Clinical trial results:
A Phase 1b (Open-Label) / Phase 2 (Randomized, Double-Blinded) Study Evaluating Nab-Paclitaxel and Gemcitabine With or Without Olaratumab in the Treatment of First-Line Metastatic Pancreatic Cancer

Summary

EudraCT number	2016-001099-31
Trial protocol	DE ES IT
Global end of trial date	17 June 2021

Results information

Result version number	v1
This version publication date	11 January 2022
First version publication date	11 January 2022

Trial information

Trial identification

Sponsor protocol code	I5B-MC-JGDP

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03086369
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 15844

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)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	05 January 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 January 2021
Global end of trial reached?	Yes
Global end of trial date	17 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine the safety and efficacy of nab-paclitaxel and gemcitabine with or without olaratumab in the treatment of first-line metastatic pancreatic cancer.

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	22 June 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 162
Country: Number of subjects enrolled	Germany: 13
Country: Number of subjects enrolled	Spain: 9
Worldwide total number of subjects	184
EEA total number of subjects	22

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	76
From 65 to 84 years	108

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

Completers included participants who died from any cause.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine

Arm description:

Participants received intravenous infusions of olaratumab 15 milligrams per kilogram (mg/kg), nab-paclitaxel 125 milligrams per meter square (mg/m^2) and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

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

Dosage and administration details:

Intravenous infusion of Olaratumab 15 milligrams per kilogram (mg/kg) on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of nab-paclitaxel 125 milligrams per meter square (mg/m^2) on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

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

Dosage and administration details:

Intravenous infusion of gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Arm title	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine

Arm description:

Participants received intravenous infusions of olaratumab 20 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for

discontinuation were met.

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

Dosage and administration details:

Intravenous infusion of Olaratumab 20 mg/kg on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

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

Dosage and administration details:

Intravenous infusion of gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of nab-paclitaxel 125mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Arm title	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine

Arm description:

Following a protocol amendment, expansion arm was added in phase 1b with new participants enrolled to confirm the safety of the olaratumab 20 mg/kg dose prior to opening the Phase 2. Participants received intravenous infusions of olaratumab 20 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

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

Dosage and administration details:

Intravenous infusion of Olaratumab 20 mg/kg on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of nab-paclitaxel 125mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion

Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Arm title	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine

Arm description:

Participants received intravenous infusions of olaratumab 20 mg/kg loading dose on days 1, 8, 15 of cycle 1 followed by 15 mg/kg on days 1, 8, 15 of all subsequent cycles, in combination with nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

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

Dosage and administration details:

Intravenous infusion of Olaratumab 20 mg/kg loading dose on days 1, 8, 15 of cycle 1 followed by 15 mg/kg on days 1, 8, 15 of all subsequent cycles until disease progression or a criterion for discontinuation were met.

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of nab-paclitaxel 125mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

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

Dosage and administration details:

Intravenous infusion of gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Arm title	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine

Arm description:

Participants received intravenous infusions of placebo, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

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

Dosage and administration details:

Intravenous infusion of placebo on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Number of subjects in period 1	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine
Started	3	7	12
Received at least 1 dose of study drug	3	7	12
Completed	2	7	12
Not completed	1	0	0
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
On Treatment	-	-	-
Adverse event, non-fatal	-	-	-
Progressive Disease	-	-	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Started	82	80
Received at least 1 dose of study drug	81	78
Completed	55	59
Not completed	27	21
Physician decision	2	5
Consent withdrawn by subject	5	5
On Treatment	1	2
Adverse event, non-fatal	3	4
Progressive Disease	14	4
Lost to follow-up	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine
Reporting group description:	
Participants received intravenous infusions of olaratumab 15 milligrams per kilogram (mg/kg), nab-paclitaxel 125 milligrams per meter square (mg/m^2) and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.	
Reporting group title	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine
Reporting group description:	
Participants received intravenous infusions of olaratumab 20 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.	
Reporting group title	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine
Reporting group description:	
Following a protocol amendment, expansion arm was added in phase 1b with new participants enrolled to confirm the safety of the olaratumab 20 mg/kg dose prior to opening the Phase 2. Participants received intravenous infusions of olaratumab 20 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.	
Reporting group title	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine
Reporting group description:	
Participants received intravenous infusions of olaratumab 20 mg/kg loading dose on days 1, 8, 15 of cycle 1 followed by 15 mg/kg on days 1, 8, 15 of all subsequent cycles, in combination with nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.	
Reporting group title	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Reporting group description:	
Participants received intravenous infusions of placebo, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.	

Reporting group values	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine
Number of subjects	3	7	12
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	0	3	4
>=65 years	3	4	8
Gender categorical Units: Subjects			
Female	2	3	3
Male	1	4	9
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	3	7	11
Unknown or Not Reported	0	0	0

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	7	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
United States	1	5	7
Germany	1	1	5
Spain	1	1	0

Reporting group values	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine	Total
Number of subjects	82	80	184
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	32	37	76
>=65 years	50	43	108
Gender categorical Units: Subjects			
Female	29	35	72
Male	53	45	112
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	7	8	16
Not Hispanic or Latino	74	70	165
Unknown or Not Reported	1	2	3
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	1
Asian	4	1	5
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	3	7
White	72	73	167
More than one race	0	0	0
Unknown or Not Reported	2	2	4
Region of Enrollment Units: Subjects			
United States	76	73	162
Germany	3	3	13
Spain	3	4	9

End points

End points reporting groups

Reporting group title	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine

Reporting group description:

Participants received intravenous infusions of olaratumab 15 milligrams per kilogram (mg/kg), nab-paclitaxel 125 milligrams per meter square (mg/m^2) and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Reporting group title	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine

Reporting group description:

Participants received intravenous infusions of olaratumab 20 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Reporting group title	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine

Reporting group description:

Following a protocol amendment, expansion arm was added in phase 1b with new participants enrolled to confirm the safety of the olaratumab 20 mg/kg dose prior to opening the Phase 2. Participants received intravenous infusions of olaratumab 20 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Reporting group title	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine

Reporting group description:

Participants received intravenous infusions of olaratumab 20 mg/kg loading dose on days 1, 8, 15 of cycle 1 followed by 15 mg/kg on days 1, 8, 15 of all subsequent cycles, in combination with nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Reporting group title	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine

Reporting group description:

Participants received intravenous infusions of placebo, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

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

End point title	Phase 1b: Number of Participants with Dose Limiting Toxicities (DLTs)[1][2]

End point description:

A DLT is an adverse event that is likely related to the study medication or combination, and fulfils any one of the following criteria, graded according to NCI-CTCAE version 4.03: Any febrile neutropenia, Grade 4 thrombocytopenia, or Grade 3 thrombocytopenia complicated by clinically significant hemorrhage, Grade 4 neutropenia lasting 7 days or longer, Nonhematologic Grade ≥3 toxicity, except for toxicities such as nausea, vomiting, transient electrolyte abnormalities, diarrhea which can be controlled with optimal medical management within 48 hours; non-clinically significant, treatable, or reversible laboratory abnormalities including liver function tests, uric acid, electrolytes, etc., Any other significant toxicity deemed to be dose-limiting (e.g., any toxicity that is possibly related to the study medication that requires the withdrawal of the participant from the study).

Analysis Population Description: All participants in phase 1b who received at least one dose of Olaratumab.

End point type	Primary

End point timeframe:

Cycle 1 (Up to 28 days)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistics were planned for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome is specific to phase 1b arms only.

End point values	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	7	12	
Units: participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Overall Survival (OS)

End point title	Phase 2: Overall Survival (OS)[3]

End point description:

OS is defined as the time from the date of randomization to the date of death from any cause. If the participant is alive or lost to follow-up at the time of data analysis, OS data will be censored on the last date the participant is known to be alive. For any patient who has withdrawn consent for further follow-up of survival data, OS will be censored at the last date for which the participant consented to be followed for the study.

Analysis Population Description (APD): All randomized participants in phase 2 (including the censored participants). Number of participants censored in Olaratumab+Nab-paclitaxel+Gemcitabine=26, Placebo+Nab-paclitaxel+Gemcitabine=21.

End point type	Primary

End point timeframe:

Baseline to Date of Death from Any Cause (Up To 29 Months)

Notes:

[3] - 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: This outcome is specific to phase 2 arms only.

End point values	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	80		
Units: Months				
median (confidence interval 95%)	9.10 (7.49 to 14.09)	10.81 (8.51 to 14.75)		

Statistical analyses

Statistical analysis title	Phase 2: Overall Survival (OS)
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	162
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7902
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.054
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.728
upper limit	1.527

Secondary: Phase 1b/2: Pharmacokinetics (PK): Minimum Concentration (Cmin) of Olaratumab

End point title	Phase 1b/2: Pharmacokinetics (PK): Minimum Concentration (Cmin) of Olaratumab[4]

End point description:

PK: Cmin of olaratumab

APD: All participants in phase 1b/2 who received at least one dose of Olaratumab and had evaluable PK data.

9999 = N/A = Geometric Mean and Geometric Coefficient of Variation couldn't be calculated as there was only one participant.

End point type	Secondary

End point timeframe:

Pre-dose, 5 min, 1, 4, 4.5, 24, 96, 168, 336 h post-dose on Cycle 1 Day 1, Cycle 1 Day 15, Cycle 3 Day 1, Cycle 3 Day 15

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome was analysed in phase 1b/2 arms that received Olaratumab drug.

End point values	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5[5]	9	66[6]
Units: micrograms per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 (Day 1)	128 (± 36)	86.3 (± 90)	87.8 (± 91)	112 (± 40)
Cycle 1 (Day 15)	78.7 (± 42)	172 (± 76)	101 (± 36)	94.7 (± 62)
Cycle 3 (Day 1)	204 (± 13)	9999 (± 9999)	173 (± 33)	147 (± 38)
Cycle 3 (Day 15)	159 (± 17)	9999 (± 9999)	101 (± 37)	106 (± 68)

Notes:

[5] - Cycle 3 (Day 1)=1; Individual value : 184 µg/mL
Cycle 3 (Day 15)=1; Individual value : 99.7 µg/mL
[6] - Cycle 1 (Day 1)=61
Cycle 3 (Day 1)=51
Cycle 3 (Day 15)=44

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants With Treatment Emergent Anti-Olaratumab Antibodies

End point title	Phase 2: Number of Participants With Treatment Emergent Anti-Olaratumab Antibodies[7]

End point description:

Number of Participants With Treatment Emergent Anti-Olaratumab Antibodies.

APD: All randomized participants in phase 2 who received at least one dose of Olaratumab and had evaluable immunogenicity data.

End point type	Secondary

End point timeframe:

Baseline through Follow-up (Up To 29 Months)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome was analysed in phase 2 arms that received Olaratumab drug.

End point values	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b: Overall Survival (OS)

End point title	Phase 1b: Overall Survival (OS)[8]

End point description:

OS is defined as the time from the date of randomization to the date of death from any cause. If the participant is alive or lost to follow-up at the time of data analysis, OS data will be censored on the last date the participant is known to be alive. For any participant who has withdrawn consent for further follow-up of survival data, OS will be censored at the last date for which the participant consented to be followed for the study.

APD: Zero participants analysed as data was not collected. OS was not measured in phase 1b.

End point type	Secondary

End point timeframe:

Baseline to Date of Death from Any Cause (Approximately 9 Months)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome is specific to phase 1b arms only.

End point values	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[9]	0[10]	0[11]	
Units: Months				
median (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[9] - Zero participants analysed as data was not collected. OS was not measured in phase 1b.

[10] - Zero participants analysed as data was not collected. OS was not measured in phase 1b.

[11] - Zero participants analysed as data was not collected. OS was not measured in phase 1b.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Progression-Free Survival (PFS)

End point title	Phase 2: Progression-Free Survival (PFS)[12]

End point description:

PFS is defined as the time from randomization to the first date of radiologic disease progression (as defined by Response Evaluation Criteria In Solid Tumors, Version 1.1 [RECIST v.1.1]) or death due to any cause in the absence of progressive disease (PD). Participants who did not progress or are lost to follow-up were censored at the day of their last radiographic tumor assessment, if available, or date of randomization if no post-baseline radiographic assessment is available. If death or PD occurs after 2 or more consecutive missing radiographic visits, censoring will occur at the date of the last radiographic visit prior to the missed visits.
APD: All randomized participants in phase 2 (including the censored participants). Number of participants censored in Olaratumab+Nab-paclitaxel+Gemcitabine=24, Placebo+Nab-paclitaxel+Gemcitabine=26.

End point type	Secondary

End point timeframe:

Baseline to Disease Progression or Death (Up To 26 Months)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome is specific to phase 2 arms only.

End point values	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	80		
Units: Months				
median (confidence interval 95%)	5.55 (4.14 to 7.0)	6.41 (5.42 to 7.98)		

Statistical analyses

Statistical analysis title	Phase 2: Progression-Free Survival (PFS)
Comparison groups	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine v Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	162
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3771
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.192
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.806
upper limit	1.764

Secondary: Phase 1b/2: Objective Response Rate (ORR): Percentage of Participants Who Achieve Complete Response (CR) or Partial Response (PR)

End point title	Phase 1b/2: Objective Response Rate (ORR): Percentage of Participants Who Achieve Complete Response (CR) or Partial Response (PR)

End point description:

ORR is the best overall tumor response of CR or PR as classified by the investigator according to the Response Evaluation Criteria In Solid Tumors (RECIST v1.1). CR is a disappearance of all target and non-target lesions and normalization of tumor marker level. PR is an at least 30% decrease in the sum of the diameters of target lesions (taking as reference the baseline sum diameter) without progression of non-target lesions or appearance of new lesions.
APD: All participants in phase 1b/2.

End point type	Secondary

End point timeframe:

Baseline through Disease Progression or Death (Up To 26 Months)

End point values	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	7	12	82
Units: Percentage of participants				
number (not applicable)	33.3	14.3	0	30.5

End point values	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine			
Subject group type	Reporting group			
Number of subjects analysed	80			
Units: Percentage of participants				
number (not applicable)	33.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b/2: Duration of Response (DoR)

End point title	Phase 1b/2: Duration of Response (DoR)

End point description:

DoR is defined as the time from the date measurement criteria for CR or PR (whichever is first recorded) are first met until the first date that disease is recurrent or objective progression is observed, per RECIST 1.1 criteria, or the date of death from any cause in the absence of objectively determined disease progression or recurrence.

APD: All participants in phase 1b/2 who had CR or PR responses. For phase 1b cohort expansion arm, there were no participants with CR or PR responses to evaluate DoR, hence, zero participants analysed. 9999 = N/A = Median and 95% Confidence Interval couldn't be calculated as there was only one participant.

End point type	Secondary

End point timeframe:

From Date of CR or PR to Date of Objective Disease Progression or Death Due to Any Cause (Up To 19 Months)

End point values	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b Expansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[13]	1[14]	0[15]	25
Units: Months				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	(to)	5.55 (2.63 to 9.23)

Notes:

[13] - Individual value reported: 6.24 months.

[14] - Individual value reported: 3.68 months.

[15] - There were no participants with CR or PR responses to evaluate DoR, thus, zero participants analysed

End point values	Phase 2:			

	Placebo + Nab-paclitaxel + Gemcitabine			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Months				
median (confidence interval 95%)	5.55 (3.84 to 7.26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Time to First Worsening of the Brief Pain Inventory Short Form Modified (mBPI-sf) "Worst Pain Score"

End point title	Phase 2: Time to First Worsening of the Brief Pain Inventory Short Form Modified (mBPI-sf) "Worst Pain Score"[16]

End point description:

The mBPI-sf is a 11-item instrument used as a multiple-item measure of cancer pain intensity ranging from 0 (no pain or does not interfere) and ranged through 10 (pain as bad as you can imagine or completely interferes). Time to first worsening of the mBPI-sf "worst pain score" (TWP) was defined as the time from the date of randomization to the first date of either a "worst pain" score increase of greater than or equal to (≥) 2 points from baseline or an analgesic drug class increase of ≥1 level. If the participant has not worsened by either of these criteria, TWP was censored for analysis on the last date the mBPI-sf was administered.
APD: All randomized participants in phase 2 who had baseline and at least one post-baseline assessment.

End point type	Secondary

End point timeframe:

Baseline through Follow-up (Up To 21 Months)

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: This outcome is specific to phase 2 arms only.

End point values	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51[17]	47		
Units: Months				
median (confidence interval 95%)	14.13 (5.19 to 9999)	6.11 (2.04 to 9.95)		

Notes:

[17] - 9999 = N/A = There were not enough events to estimate the lower confidence limit.

Statistical analyses

Statistical analysis title	Phase 2: TWP
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine

Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.017
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.175
upper limit	0.872

Secondary: Phase 2: Time to First Worsening of Symptom Burden on the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) - Symptom Scales.

End point title	Phase 2: Time to First Worsening of Symptom Burden on the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) - Symptom Scales.[18]

End point description:

The EORTC QLQ-C30 is a self-reported general cancer instrument consisting of 30 items covered by 1 of 3 dimensions: global health status/quality of life (2 items), functional scales (15 total items addressing either physical, role, emotional, cognitive, or social functioning), symptom scales (13 total items addressing either fatigue, nausea/vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea, or financial impact). Time to first worsening of Symptom Burden was defined as the time from randomization to the first observation of worsening on symptom scales (i.e.,) increase of at least 10 points from baseline. For symptom scales, a linear transformation was used to obtain total score ranging from 0 to 100, a high score represents a high level of symptomatology or problems.
APD: All randomized participants in phase 2 who had baseline and at least one post-baseline assessment.
9999=N/A=Not enough events to estimate the median/upper confidence limit, as applicable.

End point type	Secondary

End point timeframe:

Baseline through Follow-up (Up To 21 Months)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome is specific to phase 2 arms only.

End point values	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	68[19]	66[20]		
Units: Months				
median (confidence interval 95%)				
Appetite loss	9999 (2.79 to 9999)	2.86 (1.94 to 9999)		
Constipation	9999 (2.76 to 9999)	9999 (1.94 to 9999)		
Diarrhoea	2.79 (1.87 to 9999)	1.97 (1.91 to 9999)		

Dyspnoea	2.79 (2.10 to 9999)	3.12 (2.07 to 9999)		
Fatigue	1.87 (1.05 to 2.33)	1.87 (1.12 to 2.07)		
Financial difficulties	9999 (2.37 to 9999)	9999 (2.79 to 9999)		
Insomnia	3.19 (2.10 to 9999)	9999 (2.83 to 9999)		
Nausea and vomiting	3.19 (2.10 to 9999)	2.86 (1.97 to 9999)		
Pain	9999 (2.76 to 9999)	3.25 (2.04 to 9999)		

Notes:

[19] - Appetite loss=57
Constipation/Pain=64
Dysp/Fatigue/Nausea&vomit=66
Financial diff=65
Insomnia=60
[20] - Appetite loss/Insomnia=60
Constipation=59
Diarrhoea=62
Fatigue=64
Financial diff=61
Pain=58

Statistical analyses

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden
Statistical analysis description:	
Appetite loss	
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[21]
P-value	= 0.288
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.718
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.392
upper limit	1.317

Notes:

[21] - Appetite loss

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden
Statistical analysis description:	
Constipation	
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine

Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[22]
P-value	= 0.442
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.788
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.423
upper limit	1.468

Notes:

[22] - Constipation

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden
Statistical analysis description:	
Diarrhoea	
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[23]
P-value	= 0.883
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.037
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.612
upper limit	1.755

Notes:

[23] - Diarrhoea

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden
Statistical analysis description:	
Dyspnoea	
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[24]
P-value	= 0.803
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.933

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.532
upper limit	1.636

Notes:

[24] - Dyspnoea

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden

Statistical analysis description:

Fatigue

Comparison groups	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine v Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[25]
P-value	= 0.805
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.053
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.675
upper limit	1.645

Notes:

[25] - Fatigue

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden

Statistical analysis description:

Financial difficulties

Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[26]
P-value	= 0.465
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.784
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	1.464

Notes:

[26] - Financial difficulties

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden

Statistical analysis description:	
Insomnia	
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[27]
P-value	= 0.231
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.457
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.787
upper limit	2.698

Notes:

[27] - Insomnia

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden
Statistical analysis description:	
Nausea and vomiting	
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[28]
P-value	= 0.748
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.914
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.532
upper limit	1.57

Notes:

[28] - Nausea and vomiting

Statistical analysis title	Phase 2:Time to First Worsening of Symptom Burden
Statistical analysis description:	
Pain	
Comparison groups	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine v Phase 2: Placebo + Nab-paclitaxel + Gemcitabine
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority[29]
P-value	= 0.875
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.947

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.491
upper limit	1.827

Notes:

[29] - Pain

Secondary: Phase 2: Health Status on the EuroQol 5-Dimension 5 Level (EQ-5D-5L)

End point title	Phase 2: Health Status on the EuroQol 5-Dimension 5 Level (EQ-5D-5L)[30]

End point description:

The EQ-5D-5L is a standardized instrument for use as a measure of self-reported health status. Five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) of health status are each assessed with 5 response options (1=no problem, 2=slight, 3=moderate, 4=severe, and 5=extreme problem) and scored as a composite index which were anchored on a scale of 0 to 1 with a higher score representing better health status. Additionally, current health status was assessed on a visual analogue scale (VAS) ranging from 0 to 100 with a higher score representing better health status.
APD: All randomized participants in phase 2 who completed EQ-5D-5L.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1, Cycle 7 Day 1

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: This outcome is specific to phase 2 arms only.

End point values	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	70[31]	70[32]		
Units: score on a scale				
arithmetic mean (standard deviation)				
Index Value [Cycle 1 (Day1)]	0.8 (± 0.2)	0.8 (± 0.2)		
Index Value [Cycle 7 (Day1)]	0.8 (± 0.1)	0.8 (± 0.2)		
VAS Score [Cycle 1 (Day1)]	70.1 (± 21.7)	69.7 (± 20.4)		
VAS Score [Cycle 7 (Day1)]	71.7 (± 20.2)	73.2 (± 22.5)		

Notes:

[31] - Cycle 1 (Day1)=Index Value=69
Cycle 7 (Day1)=Index Value=22, VAS Score=23
[32] - Cycle 7 (Day1)=Index Value, VAS Score=33

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to Follow-up (Up To 29 Months)

Adverse event reporting additional description:

All participants in phase 1b/2 who received at least one dose of study drug. Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine

Reporting group description:

Participants received intravenous infusions of olaratumab 15 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Reporting group title	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine

Reporting group description:

Participants received intravenous infusions of olaratumab 20 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Reporting group title	Phase1bExpansion:Olaratumab20mg/kg+Nab-paclitaxel+Gemcitabine

Reporting group description:

Following a protocol amendment, expansion arm was added in phase 1b with new participants enrolled to confirm the safety of the olaratumab 20 mg/kg dose prior to opening the Phase 2. Participants received intravenous infusions of olaratumab 20 mg/kg, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Reporting group title	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine

Reporting group description:

Participants received intravenous infusions of olaratumab 20 mg/kg loading dose on days 1, 8, 15 of cycle 1 followed by 15 mg/kg on days 1, 8, 15 of all subsequent cycles, in combination with nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Reporting group title	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine

Reporting group description:

Participants received intravenous infusions of placebo, nab-paclitaxel 125 mg/m^2 and gemcitabine 1000 mg/m^2 on days 1, 8, 15 of a 28-day cycle until disease progression or a criterion for discontinuation were met.

Serious adverse events	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1bExpansion: Olaratumab20mg/kg +Nab-paclitaxel+Gemcitabine
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 7 (42.86%)	8 / 12 (66.67%)

number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events	1	0	0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (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
Surgical and medical procedures			
abdominal cavity drainage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chills			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fatigue			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral swelling			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cough			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (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
dyspnoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oropharyngeal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (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
pleural effusion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary oedema			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pulmonary thrombosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory failure			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
blood bilirubin increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
platelet count decreased			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
anastomotic ulcer			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
drain site complication			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (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
hip fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure congestive			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardio-respiratory arrest			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
cerebrovascular accident			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (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
ischaemic cerebral infarction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukoencephalopathy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
memory impairment			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
disseminated intravascular coagulation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
amaurosis fugax			

alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 distension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ascites			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal obstruction			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal stenosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal ulcer			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 necrosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematemesis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

intestinal obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal perforation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
melaena			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obstruction gastric			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatic cyst			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (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
proctitis			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
biliary obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholestasis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
portal vein thrombosis			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (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
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
flank pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myositis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
bacteraemia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile colitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colonic abscess			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related bacteraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (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

device related infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (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
diverticulitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enterocolitis infectious			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
escherichia urinary tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
kidney infection			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
liver abscess			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia klebsiella			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sepsis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
septic shock			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (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
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperglycaemia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoglycaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyponatraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vitamin b12 deficiency			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine	
Total subjects affected by serious adverse events			
subjects affected / exposed	50 / 81 (61.73%)	41 / 78 (52.56%)	
number of deaths (all causes)	56	58	
number of deaths resulting from adverse events	7	4	
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypotension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
abdominal cavity drainage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
chills			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
fatigue			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral swelling			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyrexia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	5 / 81 (6.17%)	4 / 78 (5.13%)	
occurrences causally related to treatment / all	4 / 5	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cough			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspnoea			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oropharyngeal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleural effusion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary embolism			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
pulmonary oedema			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary thrombosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

respiratory failure			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 1	
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mental status changes			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
blood bilirubin increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
platelet count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			

anastomotic ulcer			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
drain site complication			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
fall			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hip fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar vertebral fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac arrest			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac failure congestive			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardio-respiratory arrest			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
myocardial infarction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Nervous system disorders			
cerebrovascular accident			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
embolic stroke			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
epilepsy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic cerebral infarction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
leukoencephalopathy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
memory impairment			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
presyncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
seizure			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

subarachnoid haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
syncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient ischaemic attack			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
disseminated intravascular coagulation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
febrile neutropenia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
amaurosis fugax			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

abdominal distension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ascites			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diarrhoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
duodenal obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
duodenal stenosis			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
duodenal ulcer			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastritis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal necrosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
haematemesis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

intestinal perforation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
melaena			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nausea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
obstruction gastric			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatic cyst			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
proctitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
small intestinal obstruction			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vomiting			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
biliary obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholangitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholestasis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
portal vein thrombosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
flank pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
myositis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
bacteraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
biliary tract infection			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
covid-19			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium difficile colitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colonic abscess			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
device related bacteraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
device related infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

diverticulitis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
enterocolitis infectious				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
escherichia urinary tract infection				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastroenteritis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)		
occurrences causally related to treatment / all	1 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
influenza				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
kidney infection				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
liver abscess				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	2 / 81 (2.47%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritonitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	8 / 78 (10.26%)	
occurrences causally related to treatment / all	1 / 1	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia klebsiella			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative wound infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sepsis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	7 / 81 (8.64%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	2 / 7	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	

septic shock			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	2 / 78 (2.56%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperglycaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperkalaemia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoglycaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyponatraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vitamin b12 deficiency			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Phase1b: Olaratumab 15 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1b: Olaratumab 20 mg/kg + Nab-paclitaxel + Gemcitabine	Phase1bExpansion: Olaratumab20mg/kg +Nab-paclitaxel+Gemcitabine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	7 / 7 (100.00%)	12 / 12 (100.00%)
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
embolism			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
hypertension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
hypotension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
lymphoedema			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Surgical and medical procedures			
central venous catheterisation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
dental implantation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
pancreatic pseudocyst drainage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
chills			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
fatigue			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 3 (66.67%)	3 / 7 (42.86%)	9 / 12 (75.00%)
occurrences (all)	10	4	19
general physical health deterioration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
influenza like illness			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
mucosal inflammation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
oedema peripheral			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	5 / 12 (41.67%)
occurrences (all)	4	0	8
pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	2	1

Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
seasonal allergy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
vulvovaginal pruritus			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed[1]	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
dyspnoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
epistaxis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
nasal congestion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
pulmonary embolism			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
rhinorrhoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
agitation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
anxiety			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
confusional state			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
delirium			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
depression			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
insomnia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	0	1	3
restlessness			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Investigations			
activated partial thromboplastin time prolonged			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
blood potassium decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
liver function test increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
lymphocyte count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	3
neutrophil count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 3 (66.67%)	3 / 7 (42.86%)	4 / 12 (33.33%)
occurrences (all)	4	15	11
platelet count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	3 / 12 (25.00%)
occurrences (all)	3	3	9
troponin increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
weight decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
white blood cell count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	3 / 12 (25.00%)
occurrences (all)	0	2	5

Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
fall			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	3	0	1
incisional hernia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
infusion related reaction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
skin abrasion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
skin laceration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
sinus bradycardia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
tachycardia			

alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nervous system disorders			
balance disorder			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
cognitive disorder			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
dizziness			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
dysgeusia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
formication			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
headache			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
memory impairment			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
neuropathy peripheral			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	3 / 12 (25.00%)
occurrences (all)	3	0	9
neurotoxicity			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
paraesthesia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	4	0
polyneuropathy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
presyncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
restless legs syndrome			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
syncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	2 / 3 (66.67%)	2 / 7 (28.57%)	5 / 12 (41.67%)
occurrences (all)	8	7	9
iron deficiency anaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
neutropenia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	3 / 12 (25.00%)
occurrences (all)	13	2	6
thrombocytopenia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	5 / 12 (41.67%)
occurrences (all)	5	3	6
Eye disorders			
dry eye			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
eye haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
eye swelling			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
ocular hyperaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
vision blurred			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
abdominal distension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
abdominal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	6 / 12 (50.00%)
occurrences (all)	0	1	12
ascites			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 3 (66.67%)	4 / 7 (57.14%)	4 / 12 (33.33%)
occurrences (all)	2	4	5
diarrhoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	7 / 12 (58.33%)
occurrences (all)	4	1	9
dyspepsia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
dysphagia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
haemorrhoids			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
lip swelling			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
nausea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	6 / 12 (50.00%)
occurrences (all)	1	3	15
paraesthesia oral			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
stomatitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
vomiting			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	4

Hepatobiliary disorders			
bile duct stenosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	6 / 12 (50.00%)
occurrences (all)	1	0	7
dermatitis acneiform			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
dermatitis allergic			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
erythema			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
erythema multiforme			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
hyperhidrosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
nail disorder			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
pruritus			

alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	3 / 12 (25.00%)
occurrences (all)	0	0	4
rash maculo-papular			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
skin burning sensation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
skin lesion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
urticaria			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Renal and urinary disorders			
chronic kidney disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
dysuria			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
pollakiuria			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
urinary tract obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
back pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
joint effusion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
muscle spasms			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
muscular weakness			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
myalgia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
pain in extremity			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
spinal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
erysipelas			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
pneumonia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
sinusitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
skin infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
dehydration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	1 / 12 (8.33%)
occurrences (all)	1	2	1
hyperglycaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
hypoalbuminaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
hypocalcaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	3 / 12 (25.00%)
occurrences (all)	0	1	4
hypomagnesaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
hyponatraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	3 / 12 (25.00%)
occurrences (all)	0	3	4
vitamin d deficiency			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Non-serious adverse events	Phase 2: Olaratumab + Nab-paclitaxel + Gemcitabine	Phase 2: Placebo + Nab-paclitaxel + Gemcitabine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 81 (97.53%)	78 / 78 (100.00%)	
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	3 / 81 (3.70%)	4 / 78 (5.13%)	
occurrences (all)	3	4	
embolism			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	5 / 81 (6.17%)	2 / 78 (2.56%)	
occurrences (all)	5	2	
hypertension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	7 / 81 (8.64%)	4 / 78 (5.13%)	
occurrences (all)	14	6	
hypotension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	14 / 81 (17.28%)	6 / 78 (7.69%)	
occurrences (all)	18	7	
lymphoedema			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences (all)	0	1	
Surgical and medical procedures			
central venous catheterisation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
dental implantation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
pancreatic pseudocyst drainage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	11 / 81 (13.58%)	10 / 78 (12.82%)	
occurrences (all)	12	18	
chills			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	8 / 81 (9.88%)	12 / 78 (15.38%)	
occurrences (all)	10	17	
fatigue			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	53 / 81 (65.43%)	44 / 78 (56.41%)	
occurrences (all)	74	84	
general physical health deterioration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences (all)	0	2	
influenza like illness			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	5 / 78 (6.41%)	
occurrences (all)	3	14	
mucosal inflammation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)	
occurrences (all)	3	0	
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	3 / 78 (3.85%)	
occurrences (all)	2	4	
oedema peripheral			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	25 / 81 (30.86%)	28 / 78 (35.90%)	
occurrences (all)	43	44	
pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	4 / 78 (5.13%)	
occurrences (all)	2	4	

pyrexia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	20 / 81 (24.69%)	21 / 78 (26.92%)	
occurrences (all)	30	28	
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
seasonal allergy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
vulvovaginal pruritus			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed[1]	0 / 29 (0.00%)	0 / 35 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	13 / 81 (16.05%)	10 / 78 (12.82%)	
occurrences (all)	14	10	
dyspnoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	14 / 81 (17.28%)	13 / 78 (16.67%)	
occurrences (all)	17	25	
epistaxis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	8 / 78 (10.26%)	
occurrences (all)	4	10	
nasal congestion			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	2 / 81 (2.47%)	4 / 78 (5.13%)	
occurrences (all)	2	4	
oropharyngeal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	4 / 78 (5.13%)	
occurrences (all)	1	4	
productive cough			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	4 / 78 (5.13%)	
occurrences (all)	1	4	
pulmonary embolism			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	4 / 78 (5.13%)	
occurrences (all)	4	4	
rhinorrhoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences (all)	0	1	
Psychiatric disorders			
agitation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
anxiety			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	5 / 81 (6.17%)	8 / 78 (10.26%)	
occurrences (all)	5	11	
confusional state			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	2 / 78 (2.56%)	
occurrences (all)	0	2	
delirium			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
depression			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	7 / 81 (8.64%)	5 / 78 (6.41%)	
occurrences (all)	9	7	
insomnia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	10 / 81 (12.35%)	11 / 78 (14.10%)	
occurrences (all)	11	13	
restlessness			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences (all)	0	1	
Investigations			
activated partial thromboplastin time prolonged			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	5 / 78 (6.41%)	
occurrences (all)	4	6	
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	13 / 81 (16.05%)	14 / 78 (17.95%)	
occurrences (all)	28	26	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	15 / 81 (18.52%)	13 / 78 (16.67%)	
occurrences (all)	38	20	
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	8 / 81 (9.88%)	9 / 78 (11.54%)	
occurrences (all)	23	20	
blood bilirubin increased			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	8 / 81 (9.88%)	9 / 78 (11.54%)	
occurrences (all)	12	11	
blood creatinine increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	5 / 78 (6.41%)	
occurrences (all)	4	10	
blood potassium decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	0 / 78 (0.00%)	
occurrences (all)	13	0	
liver function test increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
lymphocyte count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	12 / 81 (14.81%)	7 / 78 (8.97%)	
occurrences (all)	88	34	
neutrophil count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	31 / 81 (38.27%)	25 / 78 (32.05%)	
occurrences (all)	184	128	
platelet count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	29 / 81 (35.80%)	31 / 78 (39.74%)	
occurrences (all)	134	106	
troponin increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
weight decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	23 / 81 (28.40%)	9 / 78 (11.54%)	
occurrences (all)	36	14	

white blood cell count decreased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	23 / 81 (28.40%)	16 / 78 (20.51%)	
occurrences (all)	127	92	
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences (all)	1	0	
fall			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	6 / 78 (7.69%)	
occurrences (all)	4	6	
incisional hernia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
infusion related reaction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
skin abrasion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	0 / 78 (0.00%)	
occurrences (all)	3	0	
skin laceration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	1 / 78 (1.28%)	
occurrences (all)	4	1	
sinus bradycardia			

alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences (all)	1	0	
tachycardia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	2 / 78 (2.56%)	
occurrences (all)	3	3	
Nervous system disorders			
balance disorder			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences (all)	1	0	
cognitive disorder			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences (all)	0	1	
dizziness			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	20 / 81 (24.69%)	21 / 78 (26.92%)	
occurrences (all)	26	30	
dysgeusia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	8 / 81 (9.88%)	13 / 78 (16.67%)	
occurrences (all)	11	15	
formication			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
headache			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	6 / 81 (7.41%)	10 / 78 (12.82%)	
occurrences (all)	9	11	
memory impairment			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	3 / 81 (3.70%)	4 / 78 (5.13%)	
occurrences (all)	4	4	
neuropathy peripheral			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	18 / 81 (22.22%)	12 / 78 (15.38%)	
occurrences (all)	36	23	
neurotoxicity			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences (all)	1	0	
paraesthesia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	3 / 78 (3.85%)	
occurrences (all)	3	5	
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	15 / 81 (18.52%)	17 / 78 (21.79%)	
occurrences (all)	29	30	
polyneuropathy			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
presyncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	4 / 78 (5.13%)	
occurrences (all)	0	4	
restless legs syndrome			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	2 / 78 (2.56%)	
occurrences (all)	0	2	
syncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	1 / 78 (1.28%)	
occurrences (all)	3	1	

Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	46 / 81 (56.79%)	45 / 78 (57.69%)	
occurrences (all)	186	165	
iron deficiency anaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 78 (2.56%)	
occurrences (all)	1	2	
neutropenia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	20 / 81 (24.69%)	16 / 78 (20.51%)	
occurrences (all)	53	70	
thrombocytopenia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	7 / 81 (8.64%)	12 / 78 (15.38%)	
occurrences (all)	19	93	
Eye disorders			
dry eye			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 78 (2.56%)	
occurrences (all)	1	2	
eye haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
eye swelling			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences (all)	1	0	
ocular hyperaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
vision blurred			

alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	6 / 81 (7.41%)	2 / 78 (2.56%)	
occurrences (all)	6	2	
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 78 (2.56%)	
occurrences (all)	1	3	
abdominal distension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	4 / 78 (5.13%)	
occurrences (all)	5	5	
abdominal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	15 / 81 (18.52%)	16 / 78 (20.51%)	
occurrences (all)	21	22	
ascites			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	5 / 81 (6.17%)	5 / 78 (6.41%)	
occurrences (all)	6	7	
constipation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	22 / 81 (27.16%)	30 / 78 (38.46%)	
occurrences (all)	26	31	
diarrhoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	40 / 81 (49.38%)	30 / 78 (38.46%)	
occurrences (all)	72	58	
dyspepsia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	4 / 78 (5.13%)	
occurrences (all)	3	5	
dysphagia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	4 / 78 (5.13%)	
occurrences (all)	0	4	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	4 / 78 (5.13%)	
occurrences (all)	0	6	
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences (all)	1	1	
haemorrhoids			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	0 / 78 (0.00%)	
occurrences (all)	2	0	
lip swelling			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
nausea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	33 / 81 (40.74%)	39 / 78 (50.00%)	
occurrences (all)	46	62	
paraesthesia oral			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
stomatitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	9 / 81 (11.11%)	9 / 78 (11.54%)	
occurrences (all)	11	11	
vomiting			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	19 / 81 (23.46%)	19 / 78 (24.36%)	
occurrences (all)	26	23	

Hepatobiliary disorders			
bile duct stenosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	28 / 81 (34.57%)	16 / 78 (20.51%)	
occurrences (all)	34	21	
dermatitis acneiform			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	2 / 78 (2.56%)	
occurrences (all)	0	2	
dermatitis allergic			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
erythema			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
erythema multiforme			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
hyperhidrosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences (all)	1	1	
nail disorder			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	1 / 78 (1.28%)	
occurrences (all)	1	1	
pruritus			

alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	5 / 81 (6.17%)	5 / 78 (6.41%)	
occurrences (all)	5	5	
rash			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	6 / 81 (7.41%)	13 / 78 (16.67%)	
occurrences (all)	9	22	
rash maculo-papular			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	7 / 78 (8.97%)	
occurrences (all)	6	8	
skin burning sensation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
skin lesion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
urticaria			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 78 (0.00%)	
occurrences (all)	4	0	
Renal and urinary disorders			
chronic kidney disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
dysuria			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	2 / 78 (2.56%)	
occurrences (all)	0	2	
pollakiuria			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences (all)	0	1	
urinary tract obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	7 / 78 (8.97%)	
occurrences (all)	5	9	
back pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	6 / 81 (7.41%)	11 / 78 (14.10%)	
occurrences (all)	6	13	
joint effusion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
muscle spasms			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	4 / 78 (5.13%)	
occurrences (all)	2	5	
muscular weakness			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	11 / 81 (13.58%)	4 / 78 (5.13%)	
occurrences (all)	14	5	
musculoskeletal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 78 (1.28%)	
occurrences (all)	0	1	
myalgia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	8 / 81 (9.88%)	8 / 78 (10.26%)	
occurrences (all)	8	12	
pain in extremity			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	9 / 81 (11.11%)	6 / 78 (7.69%)	
occurrences (all)	10	11	
spinal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 81 (4.94%)	3 / 78 (3.85%)	
occurrences (all)	4	8	
erysipelas			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
nasopharyngitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	1 / 78 (1.28%)	
occurrences (all)	2	2	
pneumonia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	6 / 81 (7.41%)	5 / 78 (6.41%)	
occurrences (all)	7	5	
postoperative wound infection			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
sinusitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 81 (2.47%)	3 / 78 (3.85%)	
occurrences (all)	2	3	
skin infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	2 / 78 (2.56%)	
occurrences (all)	7	5	
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	4 / 78 (5.13%)	
occurrences (all)	3	4	
urinary tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 81 (3.70%)	8 / 78 (10.26%)	
occurrences (all)	3	16	
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	22 / 81 (27.16%)	24 / 78 (30.77%)	
occurrences (all)	26	37	
dehydration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	14 / 81 (17.28%)	15 / 78 (19.23%)	
occurrences (all)	20	30	
hyperglycaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	5 / 81 (6.17%)	4 / 78 (5.13%)	
occurrences (all)	5	10	
hyperlipidaemia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	
hypoalbuminaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	13 / 81 (16.05%)	4 / 78 (5.13%)	
occurrences (all)	60	7	
hypocalcaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	10 / 81 (12.35%)	3 / 78 (3.85%)	
occurrences (all)	13	3	
hypokalaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	19 / 81 (23.46%)	17 / 78 (21.79%)	
occurrences (all)	40	31	
hypomagnesaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	16 / 81 (19.75%)	12 / 78 (15.38%)	
occurrences (all)	27	20	
hyponatraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	15 / 81 (18.52%)	6 / 78 (7.69%)	
occurrences (all)	41	11	
vitamin d deficiency			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 78 (0.00%)	
occurrences (all)	0	0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: There are gender specific adverse events occurring only in male or female participants. The number of participants exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 December 2016	Amendment (a) updated the Phase 1b design to enroll participants in the Days 1, 8 and 15 cohort first, and begin enrollment in the Days 1 and 15 dosing cohorts if the Days 1, 8 and 15 cohort is not tolerable. In addition, the design was changed to add a cohort expansion to ensure an appropriate number of participants (12 to 15 participants) are evaluated for safety in Phase 1b at the highest tolerated dose.
27 February 2017	Amendment (b) revised the definition of DLT based on Food and Drug Administration (FDA) feedback to include toxicities related to the combination of olaratumab plus gemcitabine and nab-paclitaxel.
04 December 2017	-Amendment (c) addresses several requests from FDA including language urging caution when administering nab-paclitaxel with CYP2C8 or CYP3A4 inhibitors or inducers as well as further details regarding the sample size justification. -In addition, the amendment adjusts the study entry criteria-related prior therapies, DLT wordings, participant's dose re-escalatation after dose reduction, schedule and timing of PROs in the follow-up periods (both long-term and shortterm), plans for the Phase 2 interim analysis and the Internal Assessment Committee (IAC) and several administrative items to provide clarity or correct errors.
10 December 2018	-Amendment D updates the protocol to include dose and schedule of olaratumab to be administered in the Phase 2 part, based on the results of the Phase 1b part of study JGDP. -This amendment also formalizes a change from an IAC (internal assessment committee) to an IDMC (independent data monitoring committee) for the Phase 2 part of the study.
20 March 2019	Amendment (e) updates the protocol to include screening criteria for Immunoglobulin E (IgE) antibodies against galactose-α-1-3-galactose (α-gal) and premedication requirements.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported