Clinical trial results:
A Phase 1, Open-Label, Dose-Escalation Study of Olaratumab as a Single Agent and in Combination with Doxorubicin, Vincristine/Irinotecan, or High-dose Ifosfamide in Pediatric Patients with Relapsed or Refractory Solid Tumors

Summary

EudraCT number	2015-005721-39
Trial protocol	Outside EU/EEA
Global end of trial date	03 April 2019

Results information

Result version number	v1 (current)
This version publication date	20 November 2020
First version publication date	20 November 2020

Trial information

Trial identification

Sponsor protocol code	I5B-MC-JGDN

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02677116
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 15841

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001760-PIP01-15
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	03 April 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate the safety of different doses of olaratumab and to determine which dose should be used for future pediatric studies. The present study was open to children with advanced cancer or cancer that had spread to another part of the body. The study had three parts. In the first two parts, a specific dose of olaratumab was given in 21 day cycles, followed by one of three standard chemotherapy regimens. In the third part, a specific dose of olaratumab was given with one of three standard chemotherapy regimens in 21 day cycles. Participants could only enroll in one part.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 August 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 59
Country: Number of subjects enrolled	Japan: 9
Worldwide total number of subjects	68
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)	37
Adolescents (12-17 years)	31

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

Completers include the participants who died due to any cause or disease progression, alive and on study at conclusion, but off treatment.

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	Olaratumab + Vincristine + Irinotecan (Part A)

Arm description:

Cycle 1: Olaratumab 15 milligram/kilogram (mg/kg) was administered alone intravenously (IV) on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Vincristine administered IV.

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

Dosage and administration details:

Irinotecan administered IV.

Arm title	Olaratumab + Doxorubicin (Part A)

Arm description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Doxorubicin administered IV.

Arm title	Olaratumab + Ifosfamide (Part A)

Arm description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Ifosfamide administered IV.

Arm title	Olaratumab + Vincristine + Irinotecan (Part B)

Arm description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental

Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Vincristine administered IV.

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

Dosage and administration details:

Irinotecan administered IV.

Arm title	Olaratumab + Doxorubicin (Part B)

Arm description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Doxorubicin administered IV.

Arm title	Olaratumab + Ifosfamide (Part B)

Arm description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental

Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Doxorubicin administered IV.

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

Dosage and administration details:

Ifosfamide administered IV.

Arm title	Olaratumab + Vincristine + Irinotecan (Part C)

Arm description:

Cycle 1 and beyond: Olaratumab 20 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Vincristine administered IV.

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

Dosage and administration details:

Irinotecan administered IV.

Arm title	Olaratumab + Ifosfamide (Part C)

Arm description:

Cycle 1 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide

administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Ifosfamide administered IV.

Arm title	Olaratumab + Doxorubicin (Part C)

Arm description:

Cycle 1 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Olaratumab administered IV.

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

Dosage and administration details:

Doxorubicin administered IV.

Number of subjects in period 1	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Doxorubicin (Part A)	Olaratumab + Ifosfamide (Part A)
Started	10	11	9
Cycle 1 Olaratumab Alone	10	11	9
Progressive Disease	7	7	6
Completed	7	7	6
Not completed	3	4	3
Consent withdrawn by subject	1	-	-

Physician decision	-	2	3
Adverse event, non-fatal	-	1	-
Withdrawal by parent or guardian	2	1	-

Number of subjects in period 1	Olaratumab + Vincristine + Irinotecan (Part B)	Olaratumab + Doxorubicin (Part B)	Olaratumab + Ifosfamide (Part B)
Started	10	1	13
Cycle 1 Olaratumab Alone	10	1	13
Progressive Disease	7	0	9
Completed	7	0	9
Not completed	3	1	4
Consent withdrawn by subject	-	-	-
Physician decision	2	1	3
Adverse event, non-fatal	-	-	1
Withdrawal by parent or guardian	1	-	-

Number of subjects in period 1	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)	Olaratumab + Doxorubicin (Part C)
Started	6	4	4
Cycle 1 Olaratumab Alone	6	4	4
Progressive Disease	2	2	2
Completed	2	2	2
Not completed	4	2	2
Consent withdrawn by subject	-	-	-
Physician decision	1	1	2
Adverse event, non-fatal	1	-	-
Withdrawal by parent or guardian	2	1	-

Baseline characteristics

Reporting groups

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 milligram/kilogram (mg/kg) was administered alone intravenously (IV) on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group values	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Doxorubicin (Part A)	Olaratumab + Ifosfamide (Part A)
Number of subjects	10	11	9
Age categorical Units: Subjects			
Children (2-11 years)	6	9	4
Adolescents (12-17 years)	4	2	5
Gender categorical Units: Subjects			
Female	4	3	2
Male	6	8	7
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	1	2
White	9	8	5
More than one race	0	0	0
Unknown or Not Reported	0	1	1
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	4	1
Not Hispanic or Latino	9	7	7
Not Reported	0	0	0
Missing	0	0	1

Reporting group values	Olaratumab + Vincristine + Irinotecan (Part B)	Olaratumab + Doxorubicin (Part B)	Olaratumab + Ifosfamide (Part B)
Number of subjects	10	1	13
Age categorical Units: Subjects			
Children (2-11 years)	5	1	4
Adolescents (12-17 years)	5	0	9
Gender categorical Units: Subjects			
Female	6	0	6
Male	4	1	7

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	2	0	2
White	7	1	11
More than one race	0	0	0
Unknown or Not Reported	1	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	0	3
Not Hispanic or Latino	8	1	10
Not Reported	0	0	0
Missing	1	0	0

Reporting group values	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)	Olaratumab + Doxorubicin (Part C)
Number of subjects	6	4	4
Age categorical Units: Subjects			
Children (2-11 years)	4	2	2
Adolescents (12-17 years)	2	2	2
Gender categorical Units: Subjects			
Female	4	1	2
Male	2	3	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	3	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	1	1
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	2	1	1
Not Hispanic or Latino	1	0	0
Not Reported	1	1	2
Missing	2	2	1

Reporting group values	Total		
Number of subjects	68		
Age categorical Units: Subjects			
Children (2-11 years)	37		
Adolescents (12-17 years)	31		

Gender categorical Units: Subjects			
Female	28		
Male	40		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	11		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	8		
White	46		
More than one race	0		
Unknown or Not Reported	3		
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	14		
Not Hispanic or Latino	43		
Not Reported	4		
Missing	7		

End points

End points reporting groups

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 milligram/kilogram (mg/kg) was administered alone intravenously (IV) on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Subject analysis set title	Olaratumab Alone (Part A)
Subject analysis set type	Per protocol

Subject analysis set description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8.

All cycles are 21 days.

Subject analysis set title	Olaratumab Alone (Part B)
Subject analysis set type	Per protocol

Subject analysis set description:

Cycle 1: Olaratumab 20-mg/kg was administered alone IV on Days 1 and 8.

All cycles are 21 days.

Subject analysis set title	Olaratumab + Doxorubicin Cycle 1 (Part C)
Subject analysis set type	Per protocol

Subject analysis set description:

Cycle 1: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Subject analysis set title	Olaratumab + Vincristine + Irinotecan (Part A)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who had evaluable PK data for Olaratumab combinations.

Primary: Number of Participants with Olaratumab Dose Limiting Toxicities (DLTs)

End point title	Number of Participants with Olaratumab Dose Limiting Toxicities (DLTs)[1]

End point description:

A dose limiting toxicity (DLT) was defined as an adverse event (AE) during the first 21 days that was possibly related to the study drug and fulfilled any of the following criteria using the National Cancer Institute's (NCI) Common Terminology Criteria for Adverse Events (CTCAE), Version 4.0: CTCAE Grade 3 nonhematologic toxicity, grade 4 neutropenia that lasted longer than 2 weeks, grade ≥3 thrombocytopenia complicated by hemorrhage, and any hematologic toxicity that caused a cycle delay of >14 days.

End point type	Primary

End point timeframe:

Parts A and B: Cycle 1 through Cycle 2 in each arm (21-day cycle); Part C: Cycle 1 only (21-day cycle)

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 have been prespecified for this primary end point, dose limiting toxicities.

End point values	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Doxorubicin (Part A)	Olaratumab + Ifosfamide (Part A)	Olaratumab + Vincristine + Irinotecan (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10[2]	11[3]	9[4]	10[5]
Units: participants	0	0	1	1

Notes:

[2] - All participants who received at least one dose of study drug and were evaluable for DLTs.

[3] - All participants who received at least one dose of study drug and were evaluable for DLTs.

[4] - All participants who received at least one dose of study drug and were evaluable for DLTs.

[5] - All participants who received at least one dose of study drug and were evaluable for DLTs.

End point values	Olaratumab + Doxorubicin (Part B)	Olaratumab + Ifosfamide (Part B)	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[6]	13[7]	6[8]	4[9]
Units: participants	1	0	1	0

Notes:

[6] - All participants who received at least one dose of study drug and were evaluable for DLTs.

[7] - All participants who received at least one dose of study drug and were evaluable for DLTs.

[8] - All participants who received at least one dose of study drug and were evaluable for DLTs.

[9] - All participants who received at least one dose of study drug and were evaluable for DLTs.

End point values	Olaratumab + Doxorubicin (Part C)			
Subject group type	Reporting group			
Number of subjects analysed	4[10]			
Units: participants	0			

Notes:

[10] - All participants who received at least one dose of study drug and were evaluable for DLTs.

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Maximum Concentration (Cmax) of Olaratumab Part A

End point title	Pharmacokinetics (PK): Maximum Concentration (Cmax) of Olaratumab Part A[11]

End point description:

Pharmacokinetics (PK): Maximum serum concentration (Cmax) data of Olaratumab was reported from available sample data. Geometric coefficient of variation is represented as a percent.

End point type	Secondary

End point timeframe:

Cycle 1, Day 8 and Cycle 2, Days 1 and 8: 1.25 hour (h), 2.5 h, 3.5h Postdose

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants who had evaluable Part A PK data was reported for this endpoint.

End point values	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Doxorubicin (Part A)	Olaratumab + Ifosfamide (Part A)	Olaratumab Alone (Part A)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	7[12]	6[13]	9[14]	28[15]
Units: microgram/milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 8	0 (± 0)	0 (± 0)	0 (± 0)	439 (± 23)
Cycle 2, Day 1	437 (± 44)	406 (± 21)	396 (± 39)	0 (± 0)
Cycle 2, Day 8	523 (± 26)	422 (± 30)	398 (± 44)	0 (± 0)

Notes:

[12] - All participants who had evaluable PK data for Olaratumab alone and combinations Part A.

[13] - All participants who had evaluable PK data for Olaratumab alone and combinations Part A.

[14] - All participants who had evaluable PK data for Olaratumab alone and combinations Part A.

[15] - All participants who had evaluable PK data for Olaratumab alone and combinations Part A.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Maximum Concentration (Cmax) of Olaratumab Part B

End point title	PK: Maximum Concentration (Cmax) of Olaratumab Part B[16]

End point description:

PK: Maximum serum concentration (Cmax) data of Olaratumab was reported from available sample data. Zero participants analyzed for Olaratumab and Doxorubicin being below the quantifiable limit. Geometric coefficient of variation is represented as a percent.

End point type	Secondary

End point timeframe:

Cycle 1, Day 8 and Cycle 2, Days 1 and 8: 1.25 hour (h), 2.5 h, 3.5h Postdose

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants who had evaluable Part B PK data was reported for this endpoint.

End point values	Olaratumab + Vincristine + Irinotecan (Part B)	Olaratumab + Ifosfamide (Part B)	Olaratumab Alone (Part B)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	8[17]	11[18]	21[19]	
Units: microgram/milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 8	0 (± 0)	0 (± 0)	639 (± 27)	
Cycle 2, Day 1	585 (± 30)	629 (± 32)	0 (± 0)	
Cycle 2, Day 8	647 (± 27)	696 (± 27)	0 (± 0)	

Notes:

[17] - All participants who had evaluable PK data for Olaratumab alone and combinations Part B.

[18] - All participants who had evaluable PK data for Olaratumab alone and combinations Part B.

[19] - All participants who had evaluable PK data for Olaratumab alone and combinations Part B.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Maximum Concentration (Cmax) of Olaratumab Part C

End point title	PK: Maximum Concentration (Cmax) of Olaratumab Part C[20]

End point description:

Pharmacokinetics (PK): Maximum serum concentration (Cmax) data of Olaratumab was reported from available sample data. Geometric coefficient of variation is represented as a percent.

End point type	Secondary

End point timeframe:

Cycle 1, Days 1 and 8; Cycle 2, Days 1 and 8: 1.25 hour (h), 2.5 h, 3.5h Postdose

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants who had evaluable Part C PK data was reported for this endpoint.

End point values	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)	Olaratumab + Doxorubicin (Part C)	Olaratumab + Doxorubicin Cycle 1 (Part C)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	6[21]	4[22]	3[23]	4[24]
Units: microgram/milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 1	548 (± 15)	363 (± 39)	0 (± 0)	406 (± 20)
Cycle 1, Day 8	695 (± 37)	498 (± 43)	0 (± 0)	493 (± 20)
Cycle 2, Day 1	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle 2, Day 8	707 (± 3)	567 (± 38)	502 (± 38)	0 (± 0)

Notes:

[21] - All participants who had evaluable PK data for Olaratumab combinations Part C.

[22] - All participants who had evaluable PK data for Olaratumab combinations Part C.

[23] - All participants who had evaluable PK data for Olaratumab combinations Part C.

[24] - All participants who had evaluable PK data for Olaratumab combinations Part C.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Trough Serum Concentration (Cmin) of Olaratumab Part A

End point title	PK: Trough Serum Concentration (Cmin) of Olaratumab Part

End point description:

PK: Trough serum concentration (Cmin) of Olaratumab was reported. A sample was collected from cycles 1, 2 every other cycle 3-25. Geometric coefficient of variation is represented as a percent.

End point type	Secondary

End point timeframe:

Cycles 1, 2, 3-25; Day 8: 336 Hours Postdose

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants who had evaluable Part A PK data was reported for this endpoint.

End point values	Olaratumab + Doxorubicin (Part A)	Olaratumab + Ifosfamide (Part A)	Olaratumab Alone (Part A)	Olaratumab + Vincristine + Irinotecan (Part A)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	5[26]	9[27]	6[28]	17[29]
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 8	0 (± 0)	46.3 (± 284)	73 (± 56)	97.8 (± 29)
Cycle 2, Day 8	38.5 (± 29.1)	114 (± 85)	0 (± 0)	37.7 (± 112)
Cycle 3-25, Day 8	94.4 (± 41)	88.2 (± 77)	0 (± 0)	95.1 (± 85)

Notes:

[26] - All participants who had evaluable PK data for Olaratumab alone and combinations Part A.

[27] - All participants who had evaluable PK data for Olaratumab alone and combinations Part A.

[28] - All participants who had evaluable PK data for Olaratumab alone and combinations Part A.

[29] - All participants who had evaluable PK data for Olaratumab alone and combinations Part A.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Trough Serum Minimum Concentration (Cmin) of Olaratumab Part B

End point title	PK: Trough Serum Minimum Concentration (Cmin) of Olaratumab Part B[30]

End point description:

PK: Trough serum concentration (Cmin) of Olaratumab was reported. A sample was collected every other cycle from cycles 1, 2, 3-25. Zero participants were analyzed for Cmin of Olaratumab alone (Part B) and Olaratumab + Doxorubicin (Part B). Geometric coefficient of variation is represented as a percent.

End point type	Secondary

End point timeframe:

Cycles 1, 2, 3-25; Day 8: 336 Hours Postdose

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants who had evaluable Part B PK data was reported for this endpoint.

End point values	Olaratumab + Vincristine + Irinotecan (Part B)	Olaratumab + Ifosfamide (Part B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[31]	11[32]		
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 8	99.1 (± 65)	125 (± 55)		
Cycle 2, Day 8	230 (± 17)	199 (± 36)		
Cycle 3-25, Day 8	348 (± 15)	289 (± 14)		

Notes:

[31] - All participants who had evaluable PK data for Olaratumab combinations Part B.

[32] - All participants who had evaluable PK data for Olaratumab combinations Part B.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Trough Serum Minimum Concentration (Cmin) of Olaratumab Part C

End point title	PK: Trough Serum Minimum Concentration (Cmin) of Olaratumab Part C[33]

End point description:

PK: Trough serum concentration (Cmin) of Olaratumab was reported. A sample was collected every other cycle from cycles 1, 2, 3-25. Geometric coefficient of variation is represented as a percent.

End point type	Secondary

End point timeframe:

Cycles 1, 2, 3-25; Day 8: 336 Hours Postdose

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All participants who had evaluable Part C PK data was reported for this endpoint.

End point values	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)	Olaratumab + Doxorubicin (Part C)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5[34]	3[35]	3[36]	
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 8	83.7 (± 8)	124 (± 32)	90.3 (± 33)	
Cycle 2, Day 8	134 (± 54)	9999 (± 9999)	141 (± 18)	
Cycle 3-25, Day 8	83.7 (± 48)	9999 (± 9999)	156 (± 24)	

Notes:

[34] - All participants who had evaluable PK data for Part C.

[35] - Individual PK participant data reported: 250 and 210.

[36] - All participants who had evaluable PK data for Part C.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Complete Response (CR) or Partial Response (PR) (Objective Response Rate [ORR])

End point title	Percentage of Participants With a Complete Response (CR) or Partial Response (PR) (Objective Response Rate [ORR])

End point description:

Objective Response Rate (ORR) is the percentage of participants achieving a confirmed best overall tumor response of CR or PR. According to RECIST v1.1, PR defined as a >30% decrease in the sum of the longest diameters (LD) of the target lesions, taking as reference the baseline sum of the LD; CR was defined as the disappearance of all target and non-target lesions.

End point type	Secondary

End point timeframe:

Baseline to objective progression or start of new anti-cancer therapy (Up to 7 months)

End point values	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Doxorubicin (Part A)	Olaratumab + Ifosfamide (Part A)	Olaratumab + Vincristine + Irinotecan (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10[37]	11[38]	9[39]	10[40]
Units: percentage of participants				
number (not applicable)	0	9.1	0	20.0

Notes:

[37] - All participants who received at least one dose of study drug and had evaluable ORR data.

[38] - All participants who received at least one dose of study drug and had evaluable ORR data.

[39] - All participants who received at least one dose of study drug and had evaluable ORR data.

[40] - All participants who received at least one dose of study drug and had evaluable ORR data.

End point values	Olaratumab + Doxorubicin (Part B)	Olaratumab + Ifosfamide (Part B)	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[41]	13[42]	6[43]	4[44]
Units: percentage of participants				
number (not applicable)	0	0	0	0

Notes:

[41] - All participants who received at least one dose of study drug and had evaluable ORR data.1

[42] - All participants who received at least one dose of study drug and had evaluable ORR data.

[43] - All participants who received at least one dose of study drug and had evaluable ORR data.

[44] - All participants who received at least one dose of study drug and had evaluable ORR data.

End point values	Olaratumab + Doxorubicin (Part C)			
Subject group type	Reporting group			
Number of subjects analysed	4[45]			
Units: percentage of participants				
number (not applicable)	25.0			

Notes:

[45] - All participants who received at least one dose of study drug and had evaluable ORR data.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

Progression-free survival (PFS) is defined as the time from baseline to the first date of radiological disease progression or death due to any cause. Progressive disease (PD) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 is defined as at least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study (including the baseline sum if that is the smallest). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 millimeters (mm). The appearance of one or more new lesions is also considered progression. If participant started new treatment before PD, the participant was censored at the date of last tumor assessment prior to new therapy. If treatment was discontinued for reasons other than PD and no further assessment, censoring occurred at last tumor assessment. Part A censored: 2, 2, and 2; Part B censored: 2, 2, and 1 and Part C censored: 2,1, and 4.

End point type	Secondary

End point timeframe:

Baseline to radiological disease progression or death from any cause (Up to 2 Years)

End point values	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Doxorubicin (Part A)	Olaratumab + Ifosfamide (Part A)	Olaratumab + Vincristine + Irinotecan (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10[46]	11[47]	9[48]	10[49]
Units: Months				
median (confidence interval 95%)	1.54 (0.69 to 15.74)	1.26 (0.26 to 5.26)	1.38 (0.62 to 5.68)	1.28 (0.53 to 11.07)

Notes:

[46] - All participants who received at least one dose of study drug.

[47] - All participants who received at least one dose of study drug.

[48] - All participants who received at least one dose of study drug.

[49] - All participants who received at least one dose of study drug.

End point values	Olaratumab + Doxorubicin (Part B)	Olaratumab + Ifosfamide (Part B)	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[50]	13[51]	6[52]	4[53]
Units: Months				
median (confidence interval 95%)	0 (0 to 0)	1.25 (1.15 to 3.12)	4.07 (1.41 to 4.07)	4.88 (0.69 to 8.54)

Notes:

[50] - The PFS was not calculated for median and 95% confidence interval due to n=1.

[51] - All participants who received at least one dose of study drug.

[52] - All participants who received at least one dose of study drug.

[53] - All participants who received at least one dose of study drug.

End point values	Olaratumab + Doxorubicin (Part C)			
Subject group type	Reporting group			
Number of subjects analysed	4[54]			
Units: Months				
median (confidence interval 95%)	5.52 (1.22 to 5.52)			

Notes:

[54] - All participants who received at least one dose of study drug.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Treatment Emergent (TE) Positive Anti-Olaratumab Antibodies

End point title	Percentage of Participants with Treatment Emergent (TE) Positive Anti-Olaratumab Antibodies

End point description:

Percentage of participants with a TE positive anti-olaratumab antibodies defined as a participant with a 4-fold (2 dilutions) increase over a positive baseline antibody titer.

End point type	Secondary

End point timeframe:

From Baseline to Study Completion (Up to 33 Months)

End point values	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Doxorubicin (Part A)	Olaratumab + Ifosfamide (Part A)	Olaratumab + Vincristine + Irinotecan (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10[55]	11[56]	9[57]	10[58]
Units: percentage of participants				
number (not applicable)	0	0	0	0

Notes:

[55] - All participants who received at least one dose of study drug and had evaluable data post baseline.
[56] - All participants who received at least one dose of study drug and had evaluable data post baseline.
[57] - All participants who received at least one dose of study drug and had evaluable data post baseline.
[58] - All participants who received at least one dose of study drug and had evaluable data post baseline.

End point values	Olaratumab + Doxorubicin (Part B)	Olaratumab + Ifosfamide (Part B)	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[59]	13[60]	6[61]	4[62]
Units: percentage of participants				
number (not applicable)	0	0	0	0

Notes:

[59] - All participants who received at least one dose of study drug and had evaluable data post baseline.
[60] - All participants who received at least one dose of study drug and had evaluable data post baseline.
[61] - All participants who received at least one dose of study drug and had evaluable data post baseline.
[62] - All participants who received at least one dose of study drug and had evaluable data post baseline.

End point values	Olaratumab + Doxorubicin (Part C)			
Subject group type	Reporting group			
Number of subjects analysed	4[63]			
Units: percentage of participants				
number (not applicable)	0			

Notes:

[63] - All participants who received at least one dose of study drug and had evaluable data post baseline.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 33 Months

Adverse event reporting additional description:

All participants who received at least one dose of study drug up to 30 days after last dose of study drug. Gender specific events only occurring in male and female participants have had the number of participants At Risk adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 15 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8. Cycle 2 and beyond: Olaratumab 15 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part A)

Reporting group description:

Cycle 1: Olaratumab 15 mg/kg was administered alone IV on Days 1 and 8. Cycle 2 and beyond: Olaratumab 15 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg administered alone IV on Days 1 and 8. Cycle 2 and beyond: Olaratumab 20 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg was administered alone IV on Days 1 and 8.

Cycle 2 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part B)

Reporting group description:

Cycle 1: Olaratumab 20 mg/kg alone was administered alone IV on Days 1 and 8. Cycle 2 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Vincristine + Irinotecan (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg and vincristine administered IV on Days 1 and 8. Irinotecan administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Ifosfamide (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 of each cycle. Ifosfamide administered IV on Days 1 through 5. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Reporting group title	Olaratumab + Doxorubicin (Part C)

Reporting group description:

Cycle 1 and beyond: Olaratumab 20 mg/kg administered IV on Days 1 and 8 and doxorubicin administered IV on Days 1 and 2. Treatment will cease when discontinuation criterion is met.

All cycles are 21 days.

Serious adverse events	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Ifosfamide (Part A)	Olaratumab + Doxorubicin (Part A)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 10 (30.00%)	4 / 9 (44.44%)	2 / 11 (18.18%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
vena cava thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
pain			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
aspiration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (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
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (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
pneumothorax			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcus test positive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
shunt occlusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (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
tibia fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
hydrocephalus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (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
seizure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	2 / 9 (22.22%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
febrile neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
methaemoglobinaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain lower			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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 retention			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (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
penile infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed[1]	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 8 (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
urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
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	Olaratumab + Vincristine + Irinotecan (Part B)	Olaratumab + Ifosfamide (Part B)	Olaratumab + Doxorubicin (Part B)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 10 (50.00%)	7 / 13 (53.85%)	0 / 1 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour pain			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
vena cava thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
aspiration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			

alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcus test positive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
shunt occlusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
hydrocephalus			
alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
febrile neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	6 / 13 (46.15%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 2	8 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
methaemoglobinaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain lower			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 10 (30.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary retention			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abdominal infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
penile infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed[1]	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 10 (20.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)	Olaratumab + Doxorubicin (Part C)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	1 / 4 (25.00%)	4 / 4 (100.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
vena cava thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
aspiration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcus test positive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (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
Injury, poisoning and procedural complications			

shunt occlusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
hydrocephalus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	2 / 4 (50.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
methaemoglobinaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 lower			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 retention			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
penile infection			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed[1]	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

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

Non-serious adverse events	Olaratumab + Vincristine + Irinotecan (Part A)	Olaratumab + Ifosfamide (Part A)	Olaratumab + Doxorubicin (Part A)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	9 / 9 (100.00%)	11 / 11 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	3 / 9 (33.33%)	0 / 11 (0.00%)
occurrences (all)	2	3	0
Vascular disorders			
embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
flushing			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
hypertension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	1	1	2
hypotension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	3	1	0
pallor			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
pelvic venous thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
phlebitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
catheter site pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
chills			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
early satiety			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
face oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
facial pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	0	2	2
fatigue			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 10 (60.00%)	2 / 9 (22.22%)	4 / 11 (36.36%)
occurrences (all)	15	3	4
gait disturbance			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	4	1	0
localised oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
malaise			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0

oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
pyrexia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 9 (22.22%)	3 / 11 (27.27%)
occurrences (all)	2	4	3
Respiratory, thoracic and mediastinal disorders			
atelectasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
bradypnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 9 (11.11%)	2 / 11 (18.18%)
occurrences (all)	1	2	3
dyspnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	2	1	0
epistaxis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
hypoxia			
alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 9 (11.11%)	2 / 11 (18.18%)
occurrences (all)	1	1	2
nasal congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
pharyngeal erythema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
pleural effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
pleuritic pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
productive cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
rales			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
tachypnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	10	0	0
upper-airway cough syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
wheezing			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
depression			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
hallucination			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 10 (30.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	3	1	0
irritability			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
mood swings			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
restlessness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Investigations			
activated partial thromboplastin time			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
activated partial thromboplastin time prolonged			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
alanine aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 9 (22.22%)	1 / 11 (9.09%)
occurrences (all)	9	9	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	4 / 9 (44.44%)	1 / 11 (9.09%)
occurrences (all)	3	6	1
bilirubin conjugated increased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 9 (22.22%)	1 / 11 (9.09%)
occurrences (all)	2	3	1
blood bicarbonate decreased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
blood bilirubin increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	4	0	0
blood creatinine increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
blood lactate dehydrogenase increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
blood phosphorus increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
blood thyroid stimulating hormone decreased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
blood thyroid stimulating hormone increased alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
electrocardiogram pr shortened			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
eosinophil percentage decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	4 / 9 (44.44%)	0 / 11 (0.00%)
occurrences (all)	0	7	0
haemoglobin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
heart rate irregular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
international normalised ratio increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 10 (20.00%)	5 / 9 (55.56%)	2 / 11 (18.18%)
occurrences (all)	3	29	6
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	3 / 9 (33.33%)	5 / 11 (45.45%)
occurrences (all)	16	13	22
neutrophil count increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
platelet count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	7 / 9 (77.78%)	3 / 11 (27.27%)
occurrences (all)	0	43	12
protein total decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
prothrombin time prolonged			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	2	1	0
weight increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	7 / 9 (77.78%)	3 / 11 (27.27%)
occurrences (all)	15	45	21

white blood cell count increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	2 / 9 (22.22%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
white blood cells urine positive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ph urine increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	0 / 9 (0.00%)	2 / 11 (18.18%)
occurrences (all)	3	0	2
fall			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
femur fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
infusion related reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
procedural pain			
alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
radiation skin injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
recall phenomenon			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
scratch			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
suture related complication			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Cardiac disorders			
left ventricular dysfunction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
palpitations			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
pericardial effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
sinus bradycardia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
sinus tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	8	2	7
tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dysarthria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	0	3	0
dysgeusia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
headache			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 10 (40.00%)	2 / 9 (22.22%)	0 / 11 (0.00%)
occurrences (all)	8	5	0
hemiparesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
lethargy			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
paraesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
peripheral motor neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
somnolence			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
writer's cramp			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 10 (40.00%)	7 / 9 (77.78%)	6 / 11 (54.55%)
occurrences (all)	9	36	11
febrile neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	7	0	0
lymphopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	6	0	0
neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	8	0	1
thrombocytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	16	0	0
thrombocytosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
excessive cerumen production			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
hypoacusis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
otorrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
dry eye			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
eye pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
eye swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
lacrimation increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
ocular hyperaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
periorbital oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
swelling of eyelid			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
vision blurred			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
abdominal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	9	0	1
abdominal pain upper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
anal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
ascites			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
cheilitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
constipation			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 10 (30.00%)	3 / 9 (33.33%)	1 / 11 (9.09%)
occurrences (all)	3	6	1
dental caries			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 10 (60.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	41	1	1
dyspepsia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dysphagia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
gingival bleeding			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
gingival pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

haematemesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
haematochezia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
lip dry			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
lip pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
mouth haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 10 (50.00%)	4 / 9 (44.44%)	4 / 11 (36.36%)
occurrences (all)	31	12	5
oesophageal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
oral dysaesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
proctalgia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
retching			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
stomatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	3	1	0
vomiting			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 10 (70.00%)	5 / 9 (55.56%)	4 / 11 (36.36%)
occurrences (all)	34	17	8
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
alopecia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 9 (11.11%)	4 / 11 (36.36%)
occurrences (all)	1	1	5
dermatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
dermatitis acneiform			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
dermatitis diaper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
dry skin			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
pruritus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	2 / 9 (22.22%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
rash			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	4	0	0
rash maculo-papular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 10 (40.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	6	0	4
skin hyperpigmentation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2

swelling face			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
chromaturia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
dysuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
fanconi syndrome acquired			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
glycosuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
haematuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
ketonuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
micturition urgency			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
proteinuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	3	2	1
urinary incontinence			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
urinary retention			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
hyperthyroidism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
hypothyroidism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
back pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 9 (22.22%)	1 / 11 (9.09%)
occurrences (all)	3	2	1
bone pain			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
coccydynia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
joint range of motion decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
musculoskeletal chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0

osteonecrosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
pain in extremity			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	2 / 11 (18.18%)
occurrences (all)	4	0	2
pain in jaw			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
candida infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
clostridium difficile infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
cystitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
enterocolitis infectious			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
hordeolum			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
lymph gland infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
skin infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 10 (40.00%)	1 / 9 (11.11%)	2 / 11 (18.18%)
occurrences (all)	8	2	2
dehydration			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	4	0	1
hyperalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
hypercalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
hyperchloraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	2 / 9 (22.22%)	0 / 11 (0.00%)
occurrences (all)	9	10	0
hyperkalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	2 / 11 (18.18%)
occurrences (all)	1	0	2
hypermagnesaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
hypernatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	2 / 9 (22.22%)	1 / 11 (9.09%)
occurrences (all)	2	3	1
hyperphosphataemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

hyperuricaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
hypoalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	3 / 9 (33.33%)	1 / 11 (9.09%)
occurrences (all)	5	5	1
hypocalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	4 / 9 (44.44%)	0 / 11 (0.00%)
occurrences (all)	12	5	0
hypoglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
hypokalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 9 (22.22%)	0 / 11 (0.00%)
occurrences (all)	5	8	0
hypomagnesaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 9 (11.11%)	1 / 11 (9.09%)
occurrences (all)	0	1	2
hyponatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	4 / 9 (44.44%)	1 / 11 (9.09%)
occurrences (all)	2	5	1
hypophosphataemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 9 (22.22%)	2 / 11 (18.18%)
occurrences (all)	3	2	2
hypouricaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
malnutrition			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
refeeding syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 9 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Olaratumab + Vincristine + Irinotecan (Part B)	Olaratumab + Ifosfamide (Part B)	Olaratumab + Doxorubicin (Part B)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 10 (90.00%)	13 / 13 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Vascular disorders			
embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
flushing			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	4	2	0
hypotension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
pallor			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
pelvic venous thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
phlebitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
catheter site pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
chills			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
early satiety			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
face oedema			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
facial pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
fatigue			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	4 / 13 (30.77%)	0 / 1 (0.00%)
occurrences (all)	6	5	0
gait disturbance			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
localised oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
malaise			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	2	1	0

pyrexia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 10 (40.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	10	1	0
Respiratory, thoracic and mediastinal disorders			
atelectasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
bradypnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	4 / 13 (30.77%)	0 / 1 (0.00%)
occurrences (all)	3	4	0
dyspnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	5	2	0
epistaxis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
nasal congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
oropharyngeal pain			
alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
pharyngeal erythema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
pleural effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	1 / 13 (7.69%)	1 / 1 (100.00%)
occurrences (all)	2	1	1
pleuritic pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
rales			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
rhinorrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
tachypnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
upper-airway cough syndrome			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
wheezing			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
anxiety			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
depression			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
hallucination			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
insomnia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
irritability			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
mood swings			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
restlessness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
activated partial thromboplastin time			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
activated partial thromboplastin time prolonged			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
alanine aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	1 / 1 (100.00%)
occurrences (all)	3	3	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	4 / 13 (30.77%)	1 / 1 (100.00%)
occurrences (all)	1	4	1
bilirubin conjugated increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
blood bicarbonate decreased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
blood bilirubin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
blood creatinine increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
blood lactate dehydrogenase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
blood phosphorus increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
blood thyroid stimulating hormone decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
blood thyroid stimulating hormone increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
electrocardiogram pr shortened			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
eosinophil percentage decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
haemoglobin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
heart rate irregular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
international normalised ratio increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	4	4	0
neutrophil count increased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
platelet count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	5 / 13 (38.46%)	0 / 1 (0.00%)
occurrences (all)	2	30	0
protein total decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
prothrombin time prolonged			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
weight decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
weight increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	5	3	0
white blood cell count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	4 / 13 (30.77%)	0 / 1 (0.00%)
occurrences (all)	8	16	0
white blood cell count increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
white blood cells urine positive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

ph urine increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
fall			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
femur fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
infusion related reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
ligament sprain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
radiation skin injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
recall phenomenon			
alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
scratch			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
suture related complication			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
left ventricular dysfunction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
palpitations			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
pericardial effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
sinus bradycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
sinus tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	3	3	0
tachycardia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
dysarthria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
headache			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 10 (60.00%)	4 / 13 (30.77%)	0 / 1 (0.00%)
occurrences (all)	8	5	0
hemiparesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
lethargy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
peripheral motor neuropathy			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
somnolence			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
writer's cramp			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 10 (50.00%)	8 / 13 (61.54%)	0 / 1 (0.00%)
occurrences (all)	18	55	0
febrile neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
leukocytosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
leukopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	16	9	0
lymphopenia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	7	7	0
neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	26	8	0
thrombocytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	7	14	0
thrombocytosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
excessive cerumen production			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
hypoacusis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
otorrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
dry eye			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
eye swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
lacrimation increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
periorbital oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
swelling of eyelid			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 10 (50.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	10	2	0
abdominal pain upper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
anal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
ascites			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
cheilitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	6	3	0
dental caries			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 10 (70.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	20	1	0

dyspepsia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
dysphagia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
gastritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
gingival bleeding			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
gingival pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
haematemesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
lip dry			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
lip pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
mouth haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 10 (70.00%)	9 / 13 (69.23%)	1 / 1 (100.00%)
occurrences (all)	24	34	1
oesophageal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
oral dysaesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
proctalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
retching			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

stomatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	4	6	0
vomiting			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 10 (50.00%)	8 / 13 (61.54%)	0 / 1 (0.00%)
occurrences (all)	14	11	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
dermatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
dermatitis acneiform			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
dermatitis diaper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
pain of skin			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
pruritus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
rash			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
rash maculo-papular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
skin hyperpigmentation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
skin ulcer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
swelling face			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
urticaria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
chromaturia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
fanconi syndrome acquired			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
glycosuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
haematuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
ketonuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
micturition urgency			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
proteinuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	2	5	0
urinary incontinence			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

urinary retention			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
hyperthyroidism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	4 / 13 (30.77%)	1 / 1 (100.00%)
occurrences (all)	1	6	1
back pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	2	3	0
bone pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
coccydynia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
joint range of motion decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
joint swelling			

alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
muscular weakness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
musculoskeletal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	4	2	0
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	1 / 1 (100.00%)
occurrences (all)	1	0	1
neck pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
osteonecrosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
pain in jaw			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
candida infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
clostridium difficile infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
enterocolitis infectious			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
folliculitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
gastroenteritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
lymph gland infection			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
rhinitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	3	5	0
dehydration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
hyperalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
hypercalcaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
hyperchloraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
hyperglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	4 / 13 (30.77%)	0 / 1 (0.00%)
occurrences (all)	1	11	0
hyperkalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
hypermagnesaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
hypernatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
hyperphosphataemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	5	0
hyperuricaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
hypoalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	2	6	0

hypocalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
hypoglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 10 (20.00%)	5 / 13 (38.46%)	0 / 1 (0.00%)
occurrences (all)	2	14	0
hypomagnesaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	2	7	0
hyponatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	5 / 13 (38.46%)	0 / 1 (0.00%)
occurrences (all)	2	16	0
hypophosphataemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 10 (30.00%)	4 / 13 (30.77%)	0 / 1 (0.00%)
occurrences (all)	5	14	0
hypouricaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
malnutrition			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
refeeding syndrome			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Olaratumab + Vincristine + Irinotecan (Part C)	Olaratumab + Ifosfamide (Part C)	Olaratumab + Doxorubicin (Part C)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	4 / 4 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
flushing			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypotension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pallor			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pelvic venous thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
phlebitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
catheter site pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
chills			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
early satiety			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
face oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
facial pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
gait disturbance			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
localised oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	1	3	1
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	2 / 4 (50.00%)
occurrences (all)	2	1	3
Respiratory, thoracic and mediastinal disorders			
atelectasis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
bradypnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 6 (50.00%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	3	3	1
dyspnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
epistaxis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pharyngeal erythema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

pleural effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pleuritic pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
rales			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
tachypnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
upper-airway cough syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
wheezing			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

abnormal behaviour			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
depression			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hallucination			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
irritability			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
mood swings			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
restlessness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			

activated partial thromboplastin time			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
activated partial thromboplastin time prolonged			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
alanine aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 6 (50.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	7	8	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 6 (50.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	4	7	0
bilirubin conjugated increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
blood bicarbonate decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
blood creatinine increased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
blood lactate dehydrogenase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
blood phosphorus increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
blood thyroid stimulating hormone decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
blood thyroid stimulating hormone increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
electrocardiogram pr shortened			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
eosinophil percentage decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
haemoglobin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
heart rate irregular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
international normalised ratio increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
lymphocyte count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 6 (33.33%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	11	11	0
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	3	9	7
neutrophil count increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
platelet count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 6 (50.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	11	8	0
protein total decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

prothrombin time prolonged			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 6 (33.33%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
weight increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
white blood cell count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	2	13	6
white blood cell count increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
white blood cells urine positive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ph urine increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
femur fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
infusion related reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
ligament sprain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
radiation skin injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
recall phenomenon			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
scratch			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
suture related complication			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
left ventricular dysfunction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
palpitations			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pericardial effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
sinus bradycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
sinus tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dysarthria			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	2 / 4 (50.00%)
occurrences (all)	0	1	3
hemiparesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
lethargy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
peripheral motor neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
somnolence			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

writer's cramp			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 6 (66.67%)	3 / 4 (75.00%)	4 / 4 (100.00%)
occurrences (all)	12	5	11
febrile neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 4 (50.00%)	2 / 4 (50.00%)
occurrences (all)	0	2	2
leukocytosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 6 (50.00%)	2 / 4 (50.00%)	3 / 4 (75.00%)
occurrences (all)	21	16	23
lymphopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 4 (50.00%)	3 / 4 (75.00%)
occurrences (all)	0	6	26
neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 6 (66.67%)	2 / 4 (50.00%)	3 / 4 (75.00%)
occurrences (all)	19	13	24
thrombocytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 6 (33.33%)	0 / 4 (0.00%)	3 / 4 (75.00%)
occurrences (all)	3	0	15
thrombocytosis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
excessive cerumen production			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypoacusis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
otorrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
dry eye			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
eye pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
eye swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
lacrimation increased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
periorbital oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
swelling of eyelid			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
abdominal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 6 (33.33%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	6	0	1
abdominal pain upper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
anal haemorrhage			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ascites			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
cheilitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 6 (33.33%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
dental caries			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 6 (100.00%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	21	6	1
dyspepsia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dysphagia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
gingival bleeding			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
gingival pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
haematemesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
lip dry			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
lip pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
mouth haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 6 (33.33%)	3 / 4 (75.00%)	3 / 4 (75.00%)
occurrences (all)	4	10	5
oesophageal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
oral dysaesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
proctalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
retching			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	6
vomiting			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 6 (50.00%)	2 / 4 (50.00%)	2 / 4 (50.00%)
occurrences (all)	4	7	4
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
dermatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dermatitis acneiform			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dermatitis diaper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
rash			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

rash maculo-papular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
skin hyperpigmentation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
swelling face			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
chromaturia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
fanconi syndrome acquired			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
glycosuria			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
haematuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
ketonuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	9	0
micturition urgency			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
proteinuria			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
urinary incontinence			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
urinary retention			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
hyperthyroidism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
back pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
bone pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
coccydynia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
joint range of motion decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
neck pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
osteonecrosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pain in jaw			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
candida infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
clostridium difficile infection			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
enterocolitis infectious			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
gastroenteritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
lymph gland infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

upper respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 6 (33.33%)	2 / 4 (50.00%)	2 / 4 (50.00%)
occurrences (all)	5	4	4
dehydration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hyperalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypercalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hyperchloraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
hyperglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	2	5	0
hyperkalaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypermagnesaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypernatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hyperphosphataemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
hyperuricaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypoalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
hypocalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypoglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0

hypomagnesaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hyponatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
hypophosphataemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
hypouricaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
malnutrition			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
refeeding syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported