)	12 / 83 (14.46%)	20 / 176 (11.36%)
occurrences (all)	1	13	21
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	12 / 83 (14.46%)	25 / 176 (14.20%)
occurrences (all)	0	13	33
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	11 / 83 (13.25%)	30 / 176 (17.05%)
occurrences (all)	0	12	35
Costochondritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Groin pain			
subjects affected / exposed	1 / 3 (33.33%)	2 / 83 (2.41%)	2 / 176 (1.14%)
occurrences (all)	1	2	2
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	6 / 176 (3.41%)
occurrences (all)	0	2	6
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	6 / 176 (3.41%)
occurrences (all)	0	2	6
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	6 / 176 (3.41%)
occurrences (all)	0	4	6
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 83 (3.61%)	13 / 176 (7.39%)
occurrences (all)	0	3	13
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	12 / 83 (14.46%)	10 / 176 (5.68%)
occurrences (all)	1	12	13
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0

Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	6 / 83 (7.23%)	8 / 176 (4.55%)
occurrences (all)	0	6	8
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	11 / 176 (6.25%)
occurrences (all)	0	4	13
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	3 / 176 (1.70%)
occurrences (all)	0	0	3
Tendonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	1 / 176 (0.57%)
occurrences (all)	0	2	3
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	2 / 176 (1.14%)
occurrences (all)	0	0	2
Mucosal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 83 (2.41%)	3 / 176 (1.70%)
occurrences (all)	0	2	5
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	1 / 176 (0.57%)
occurrences (all)	0	1	1
Oral herpes			

subjects affected / exposed	0 / 3 (0.00%)	1 / 83 (1.20%)	3 / 176 (1.70%)
occurrences (all)	0	1	3
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	11 / 176 (6.25%)
occurrences (all)	0	0	11
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	1 / 176 (0.57%)
occurrences (all)	0	4	1
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 83 (4.82%)	6 / 176 (3.41%)
occurrences (all)	0	7	7
Subcutaneous abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	7 / 83 (8.43%)	13 / 176 (7.39%)
occurrences (all)	0	8	20
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	6 / 83 (7.23%)	13 / 176 (7.39%)
occurrences (all)	1	14	20
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 83 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			

Decreased appetite subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	22 / 83 (26.51%) 24	62 / 176 (35.23%) 69
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 83 (3.61%) 3	19 / 176 (10.80%) 28
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 83 (1.20%) 2	4 / 176 (2.27%) 4
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	8 / 83 (9.64%) 10	12 / 176 (6.82%) 17
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	7 / 83 (8.43%) 14	3 / 176 (1.70%) 8
Hypoalbuminaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	5 / 83 (6.02%) 6	14 / 176 (7.95%) 16
Hypocalcaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	3 / 83 (3.61%) 3	9 / 176 (5.11%) 13
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	12 / 83 (14.46%) 20	14 / 176 (7.95%) 18
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	5 / 83 (6.02%) 9	7 / 176 (3.98%) 12
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	13 / 83 (15.66%) 23	28 / 176 (15.91%) 35
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	4 / 83 (4.82%) 5	10 / 176 (5.68%) 16
Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 83 (0.00%) 0	0 / 176 (0.00%) 0

Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 83 (1.20%) 1	1 / 176 (0.57%) 1
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Non-serious adverse events	Total		
Total subjects affected by non-serious adverse events subjects affected / exposed	302 / 307 (98.37%)		
Vascular disorders			
Hot flush subjects affected / exposed occurrences (all)	8 / 307 (2.61%) 9		
Hypertension subjects affected / exposed occurrences (all)	31 / 307 (10.10%) 51		
Hypotension subjects affected / exposed occurrences (all)	23 / 307 (7.49%) 26		
Lymphoedema subjects affected / exposed occurrences (all)	5 / 307 (1.63%) 5		
General disorders and administration site conditions			
Chest pain subjects affected / exposed occurrences (all)	2 / 307 (0.65%) 2		
Chills subjects affected / exposed occurrences (all)	22 / 307 (7.17%) 25		
Face oedema subjects affected / exposed occurrences (all)	2 / 307 (0.65%) 2		
Facial pain subjects affected / exposed occurrences (all)	1 / 307 (0.33%) 1		
Fatigue subjects affected / exposed occurrences (all)	180 / 307 (58.63%) 194		
Gait disturbance			

subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Influenza like illness			
subjects affected / exposed	7 / 307 (2.28%)		
occurrences (all)	9		
Localised oedema			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Oedema			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Oedema peripheral			
subjects affected / exposed	37 / 307 (12.05%)		
occurrences (all)	41		
Peripheral swelling			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences (all)	4		
Pyrexia			
subjects affected / exposed	48 / 307 (15.64%)		
occurrences (all)	66		
Suprapubic pain			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Scrotal oedema			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Vaginal odour			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Vulvovaginal pain			

subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Aspiration			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Cough			
subjects affected / exposed	72 / 307 (23.45%)		
occurrences (all)	86		
Dysphonia			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences (all)	8		
Dyspnoea			
subjects affected / exposed	59 / 307 (19.22%)		
occurrences (all)	68		
Dyspnoea exertional			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences (all)	4		
Epistaxis			
subjects affected / exposed	6 / 307 (1.95%)		
occurrences (all)	8		
Haemoptysis			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	5		
Hiccups			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Hypoxia			
subjects affected / exposed	15 / 307 (4.89%)		
occurrences (all)	17		
Increased upper airway secretion			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Nasal congestion			
subjects affected / exposed	26 / 307 (8.47%)		
occurrences (all)	30		
Oropharyngeal pain			
subjects affected / exposed	19 / 307 (6.19%)		
occurrences (all)	25		
Oropharyngeal swelling			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Paranasal sinus hypersecretion			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Pleural effusion			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences (all)	8		
Pleuritic pain			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Pneumonia aspiration			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences (all)	6		
Pneumonitis			
subjects affected / exposed	6 / 307 (1.95%)		
occurrences (all)	6		
Productive cough			
subjects affected / exposed	12 / 307 (3.91%)		
occurrences (all)	13		
Respiration abnormal			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Respiratory failure			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Rhinitis allergic			

subjects affected / exposed	9 / 307 (2.93%)		
occurrences (all)	10		
Rhinorrhoea			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	5		
Throat tightness			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Tracheal pain			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	11 / 307 (3.58%)		
occurrences (all)	13		
Psychiatric disorders			
Agitation			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences (all)	4		
Anxiety			
subjects affected / exposed	19 / 307 (6.19%)		
occurrences (all)	20		
Confusional state			
subjects affected / exposed	11 / 307 (3.58%)		
occurrences (all)	14		
Depression			
subjects affected / exposed	18 / 307 (5.86%)		
occurrences (all)	18		
Insomnia			
subjects affected / exposed	43 / 307 (14.01%)		
occurrences (all)	43		
Mental status changes			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Panic attack			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	53 / 307 (17.26%)		
occurrences (all)	73		
Amylase increased			
subjects affected / exposed	29 / 307 (9.45%)		
occurrences (all)	43		
Aspartate aminotransferase increased			
subjects affected / exposed	61 / 307 (19.87%)		
occurrences (all)	93		
Blood albumin decreased			
subjects affected / exposed	7 / 307 (2.28%)		
occurrences (all)	7		
Blood alkaline phosphatase increased			
subjects affected / exposed	40 / 307 (13.03%)		
occurrences (all)	54		
Blood bilirubin increased			
subjects affected / exposed	9 / 307 (2.93%)		
occurrences (all)	12		
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Blood creatinine increased			
subjects affected / exposed	35 / 307 (11.40%)		
occurrences (all)	53		
Blood uric acid increased			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences (all)	6		
Carcinoembryonic antigen increased			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Hepatic enzyme increased			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Lipase increased			
subjects affected / exposed	35 / 307 (11.40%)		
occurrences (all)	55		
Lymphocyte count decreased			
subjects affected / exposed	20 / 307 (6.51%)		
occurrences (all)	30		
Platelet count decreased			
subjects affected / exposed	13 / 307 (4.23%)		
occurrences (all)	22		
Transaminases increased			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Troponin I increased			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Vitamin B1 decreased			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	44 / 307 (14.33%)		
occurrences (all)	47		
Weight increased			
subjects affected / exposed	12 / 307 (3.91%)		
occurrences (all)	14		
White blood cell count decreased			
subjects affected / exposed	13 / 307 (4.23%)		
occurrences (all)	16		
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Contusion			

subjects affected / exposed	7 / 307 (2.28%)		
occurrences (all)	7		
Fall			
subjects affected / exposed	28 / 307 (9.12%)		
occurrences (all)	31		
Infusion related reaction			
subjects affected / exposed	15 / 307 (4.89%)		
occurrences (all)	19		
Stoma site haemorrhage			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Stoma site pain			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Sunburn			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Wound			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	15 / 307 (4.89%)		
occurrences (all)	17		
Tachycardia			
subjects affected / exposed	16 / 307 (5.21%)		
occurrences (all)	18		
Nervous system disorders			
Aphasia			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	5		
Convulsion			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	5		
Dizziness			

subjects affected / exposed	42 / 307 (13.68%)		
occurrences (all)	49		
Dysgeusia			
subjects affected / exposed	24 / 307 (7.82%)		
occurrences (all)	25		
Head discomfort			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Headache			
subjects affected / exposed	64 / 307 (20.85%)		
occurrences (all)	80		
Hemiparesis			
subjects affected / exposed	11 / 307 (3.58%)		
occurrences (all)	14		
Hypoaesthesia			
subjects affected / exposed	7 / 307 (2.28%)		
occurrences (all)	7		
Myasthenia gravis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Neuralgia			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences (all)	4		
Neuropathy peripheral			
subjects affected / exposed	10 / 307 (3.26%)		
occurrences (all)	10		
Paraesthesia			
subjects affected / exposed	15 / 307 (4.89%)		
occurrences (all)	17		
Peripheral sensory neuropathy			
subjects affected / exposed	12 / 307 (3.91%)		
occurrences (all)	12		
Post herpetic neuralgia			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Sinus headache			

subjects affected / exposed occurrences (all)	6 / 307 (1.95%) 6		
Tremor subjects affected / exposed occurrences (all)	11 / 307 (3.58%) 11		
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	62 / 307 (20.20%) 80		
Increased tendency to bruise subjects affected / exposed occurrences (all)	3 / 307 (0.98%) 3		
Leukocytosis subjects affected / exposed occurrences (all)	3 / 307 (0.98%) 5		
Leukopenia subjects affected / exposed occurrences (all)	1 / 307 (0.33%) 1		
Lymphadenopathy subjects affected / exposed occurrences (all)	3 / 307 (0.98%) 3		
Neutropenia subjects affected / exposed occurrences (all)	6 / 307 (1.95%) 7		
Ear and labyrinth disorders			
Ear discomfort subjects affected / exposed occurrences (all)	2 / 307 (0.65%) 2		
Ear pain subjects affected / exposed occurrences (all)	8 / 307 (2.61%) 9		
Vestibular disorder subjects affected / exposed occurrences (all)	1 / 307 (0.33%) 1		
Eye disorders			

Diplopia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Dry eye			
subjects affected / exposed	9 / 307 (2.93%)		
occurrences (all)	9		
Eye pruritus			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Periorbital oedema			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Photophobia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Vision blurred			
subjects affected / exposed	18 / 307 (5.86%)		
occurrences (all)	20		
Visual impairment			
subjects affected / exposed	6 / 307 (1.95%)		
occurrences (all)	9		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	13 / 307 (4.23%)		
occurrences (all)	13		
Abdominal pain			
subjects affected / exposed	43 / 307 (14.01%)		
occurrences (all)	50		
Abdominal pain lower			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	12 / 307 (3.91%)		
occurrences (all)	12		
Anorectal discomfort			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Ascites			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	5		
Colitis			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Constipation			
subjects affected / exposed	90 / 307 (29.32%)		
occurrences (all)	99		
Diarrhoea			
subjects affected / exposed	96 / 307 (31.27%)		
occurrences (all)	149		
Dry mouth			
subjects affected / exposed	19 / 307 (6.19%)		
occurrences (all)	20		
Dyspepsia			
subjects affected / exposed	24 / 307 (7.82%)		
occurrences (all)	24		
Dysphagia			
subjects affected / exposed	14 / 307 (4.56%)		
occurrences (all)	15		
Faecal incontinence			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Flatulence			
subjects affected / exposed	7 / 307 (2.28%)		
occurrences (all)	7		
Gastrooesophageal reflux disease			
subjects affected / exposed	16 / 307 (5.21%)		
occurrences (all)	16		
Gingival bleeding			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Glossodynia			

subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Inguinal hernia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Melaena			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Mouth ulceration			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	3		
Nausea			
subjects affected / exposed	122 / 307 (39.74%)		
occurrences (all)	155		
Oral mucosal eruption			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Oral pain			
subjects affected / exposed	6 / 307 (1.95%)		
occurrences (all)	6		
Pancreatic insufficiency			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Pancreatitis acute			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Proctalgia			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Rectal discharge			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Salivary duct inflammation			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	2		
Salivary hypersecretion			

subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	25 / 307 (8.14%)		
occurrences (all)	30		
Vomiting			
subjects affected / exposed	71 / 307 (23.13%)		
occurrences (all)	101		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Jaundice			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences (all)	9		
Dermatitis			
subjects affected / exposed	9 / 307 (2.93%)		
occurrences (all)	11		
Dermatitis acneiform			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences (all)	4		
Dry skin			
subjects affected / exposed	10 / 307 (3.26%)		
occurrences (all)	10		
Erythema			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences (all)	8		
Night sweats			
subjects affected / exposed	11 / 307 (3.58%)		
occurrences (all)	11		
Photosensitivity reaction			

subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Pruritus			
subjects affected / exposed	62 / 307 (20.20%)		
occurrences (all)	86		
Pruritus generalised			
subjects affected / exposed	7 / 307 (2.28%)		
occurrences (all)	8		
Purpura			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	69 / 307 (22.48%)		
occurrences (all)	89		
Rash generalised			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	7		
Rash macular			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Rash maculo-papular			
subjects affected / exposed	43 / 307 (14.01%)		
occurrences (all)	49		
Rash papular			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences (all)	11		
Skin hypopigmentation			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Skin ulcer			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Urticaria			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	6		
Renal and urinary disorders			

Chromaturia			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Dysuria			
subjects affected / exposed	4 / 307 (1.30%)		
occurrences (all)	4		
Haematuria			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences (all)	10		
Pollakiuria			
subjects affected / exposed	7 / 307 (2.28%)		
occurrences (all)	7		
Urinary incontinence			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences (all)	8		
Urinary retention			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	5		
Urinary tract obstruction			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	8 / 307 (2.61%)		
occurrences (all)	8		
Hypogonadism			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Hypothyroidism			
subjects affected / exposed	37 / 307 (12.05%)		
occurrences (all)	39		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	42 / 307 (13.68%)		
occurrences (all)	54		
Back pain			

subjects affected / exposed	45 / 307 (14.66%)		
occurrences (all)	51		
Costochondritis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	2		
Flank pain			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Groin pain			
subjects affected / exposed	6 / 307 (1.95%)		
occurrences (all)	6		
Joint swelling			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Muscle spasms			
subjects affected / exposed	10 / 307 (3.26%)		
occurrences (all)	11		
Muscular weakness			
subjects affected / exposed	10 / 307 (3.26%)		
occurrences (all)	10		
Musculoskeletal chest pain			
subjects affected / exposed	12 / 307 (3.91%)		
occurrences (all)	12		
Musculoskeletal pain			
subjects affected / exposed	18 / 307 (5.86%)		
occurrences (all)	18		
Myalgia			
subjects affected / exposed	29 / 307 (9.45%)		
occurrences (all)	34		
Myositis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	18 / 307 (5.86%)		
occurrences (all)	18		
Pain in extremity			

subjects affected / exposed	17 / 307 (5.54%)		
occurrences (all)	19		
Pain in jaw			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	5		
Tendonitis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Infections and infestations			
Bronchitis			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	7		
Candida infection			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	5		
Ear infection			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Herpes zoster			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	4		
Mucosal infection			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	7 / 307 (2.28%)		
occurrences (all)	9		
Oral candidiasis			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		
Oral herpes			
subjects affected / exposed	5 / 307 (1.63%)		
occurrences (all)	5		
Paronychia			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		

Pharyngitis			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Pharyngitis streptococcal			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Pneumonia			
subjects affected / exposed	12 / 307 (3.91%)		
occurrences (all)	12		
Rhinitis			
subjects affected / exposed	6 / 307 (1.95%)		
occurrences (all)	6		
Sinusitis			
subjects affected / exposed	13 / 307 (4.23%)		
occurrences (all)	17		
Subcutaneous abscess			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Tooth infection			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	3		
Upper respiratory tract infection			
subjects affected / exposed	24 / 307 (7.82%)		
occurrences (all)	33		
Urinary tract infection			
subjects affected / exposed	25 / 307 (8.14%)		
occurrences (all)	43		
Viral infection			
subjects affected / exposed	2 / 307 (0.65%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	98 / 307 (31.92%)		
occurrences (all)	109		
Dehydration			

subjects affected / exposed	25 / 307 (8.14%)		
occurrences (all)	34		
Hypercalcaemia			
subjects affected / exposed	6 / 307 (1.95%)		
occurrences (all)	7		
Hyperglycaemia			
subjects affected / exposed	21 / 307 (6.84%)		
occurrences (all)	28		
Hyperuricaemia			
subjects affected / exposed	12 / 307 (3.91%)		
occurrences (all)	24		
Hypoalbuminaemia			
subjects affected / exposed	21 / 307 (6.84%)		
occurrences (all)	24		
Hypocalcaemia			
subjects affected / exposed	14 / 307 (4.56%)		
occurrences (all)	18		
Hypokalaemia			
subjects affected / exposed	33 / 307 (10.75%)		
occurrences (all)	46		
Hypomagnesaemia			
subjects affected / exposed	14 / 307 (4.56%)		
occurrences (all)	23		
Hyponatraemia			
subjects affected / exposed	45 / 307 (14.66%)		
occurrences (all)	62		
Hypophosphataemia			
subjects affected / exposed	14 / 307 (4.56%)		
occurrences (all)	21		
Vitamin B12 deficiency			
subjects affected / exposed	1 / 307 (0.33%)		
occurrences (all)	1		
Vitamin D deficiency			
subjects affected / exposed	3 / 307 (0.98%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 October 2014	The primary purpose of the amendment is to address FDA queries, including clarifications and requested changes to the inclusion criteria, updates to the definition of dose-limiting toxicities, ECG monitoring and to add regularly scheduled urine pregnancy testing for females of childbearing potential.
03 April 2015	The primary purpose of Amendment 2 is to include an additional expansion cohort in subjects with glioblastoma
16 July 2015	The primary purpose of this amendment is to change the dose for nivolumab for Phase 2 to a flat dose (240 mg) and to update the study design to allow the Phase 2 NSCLC and melanoma expansion cohorts to open with the 100 mg BID dose of INCB024360 once 100 mg BID is determined to be safe in Phase 1.
12 February 2016	The primary purpose of this amendment is to include epacadostat updates at the program level as well as clarify Phase 1 and Phase 2 cohort enrollments.
05 July 2017	Addition of new immunotherapy/chemotherapy combination cohorts in Phase 1 to evaluate the safety and tolerability of and to determine the recommended Phase 2 dose for epacadostat (INCB24360) and nivolumab in combination with standard-of-care (SOC) chemotherapy regimens in subjects with advanced or metastatic squamous cell carcinoma of the head and neck (SCCHN) and non-small lung cancer (NSCLC). Phase 1 is now divided into 2 parts: Part 1 is the original combination immunotherapy regimen, and Part 2 describes the new combination immunotherapy and chemotherapy regimens. Addition of 2 new melanoma (MEL) cohorts in Phase 2 to evaluate the safety and efficacy of epacadostat in combination with nivolumab

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported